

Effects of Therapeutic Interventions on Physical and Respiratory Functionality in Female Fibromyalgia Patients: A Cross-Over Study

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Products

Exopulse Mollii Suit vs. strength training and high-intensity interval training

Major Findings

With EXOPULSE Mollii Suit or exercise program:

→ **Significant performance improvement in the number of stand-ups in 30 seconds (chair stand test)**

- Significantly increased number of stand ups over all sessions for both treatments

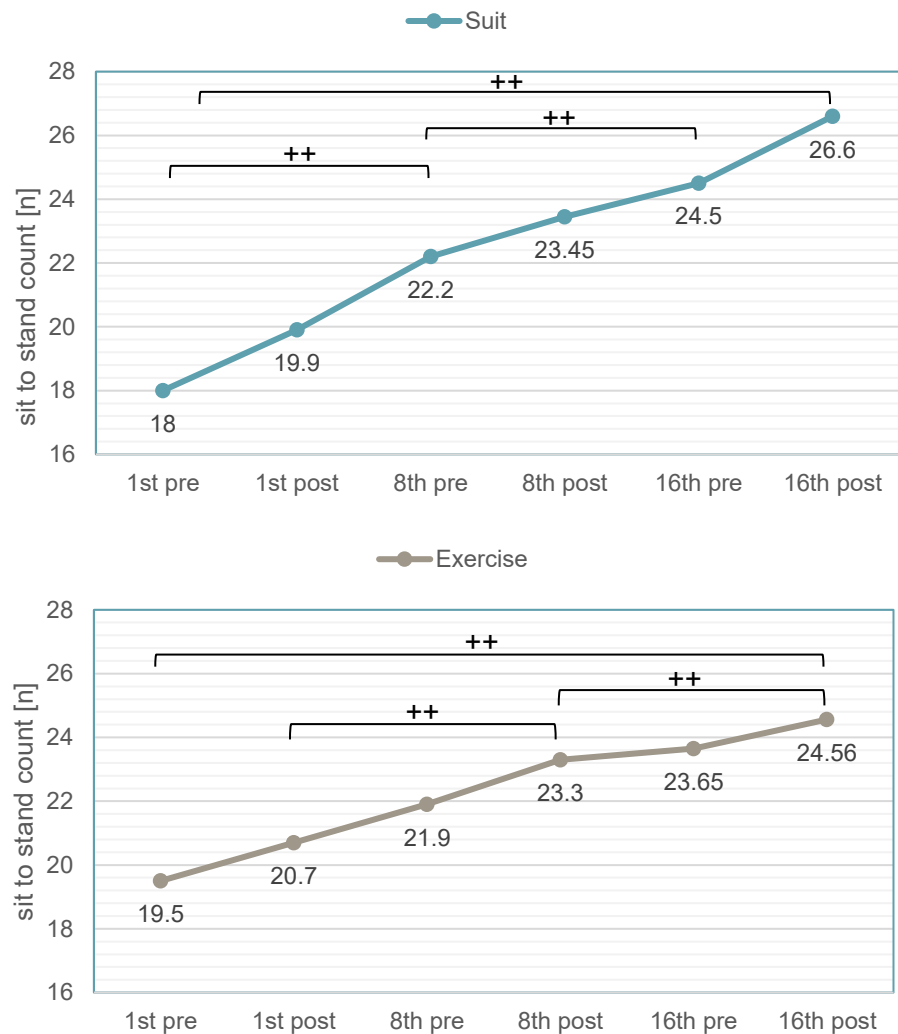
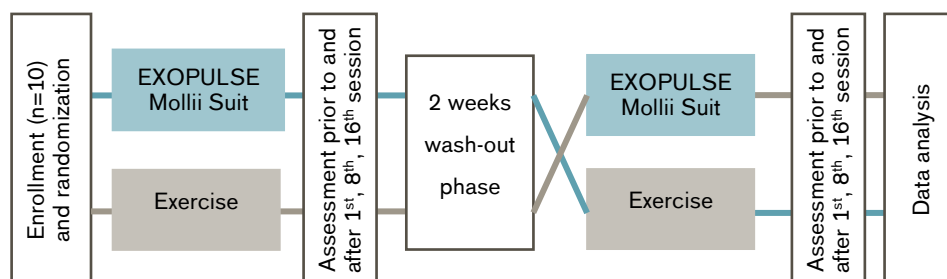


Figure 1: Counts for the Chair stand Test in [A] for the Suit and in[B] for the Exercise. Significant differences between measurement dates are marked with ++

Population	Subjects:	10 female patients
	Etiology:	Fibromyalgia (at least three months); walk independently without assistive devices; no neuromodulation therapy or structured exercise programs in the past six months
	Mean age:	51.6 ± 7.18 years
	Mean weight:	68.5 ± 8.26 kilograms
	Mean height:	160 ± 3.8 centimeters

Study Design Crossover, randomized, controlled trial:



Outcome measures were assessed before and after the interventions at the 1st, 8th, and 16th treatment sessions for each intervention (2 treatments per week for 8 weeks).

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-intervention vs. post-intervention (expressed as means ± SD for quantitative variables)				Sig.*
General Health	forced expiratory volume in 1 second (FEV1) [L]	Suit	session	pre	post	Sig.
			1 st	2.34 ± 0.52	2.28 ± 0.44	0
			8 th	2.35 ± 0.46	2.35 ± 0.55	0
			16 th	2.36 ± 0.52	2.43 ± 0.50	0
		significant difference with large effect comparing 1 st post vs. 16 th post session (d=-0.85)				--
		Exercise	session	pre	post	Sig.
			1 st	2.37 ± 0.49	2.46 ± 0.56	++
			8 th	2.38 ± 0.48	2.35 ± 0.46	0
			16 th	2.36 ± 0.53	2.27 ± 0.49	0
	FEV1 [%]	Suit	session	pre	post	Sig.
			1 st	93.33 ± 12.12	91.56 ± 9.98	0
			8 th	96.30 ± 11.81	95.70 ± 15.66	0
			16 th	96.60 ± 12.44	99.30 ± 10.91	0

Category	Outcomes	Results for pre-intervention vs. post-intervention <i>(expressed as means ± SD for quantitative variables)</i>				Sig.*
		significant difference with large effect comparing 1 st post vs. 16 th post session (d=-0.902)				++
		Exercise	session	pre	post	Sig.
			1 st	96.70 ± 11.72	100.10 ± 13.78	++
			8 th	97.00 ± 11.51	95.70 ± 10.81	0
			16 th	97.00 ± 13.60	94.44 ± 10.96	0
	forced expiratory volume in 6 second (FEV6) [L]	Suit	session	pre	post	Sig.
			1 st	2.77 ± 0.62	2.77 ± 0.65	0
			8 th	2.77 ± 0.69	2.73 ± 0.69	0
			16 th	2.76 ± 0.66	2.79 ± 0.61	0
		Exercise	session	pre	post	Sig.
			1 st	2.75 ± 0.64	2.82 ± 0.67	0
			8 th	2.71 ± 0.60	2.72 ± 0.59	0
			16 th	2.75 ± 0.61	2.72 ± 0.57	0
	FEV6 [%]	Suit	session	pre	post	Sig.
			1 st	93.89 ± 13.12	93.11 ± 13.73	0
			8 th	95.80 ± 17.81	84.88 ± 34.40	0
			16 th	95.80 ± 15.65	97.00 ± 12.89	0
		Exercise	session	pre	post	Sig.
			1 st	95.60 ± 15.01	97.80 ± 15.33	0
			8 th	93.90 ± 13.58	94.30 ± 13.99	0
			16 th	95.78 ± 13.65	94.67 ± 11.95	0
	Ratio FEV1/FEV6 [n]	Suit	session	pre	post	Sig.
			1 st	0.85 ± 0.05	0.83 ± 0.05	0
			8 th	0.86 ± 0.06	0.86 ± 0.02	0
			16 th	0.86 ± 0.04	0.87 ± 0.04	++
		significant difference with large effect				
		- 1 st post vs. 8 th post (d=-0.834)				++
		- 1 st post vs. 16 th post (d=-1.01)				--
		Exercise	session	pre	post	Sig.
			1 st	0.87 ± 0.04	0.87 ± 0.03	0
			8 th	0.88 ± 0.03	0.87 ± 0.05	0
			16 th	0.86 ± 0.05	0.84 ± 0.07	--
		significant difference with large effect				
		- 1 st pre vs. 8 th pre (d=-0.839)				--
		- 8 th pre vs. 16 th post (d=1)				++
	Ratio FEV1/FEV6 [%]	Suit	session	pre	post	Sig.

Category	Outcomes	Results for pre-intervention vs. post-intervention <i>(expressed as means ± SD for quantitative variables)</i>			Sig.*				
		1 st	107.44 ± 6.84	106.11 ± 7.36	0				
		8 th	109.40 ± 8.67	109.30 ± 4.11	0				
		16 th	109.00 ± 5.10	110.20 ± 5.65	++				
		significant difference with large effect							
		- 1 st post vs. 8 th post (d=-0.816)				--			
		- 1 st post vs. 16 th post (d=-0.934)				--			
		Exercise	session	pre	post	Sig.			
			1 st	109.30 ± 6.38	110.30 ± 4.81	0			
			8 th	111.40 ± 4.86	109.40 ± 6.93	0			
			16 th	108.78 ± 7.79	106.00 ± 9.14	--			
			significant difference with large effect						
		- 8 th pre vs. 16 th post (d= 0.998)				++			
Chest perimeter difference [cm]	Suit	session	pre	post	Sig.				
		1 st	7.62 ± 1.92	7.98 ± 1.79	0				
		8 th	7.60 ± 2.46	7.77 ± 2.52	0				
		16 th	8.80 ± 1.93	9.40 ± 2.33	0				
		- significant difference comparing 8 th pre to 16 th post session with large effect (d= 0.86)				--			
		Exercise	session	pre	post	Sig.			
			1 st	7.20 ± 1.75	7.90 ± 1.91	0			
			8 th	8.70 ± 1.34	8.85 ± 1.49	0			
			16 th	7.68 ± 2.90	8.56 ± 2.65	0			
			significant difference with large effect						
		- 1 st pre to 8 th pre (d= -0.789)				--			
		- 1 st pre to 8 th post (d= -1.28)				--			
- 1 st pre to 16 th post (d= -1.03)				--					
Activity	Handgrip strength test [kg]	Suit	session	pre	post	Sig.			
			1 st	24.07 ± 4.59	23.62 ± 4.64	0			
			8 th	24.28 ± 3.58	25.47 ± 3.99	++			
			16 th	23.38 ± 5.70	24.33 ± 5.28	0			
			significant difference comparing 1 st pre to 8 th post session with large effect (d= -0.848)				--		
			Exercise	session	pre	post	Sig.		
				1 st	23.64 ± 4.65	24.45 ± 2.95	0		
				8 th	23.55 ± 4.24	24.41 ± 3.75	0		
				16 th	24.24 ± 1.92	24.72 ± 2.29	0		
			Mobility & Safety	Chair stand test [n]	Suit	session	pre	post	Sig.
						1 st	18.00 ± 8.46	19.90 ± 9.18	0

Category	Outcomes	Results for pre-intervention vs. post-intervention (expressed as means $\pm$ SD for quantitative variables)			Sig.*
		8 th	22.20 $\pm$ 9.08	23.45 $\pm$ 9.16	0
		16 th	24.50 $\pm$ 9.35	26.60 $\pm$ 10.44	++
		significant difference with large effects comparing the following			
		-	1 st pre vs. 8 th pre (d=-0.97)		--
		-	8 th pre vs. 16 th pre (d=-0.889)		--
		-	1 st pre vs. 16 th pre (d=-0.945)		--
		-	1 st post vs. 8 th post (d=-0.863)		--
		-	8 th post vs. 16 th post (d=-1.48)		--
		-	1 st post vs. 16 th post (d=-1.28)		--
		-	1 st pre vs. 8 th post (d= -1.1)		--
		-	1 st pre vs. 16 th post (d=-1.38)		--
		-	8 th pre vs. 16 th post (d=-1.47)		--
	Exercise	session	pre	post	Sig.
		1 st	19.50 $\pm$ 8.87	20.70 $\pm$ 10.76	0
		8 th	21.90 $\pm$ 8.36	23.30 $\pm$ 9.02	0
		16 th	23.56 $\pm$ 8.97	24.56 $\pm$ 9.98	0
		significant difference with large effects comparing the following			
		-	1 st pre vs. 16 th pre (d=-1.35)		--
		-	1 st post vs. 16 th post (d=-1.06)		--
		-	1 st pre vs. 8 th post (d=-1.1)		--
		-	1 st pre vs. 8 th post (d=-1.28)		--
		-	1 st pre vs. 16 th post (d=-1.36)		--
10 m timed up and go (TUG)test [s]	Suit	session	pre	post	Sig.
		1 st	6.06 $\pm$ 1.85	5.66 $\pm$ 1.41	++
		8 th	5.45 $\pm$ 1.29	5.31 $\pm$ 1.27	0
		16 th	5.43 $\pm$ 1.20	5.40 $\pm$ 0.97	0
		significant differences with large effects			
		-	1 st pre vs. 8 th pre (d=1)		++
		-	1 st pre vs. 8 th post (d=1)		++
	Exercise	session	pre	post	Sig.
		1 st	5.45 $\pm$ 1.19	5.32 $\pm$ 1.32	0
		8 th	5.15 $\pm$ 1.22	5.05 $\pm$ 1.07	0
		16 th	5.20 $\pm$ 0.87	4.97 $\pm$ 0.85	0
		significant difference comparing 1 st pre vs. 16 th post with large effects (d=0.867)			
					++
One leg balance right [s]	Suit	session	pre	post	Sig.
		1 st	45.50 $\pm$ 37.85	42.46 $\pm$ 21.84	0
		8 th	62.45 $\pm$ 36.31	72.52 $\pm$ 59.97	0
		16 th	88.60 $\pm$ 72.19	94.63 $\pm$ 77.76	0
	Exercise	session	pre	post	Sig.

Category	Outcomes	Results for pre-intervention vs. post-intervention <i>(expressed as means $\pm$ SD for quantitative variables)</i>			Sig.*	
		1 st	71.47 $\pm$ 51.97	78.54 $\pm$ 57.38	0	
		8 th	91.19 $\pm$ 92.53	71.69 $\pm$ 56.66	0	
		16 th	57.80 $\pm$ 48.26	64.26 $\pm$ 37.11	0	
	One leg balance left [s]	Suit	session	pre	post	Sig.
			1 st	43.94 $\pm$ 33.49	53.54 $\pm$ 47.97	0
			8 th	59.09 $\pm$ 28.84	67.52 $\pm$ 55.92	0
			16 th	63.37 $\pm$ 53.37	58.91 $\pm$ 48.58	0
		Exercise	session	pre	post	Sig.
			1 st	63.51 $\pm$ 50.20	98.07 $\pm$ 91.49	0
			8 th	56.84 $\pm$ 36.52	71.03 $\pm$ 45.05	++
			16 th	74.74 $\pm$ 98.84	45.36 $\pm$ 27.95	0

^a no difference (0), positive trend (+), negative trend (–), significant (++/–), not applicable (n.a.)

^b significance set at $p < 0.05$; trends set at $0.1 > p > 0.05$

effect sizes calculated using Cohen's d with large ($d > 0.80$) effect size

Author's Conclusion

"We can conclude that Neuromodulation and Exercise Interventions have the potential to enhance the functionality of Fibromyalgia patients as shown by the increase in FEV1/FEV6 ratio in respiratory functionality as well as the increase in FEV 1 and chest perimeter references, and physical functionality shown by the increase in performance in the Chair stand test, 10m up and go test and balance in the right leg." (Rubio-Zarapuz et al., 2024)

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