Reference

Perpetuini, David[1]; Russo, Emanuele Francesco[2]; Cardone, Daniela[1]; Palmieri, Roberta[3]; De Giacomo Andreas[3]; Pellegrino, Raffaello[4]; Merla, Arcangelo[1]; Calabrò Rocco Salvatore[5]; Filoni Serena[2]

Use and Effectiveness of Electrosuit in Neurological Disorders: A Systematic Review with Clinical Implications

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Products

EXOPULSE Mollii Suit

Major Findings

With EXOPULSE Mollii Suit (EMS):

→ Improved mobility

- Children with CP improved in mobility and gross motor functions (significant in 1 of 3 publications)
- Stroke and CP patients improved in time and number of steps in the 10m comfortable gait test (1 publication)

→ Improved function

- Significant improvements in upper and lower extremity functions (Fugl-Meyer Assessment) in stroke patients (1 publication)
- trunk acceleration in the anterior-posterior direction of children with CP was altered towards that of healthy individuals (1 publication)

→ Decreased spasticity

- Spasticity measured with Modified Ashworth Scale (MAS) and Modified Tardieu scale (MTS) decreased significantly after treatment in children with CP (in 1 of 4 publications)
- Neural component of resistance to passive stretch decreased significantly in the wrist flexors of affected hand in stroke patients (1 publication)

→ Improved active and passive Range of Motion

in children with CP (pROM, significant in 1 of 3 publications)

→ Decreased pain

in children with CP and in adults with different types of pain (significant in 2 of 5 publications)

→ Improved activity

Children with CP improved in goal-attainment scaling for self-selected activities (1 publication)

	Cerebral Palsy	Cerebral Palsy + Stroke	Stroke	Pain diagnoses (Fibromyalgia, Parkinson and others)
Mobility	↑↑ GMFM (1 publication) **o** GMFM (1 publication) **o** gross motor function (1 publication)	↑ 10m comfortable gait test		
Function	↑↑ Nonlinear dynamics of trunk acceleration		↑↑ FM-UE, FM-LE	
Spasticity	↓↓ MAS (1 publication) ↓↓ MTS (1 publication) ↓ MTS (1 publication) **o** MTS (1 publication)	**o** MAS (1 publication)	**o** MAS (2 publications)	
Range of Motion	↑↑ (1 publication) **o** (2 publications)			
Pain	↓ pain (1 publication) **o** (2 publications)			↓↓ VAS (1 publication) ↓↓ NRS (1 publication)
Participation	↑↑ COPM			

↓↓↓,↑↑↑ highly statistically significant (p<0,001) Increase/Reduction; ↑↑, ↓↓ statistically significant (p<0,05) Increase/Reduction; ↑,↓ statistical trend (0<p<0.1) towards Increase/Reduction; **o** no changes; GMFM Gross Motor Function Measure; MAS Modified Ashworth Scale; MTS Modified Tardieu Scale; ROM Range of Motion; pROM passive Range of Motion, VAS Visual Analogue Scale; NRS Numerical Rating Scale, COPM Canadian Occupational Performance Measure;

Population

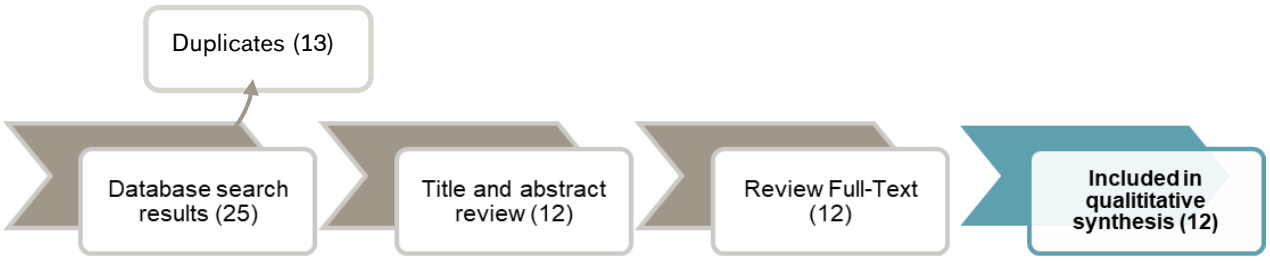
Subjects: 336 subjects[i] (273 adults, 55 children)

Etiology: Cerebral Palsy (n = 63), Cerebral Palsy or Stroke (n= 42), Stroke (n = 40), Fibromyalgia (n = 73), Parkinson (n = 29), other types of pain (n = 89)

Individual study designs: 9 studies (n=273) with before-and-after-design, 2 studies (n=47) with inactive/placebo EMS as control, 1 study (n=16) with parallel control group (n=8) with conventional therapy

Study Design

Systematic literature review



A systematic review was performed in accordance with Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement (Rethlefsen 2021). The systematic literature search was conducted in the databases PubMed, MEDLINE, Web of Science, and Scopus for literature from the inception to February 2023. The search concentrated on the words “Mollii” and “neurological disorders” and/or “stroke” and/or “PCI/cerebral palsy” and/or “rehabilitation” in the article titles, abstracts, and keywords.

[i] Discrepancy of n=10 for stated number of patients in publication of Riachi et al. 2019

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	Pathology	Results	Sig.*
Pain	Visual Analog Scala (VAS)	Fibromyalgia, Parkinson, and other types of pain	VAS-0: 6.5±1.24 (before intervention) VAS-1: 3.46±1.4 (immediately afterwards) VAS-24: 4.72±1.68 (24h later) Significant drop in VAS-1 and VAS-24 (p<0.001)	-- Riachi 2019
	Numerical or graphical rating	CP	Pain was reduced in children who reported pain at the beginning of the research [iii]	- Flodström 2022
		Fibromyalgia (n=1)	No changes	0 Arkkukangas 2022 Hedin 2022
			Numerical Rating Scale (NRS) was reduced [iv]	-- Rubio-Zarapuz 2023
Spasticity	Modified Ashworth Scale (MAS)	CP	degree of spasticity decreased after one month (p=0.007), and after six months (p=0.011).	-- Hedin 2022
		CP + stroke	No changes	0 Ertzgaard 2018
		Stroke	No changes	0 Palmcrantz 2020 Pennati 2021
	Modified Tardieu Scale	CP	Decreased after one month (p=0.030)	-- Hedin 2022
			Decreased after three (p=0.392) and six months (p=0.426)	- Hedin 2022
			No changes	0 Bakaniene 2018
	Muscle tone	CP	No changes	0 Flodström 2022
	NeuroFlexor surface EMG	Stroke	No changes	0 Pennati 2021
	NeuroFlexor® Neural Component (NC)	Stroke	NC decreased in wrist flexors of affected hand (p=0.023) [v]	-- Palmcrantz 2020
Physiological function	Passive and Active Range of Motion (pROM, ROM)	CP	After one, three, and six months of treatment, a significant number of improved muscles were observed for pROM (p=0.000, p=0.001, p=0.014)	++ Hedin 2022

Category	Outcomes	Pathology	Results	Sig.*
			No changes	0 Bakaniene 2018 Flodström 2022
		Stroke	No changes	0 Pennati 2021
General health - Oxygenation	Hands temperature	Fibromyalgia (n=1)	Decrease in hands temperature [iv]	-- Rubio-Zarapuz 2023
	Muscle oxygen saturation SmO_2	Fibromyalgia (n=1)	Increased [iv]	++ Rubio-Zarapuz 2023
	Total haemoglobin THb	Fibromyalgia (n=1)	No changes	0 Rubio-Zarapuz 2023
	Oxygenated haemoglobin O_2Hb	Fibromyalgia (n=1)	Increased [iv]	++ Rubio-Zarapuz 2023
	Deoxygenated haemoglobin HHb	Fibromyalgia (n=1)	Decreased [iv]	-- Rubio-Zarapuz 2023
	Forced expiratory volume in 1s (FEV1)	Fibromyalgia (n=1)	Decreased [iv]	-- Rubio-Zarapuz 2023
	Forced expiratory volume in 6s (FEV6)	Fibromyalgia (n=1)	Increased [iv]	++ Rubio-Zarapuz 2023
	FEV1/FEV6	Fibromyalgia (n=1)	Decreased [iv]	-- Rubio-Zarapuz 2023
General health – Vegetative system (relaxation)	Sleep	CP	No changes	0 Arkkukangas 2022 Hedin 2022
	Bowel function	CP	No changes	0 Hedin
	Cortical arousal	Fibromyalgia (n=1)	No changes	0 Rubio-Zarapuz 2023
	Saliva flux	Fibromyalgia (n=1)	Increased [iv]	++ (sic) Rubio-Zarapuz 2023
	Salivary proteins	Fibromyalgia (n=1)	Decreased [iv]	-- Rubio-Zarapuz 2023
Activity	Wolf Motor function test (WMFT) – first two tasks	CP + Stroke	No changes	0 Ertzgaard 2018
	Fugl-Meyer index - Upper Extremity total score	Stroke	Increased (p=0.000) [vi]	++ Palmcrantz 2020
	Fugl-Meyer index - Lower Extremity total score	Stroke	Increased (p=0.003) [vi]	++ Palmcrantz 2020

Category	Outcomes	Pathology	Results	Sig.*
	Action Reach Arm Test (ARAT)	Stroke	Increased [vi]	++ (sic) Palmcrantz 2020
		CP + Stroke	No changes	0 Ertzgard 2018
	Level of Sitting Scale (LSS)	CP	No changes	0 Arkkukangas 2022
	Box and Block test	CP	No changes	0 Arkkukangas 2022
	Grip strength	Stroke	No changes	0 Palmcrantz 2020
		Fibromyalgia (n=1)	Improved [iv]	++ (sic) Rubio-Zarapuz 2023
Mobility & Safety	Berg Balance Scale (BBS)	Stroke	No changes	0 Palmcrantz 2020
	Gross Motor Function Measure (GMFM)	CP	Increased [v]	++ Bakaniene 2018
			No changes	0 Hedin 2022
	Gross Motor Function	CP	No changes	0 Flodström 2022
	TUG [s]	CP	No changes	0 Bakaniene 2018 Arkkukangas 2022
		CP + Stroke	No changes	0 Ertzgaard 2018
	Chair stand test	Fibromyalgia (n=1)	Improved [iv]	++ (sic) Rubio-Zarapuz 2023
	One leg balance	Fibromyalgia (n=1)	Improved [iv]	++ (sic) Rubio-Zarapuz 2023
	10m up and go test	Fibromyalgia (n=1)	Improved [iv]	++ (sic) Rubio-Zarapuz 2023
	10m walk test	CP + Stroke	Comfortable gait test, time and number of steps improved [vi]	+ Ertzgaard 2018
		Stroke	No changes	0 Palmcrantz 2020
	6 min walk test	Stroke	No changes	0 Palmcrantz 2020
	Nonlinear dynamics of trunk acceleration	CP	Temporal structure of trunk acceleration in the anterior-posterior direction was altered towards that of healthy individuals. [ii] (Decrease in Largest Lyapunov exponent (p=0.041) and complexity Index (p=0.030))	++ Raffalt 2022
Participation	Goal Attainment Scale (GAS)	CP + Stroke	Improved [vi]	+ Ertzgaard 2018

Category	Outcomes	Pathology	Results	Sig.*
	Canadian occupational performance measure (COPM)	CP	All participants (n=6) showed improvements in total score of COPM, three of them showed significant clinical improvements [iii]	++ Flodström 2022
	Stroke Impact Scale	Stroke	No changes	0 Palmcrantz 2020
	Experiences with the suit (impact on body, self, activities, participation in ADLs)	CP	Children and parents saw improvements in children's physical and mental health after the use of the suit.	n.a. Nordstrøm 2021
	Interest in continuing using Mollii, Motivation, Usability, Support	CP + Stroke	Responder participants felt hopeful, motivated when experiencing a treatment effect, and disappointed when not.	n.a. Jonasson 2022

ADLs: Activities of Daily Life; **ARAT**: Action Reach Arm Test; **BBS**: Berg Balance Scale; **CGT**: Comfortable gait test; **COPM**: Canadian occupational performance measure; **EMG**: Electromyography; **FEV**: Forced expiratory volume; **FEV1**: Forced expiratory volume in 1s; **FEV6**: Forced expiratory volume in 6s; **FGT**: Fast gait test; **FM**: Fugl-Meyer index; **GAS**: Goal Attainment Scale; **GMFM**: Gross Motor Function Measure; **LSS**: Level of sitting scale; **MAS:** Modified Ashworth Scale; **MTS**: Modified Tardieu Scale, **NC**: Neural component; **PPT**: Pressure Pain Threshold; **pROM**: passive Range of Motion; **ROM**: active Range of Motion; **QoL**: Quality of Life; **TUG**: Timed-up and go-Test; **VAS**: Visual Analogue Scale; **WMFT**: Wolf motor function test

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

[ii] after 24 weeks of intervention; [iii] after 3 months of intervention; [iv] after 60 minutes of intervention; [v] after 3 weeks of intervention; [vi] after 6 weeks of intervention;

Author's Conclusion

"The EMS is a full-body garment with built-in electrodes that deliver electrical stimulation to the muscles, with the goal of reducing spasticity and increasing flexibility and range of motion. This review investigated the benefits of the employment of the EMS for rehabilitation purposes for CP, stroke, and other neurological disease patients. Although further studies should be performed to test the effectiveness of this device, the literature reviewed demonstrated the potentiality of the EMS in clinical practice to improve the motor functions of neurological patients." (Perpetuini et al. 2021)

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