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Title: A randomised clinical trial to assess the effect of active muscle stimulation on hospitalised patients with COPD exacerbations

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Body: Introduction: Physical exercise reduces the detrimental effects of acute exacerbations in patients with chronic obstructive pulmonary disease (COPD). The Galileo™ system (Novotec Medical, Pforzheim, Germany) is based on the principle of active muscle contraction via extension reflex triggers. Aim: To assess the effect of active muscle stimulation in hospitalised COPD patients on exercise capacity, health-related quality of life (QoI), and inflammation. Methods: 24 hospitalised COPD patients with an acute exacerbation were randomised to participate either in the standard physiotherapy programme (PT: physical and respiratory exercises) or in the standard programme with the addition of exercises on the Galileo device (PTG). On the days of admission and discharge we assessed: 6-minute walking test (6-MWT), COPD assessment test (CAT), and serum c-reactive protein (CRP). Results: The baseline characteristics are shown in table 1.

	PT	PTG	
Gender [M/F]	9/4	5/6	
Alter [years]	72,92±10,21	67±11,93	
BMI [kg/m2]	25,73±5,81	25,05±4,81	
FEV1 [%pred.]	40,47±18,49	34,49±12,17	

Mean +/- SD

While CRP decreased in both groups (p<0.05), we found a significant increase in the 6-MWT (p<0.005) and

a significant decrease in the CAT (p<0.05) in the PTG group only (table 2).

	PT	PT	PTG	PTG
	admission	discharge	admission	discharge
CRP [mg/l]	22.23±13.94	10.41±8.14	57.45±81.14	6.82±3.19
6-MWT [m]	186.22±128.23	157.92±106.61	154.72±117.8	264.82±122.38
CAT	21.69±9.49	22.21±7.34	30.91±7.59	26.09±5.38

Mean +/- SD

Conclusion: In patients hospitalised due to an exacerbation of COPD, the addition of active muscle contraction with the Galileo system results in beneficial effects on QoI and exercise capacity.