

RESEARCH LETTER

GRADUS Study: To Walk Longer and Faster — an Innovative Programme for Individuals with Peripheral Vascular Disease

Sara Pomatto ^{a,*}, Rodolfo Pini ^{a,b}, Rosario Lordi ^{c,d}, Nicola Grazi ^c, Gianluca Faggioli ^{a,b}, Mauro Gargiulo ^{a,b}

^a Vascular Surgery, Department of Medical and Surgical Sciences (DIMEC), “Alma Mater Studiorum” University of Bologna, Bologna, Italy

^b Vascular Surgery Unit, IRCCS Azienda Ospedaliero-Universitaria S. Orsola, Bologna, Italy

^c Abcardio Bologna, Department of Scientific Research and Development, Bologna, Italy

^d Centre for Exercise Science and Sport, Department of Neuroscience and Rehabilitation, University of Ferrara, Ferrara, Italy

Lower limb peripheral arterial disease is a common and costly condition. Its initial symptom is usually intermittent claudication (IC), which significantly impairs patients' quality of life (QoL).

International guidelines recommend supervised exercise therapy (SET) as the first line treatment for patients with IC, and it appears to be the most cost effective option.^{1–4} However, only a minority of patients worldwide receive SET, mainly due to several limitations, including a lack of awareness regarding its benefits, outdated opinions favouring invasive interventions, low patient motivation, logistic challenges (including location, scheduling, and social factors), and the absence of reimbursement.³

Most SET programmes are based on treadmill or track walking, but intensity, duration, and structure vary.⁵ The aim of the GRADUS study was to evaluate the effectiveness of an innovative SET using Biocircuit (Technogym S.p.A., Cesena, Italy; <https://www.technogym.com/en-INT/biocircuit-training/>) in terms of cardiopulmonary and physical performance as well as improvement in QoL.

GRADUS is a prospective, unfunded study approved by the ethics committee and carried out through collaboration between the Vascular Surgery Unit of the University of Bologna (Bologna, Italy) and the Centre for Exercise Science and Sport of the University of Ferrara (Ferrara, Italy). Since April 2021, a free SET programme using the Biocircuit system has been offered to patients with IC due to infringuinal peripheral arterial disease attending a single vascular surgery outpatient clinic. The programme included aerobic training (warm up cycling followed by three treadmill sessions of ten minutes each) and resistance training (knee extension, leg press, and leg curl exercises) performed under physiotherapist supervision three times per week for 12 weeks. Each patient underwent pre- and post-training assessments of cardiopulmonary and physical performance, including a submaximal incremental test, maximum cardiopulmonary exercise test, submaximum constant load test, six minute walking test, and one repetition maximum

test, along with QoL assessments using the 36 item short form health survey (SFHS-36) and the Vascular Quality of Life Questionnaire-6 (VascuQoL-6). Exclusion criteria included age < 65 years, aorto-iliac stenosis or obstruction, non-vascular related claudication, or previous lower limb revascularisation. Study outcomes included pain free walking distance, six minute walking distance, cardiopulmonary efficiency, and QoL scores.

Of the 101 patients who met the inclusion criteria, 51 (50.5%) declined to participate; the main reasons were lack of motivation ($n = 24$; 47%), logistic or transport related issues ($n = 21$; 41%), and lack of time ($n = 6$; 12%).

Of the 50 enrolled participants, 32 completed the 12 week SET programme (dropout rate, 36%). Of the 18 patients who did not complete the programme, three patients (17%) discontinued due to comorbidities (spondylarthrosis limiting physical activity, hospitalisation for acute myocardial infarction, and urinary tract disorder), while the remaining 15 patients (83%) withdrew due to lack of motivation.

The median age of those who completed the programme was 71 years (interquartile range [IQR] 58, 84) and 26 (81%) were men. Ten patients (31%) were current smokers and 18 (56%) were former smokers. Hypertension was present in 30 patients (94%), dyslipidaemia in 31 (97%), and diabetes mellitus in 12 (38%).

Statistically significant improvements were observed in pain free walking distance (206 ± 98 m vs. 185 ± 102 m; $p = .006$), six minute walking distance (392 ± 119 m vs. 348 ± 109 m; $p < .001$), cardiopulmonary efficiency (peak oxygen consumption [VO_2 peak] 16.2 ± 3.9 mL/min/kg vs. 15.2 ± 3.5 mL/min/kg; $p = .047$), and QoL scores (SFHS-36, 102 [IQR 97, 107] vs. 100 [IQR 94, 106], $p = .024$; VascuQoL-6, 19 [IQR 14, 24] vs. 15 [IQR 11, 19], $p < .001$) (Table 1).

The rationale behind this research letter is to highlight this initiative and raise awareness of the importance of SET. Despite the small sample size, there was a statistically significant improvement in walking distance. Cardiopulmonary exercise test showed an increase in VO_2 peak without a corresponding rise in peak heart rate, suggesting improved cardiopulmonary efficiency. QoL scores also showed significant improvements.

Biocircuit enabled personalised training, offering a manageable solution for rehabilitation experts. Each patient

* Corresponding author. Vascular Surgery, Department of Medical and Surgical Sciences (DIMEC), “Alma Mater Studiorum” University of Bologna, Policlinico S. Orsola, Via Giuseppe Massarenti 9, 40138, Bologna, Italy.

E-mail address: sara.pomatto@gmail.com

Table 1. Physical and cardiopulmonary performance tests and quality of life results before and after the 12 week supervised exercise therapy programme.

Test	Baseline	12 week follow up	p value
Pain free walking distance – m	185 ± 102	206 ± 98	.006
Six minute walking distance – m	348 ± 109	392 ± 119	<.001
VO ₂ peak – mL/min/kg	15.2 ± 3.5	16.2 ± 3.9	.047
Peak heart rate – bpm	106 ± 18	109 ± 22	.24
<i>Quality of life measure</i>			
SFHS-36	100 (94, 106)	102 (97, 107)	.024
VascuQoL-6	15 (11, 19)	19 (14, 24)	<.001

Data are presented as mean ± standard deviation or median (interquartile range). VO₂ peak = peak oxygen consumption; SFHS-36 = 36 item short form health survey; VascuQoL-6 = Vascular Quality of Life Questionnaire-6.

had a personal profile and, upon logging in, the equipment automatically adjusted to the individual's anthropometric data. The machines adapted resistance according to movement, enhancing comfort and reducing joint stress. All training data were uploaded in real time to a cloud based platform and stored in a dedicated database. This allowed ongoing monitoring and optimisation of training load.

A noteworthy observation was that most patients returned to a sedentary lifestyle after completing the free SET programme, despite encouragement to remain physically active. This raises the question of whether any further intervention is needed for this group of patients.

The main limitations of the study were its single centre design, small sample size, and high dropout rate.

Biocircuit is a relatively widely available technology, and the GRADUS SET programme appears effective in improving cardiopulmonary and physical performance as well as QoL.

CONFLICTS OF INTEREST AND FUNDING

None.

REFERENCES

- 1 Nordanstig J, Behrendt CA, Baumgartner I, Belch J, Bäck M, Fitridge R, et al. Editor's Choice – European Society for Vascular Surgery (ESVS) 2024 clinical practice guidelines on the management of asymptomatic lower limb peripheral arterial disease and intermittent claudication. *Eur J Vasc Endovasc Surg* 2024;67:9–96.
- 2 Mazzolai L, Teixido-Tura G, Lanzi S, Boc V, Bossone E, Brodmann M, et al. 2024 ESC guidelines for the management of peripheral arterial and aortic diseases. *Eur Heart J* 2024;45:3538–700.
- 3 Mazzolai L, Belch J, Venermo M, Aboyans V, Brodmann M, Bura-Rivière A, et al. Exercise therapy for chronic symptomatic peripheral artery disease: a clinical consensus document of the European Society of Cardiology Working Group on Aorta and Peripheral Vascular Diseases in collaboration with the European Society of Vascular Medicine and the European Society for Vascular Surgery. *Eur J Vasc Endovasc Surg* 2024;67:373–92.
- 4 Djerf H, Millinger J, Falkenberg M, Jivegård L, Svensson M, Nordanstig J. Absence of long-term benefit of revascularization in patients with intermittent claudication: five-year results from the IRONIC randomized controlled trial. *Circ Cardiovasc Interv* 2020;13:e008450.
- 5 Jansen SC, Abaraogu UO, Lauret GJ, Fakhry F, Fokkenrood HJ, Teijink JA. Modes of exercise training for intermittent claudication. *Cochrane Database Syst Rev* 2020;8:CD009638.

Keywords:

Cardiopulmonary efficiency, Intermittent claudication, Peripheral arterial disease, Quality of life, Supervised exercise therapy

Available online 2 September 2025

© 2025 The Authors. Published by Elsevier B.V. on behalf of European Society for Vascular Surgery. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

<https://doi.org/10.1016/j.ejvs.2025.08.061>