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Jacqueline C Outermans, Roland P S van Peppen, Harriet Wittink, Tim Takken and Gert Kwakkel
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Effects of a high-intensity task-oriented training on gait performance early after stroke: a pilot study

Jacqueline C Outermans Department of Physiotherapy, Institute for Human Movement Studies, University of Applied Sciences Utrecht, Utrecht, **Roland PS van Peppen**, **Harriet Wittink** Research Centre for Innovations in Health Care, University of Applied Sciences Utrecht, Utrecht, **Tim Takken** University Medical Centre Utrecht, Child Development & Exercise Centre, Wilhelmina Children's Hospital and **Gert Kwakkel** Department of Rehabilitation Medicine, VU University Medical Centre, Amsterdam and Department Rehabilitation Medicine, Rudolf Magnus Institute of NeuroScience, University of Utrecht, Utrecht, The Netherlands

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Objective: To investigate the feasibility and the effects on gait of a high intensity task-oriented training, incorporating a high cardiovascular workload and large number of repetitions, in patients with subacute stroke, when compared to a low intensity physiotherapy-programme.

Design and subjects: Randomized controlled clinical trial: Forty-four patients with stroke were recruited at 2 to 8 weeks after stroke onset.

Measures: Maximal gait speed assessed with the 10-metre timed walking test (10MTWT), walking capacity assessed with the six-minute walk test (6MWT). Control of standing balance assessed with the Berg Balance Scale and the Functional Reach test. Group differences were analysed using a Mann-Whitney *U*-test.

Results: Between-group analysis showed a statistically significant difference in favour of the high intensity task-oriented training in performance on the 10MTWT ($Z = -2.13$, $P = 0.03$) and the 6MWT ($Z = -2.26$, $P = 0.02$). No between-group difference were found for the Berg Balance Scale ($Z = -0.07$, $P = 0.45$) and the Functional Reach test ($Z = -0.21$, $P = 0.84$).

Conclusion: A high-intensity task-oriented training programme designed to improve hemiplegic gait and physical fitness was feasible in the present study and the effectiveness exceeds a low intensity physiotherapy-programme in terms of gait speed and walking capacity in patients with subacute stroke. In a future study, it seems appropriate to additionally use measures to evaluate physical fitness and energy expenditure while walking.

Introduction

Disability due to hemiparesis limits independent functioning, including gait related activities in more than half of the stroke survivors¹. With that, regaining and enhancing walking competency is a major target in stroke rehabilitation²

Address for correspondence: Jacqueline Outermans, Department of Physiotherapy, University of Applied Sciences Utrecht, Institute for Human Movement Studies, PO Box 85182, 3508 AD Utrecht, The Netherlands.
e-mail: jacqueline.outermans@hu.nl

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Traditionally, physiotherapy concepts were focused on restoring reduced motor control of the affected limb as well as postural control. However recently, evidence was found on improved walking ability not being associated with improved motor control of the paretic lower limb^{3,4} but rather with the development of compensation movement strategies^{5,6} and improved coping with loss of function in enhancing the ability to maintain balance over the non-paretic lower limb.^{6,7} Repetitive training of tasks results in improvement in lower limb function, as a recent Cochrane review by French and colleagues⁸ showed, supporting the idea that a high dose of repetitions are effective for improving gait-related activities.

Furthermore, muscle strength^{9,10} as well as cardiorespiratory capacity^{11,12} are decreased in stroke and are found to be significantly associated with insufficient walking capacity.^{11,13} Evidence was found on the beneficial effects of muscle strength training in terms of lower limb muscular strength,¹⁴ but no favourable effects were found of strength training in terms of mobility-related tasks, such as stair walking, turning, making transfers, walking quickly, and walking for specified distances, whereas some evidence was found for cardiorespiratory training on walking capacity in terms of distance.^{15–17}

In line with these findings, training should be oriented on those tasks that are meaningful for daily life.^{14,15}

One general problem in demonstrating the specific effects of any given task across rehabilitation trials has been the low dose of training, which might limit the robustness of finding differential effects.¹⁸ To overcome the problem of time dedicated to practice, Dean and colleagues developed circuit class training, in which patients are able to practise at their own functional level in groups.¹⁹ A recent meta-analysis demonstrated significant homogeneous summary effect sizes in favour of task-oriented circuit class training for walking distance, gait speed and a timed up-and-go.²⁰ Unfortunately, only one study did investigate the effects of circuit class training in the first weeks post stroke,²¹ and one study investigated additional cardiorespiratory workload on gait training in subacute stroke.¹⁶ Therefore, there are only few data available to guide clinical practice at present with regard to the effectiveness of task-oriented fitness training interventions after stroke.²²

The purpose of the present pilot study was to establish the feasibility of a high-intensity task-oriented training incorporating a high number of repetition and high cardiorespiratory workload when compared with a low-intensity physiotherapy programme both delivered in circuit class training in the 2nd–12th week after stroke onset, and to determine the effects on walking competency in terms of walking distance, gait speed and postural balance.

Methods

Participants

The study was performed in a neurorehabilitation clinic in Bad Berleburg, Germany. All participants were inpatients. Eligibility criteria included: (1) clinical diagnosis of hemiplegia following first or recurrent stroke, (2) time since most recent stroke and time of recruitment between 2 and 8 weeks, (3) the ability to walk 10 meters without assistance; Functional Ambulation Categories²³ ≥ 3 . Subjects were excluded in case of (a) cardiovascular instability, (b) acute impairments of the lower extremities influencing walking ability and (c) sensory communicative disorders. Cardiovascular instability was defined as resting systolic blood pressure over 200 mmHg and resting diastolic blood pressure over 100 mmHg.²⁴

Design

This pilot study was a randomized clinical trial. After baseline measurements participants were allocated to the high intensity task-oriented training or the low-intensity physiotherapy. Allocation was performed by drawing randomly generated lots enclosed in opaque envelopes.

Baseline measurements were taken on the second day after admission in the rehabilitation clinic. Post-trial measurements were scheduled immediately after the trial, or before in case of early discharge (Figure 1). All clinical assessments were conducted by one assessor (JO), who was not blinded for allocation. To minimize bias the assessor was not present at the group training at any

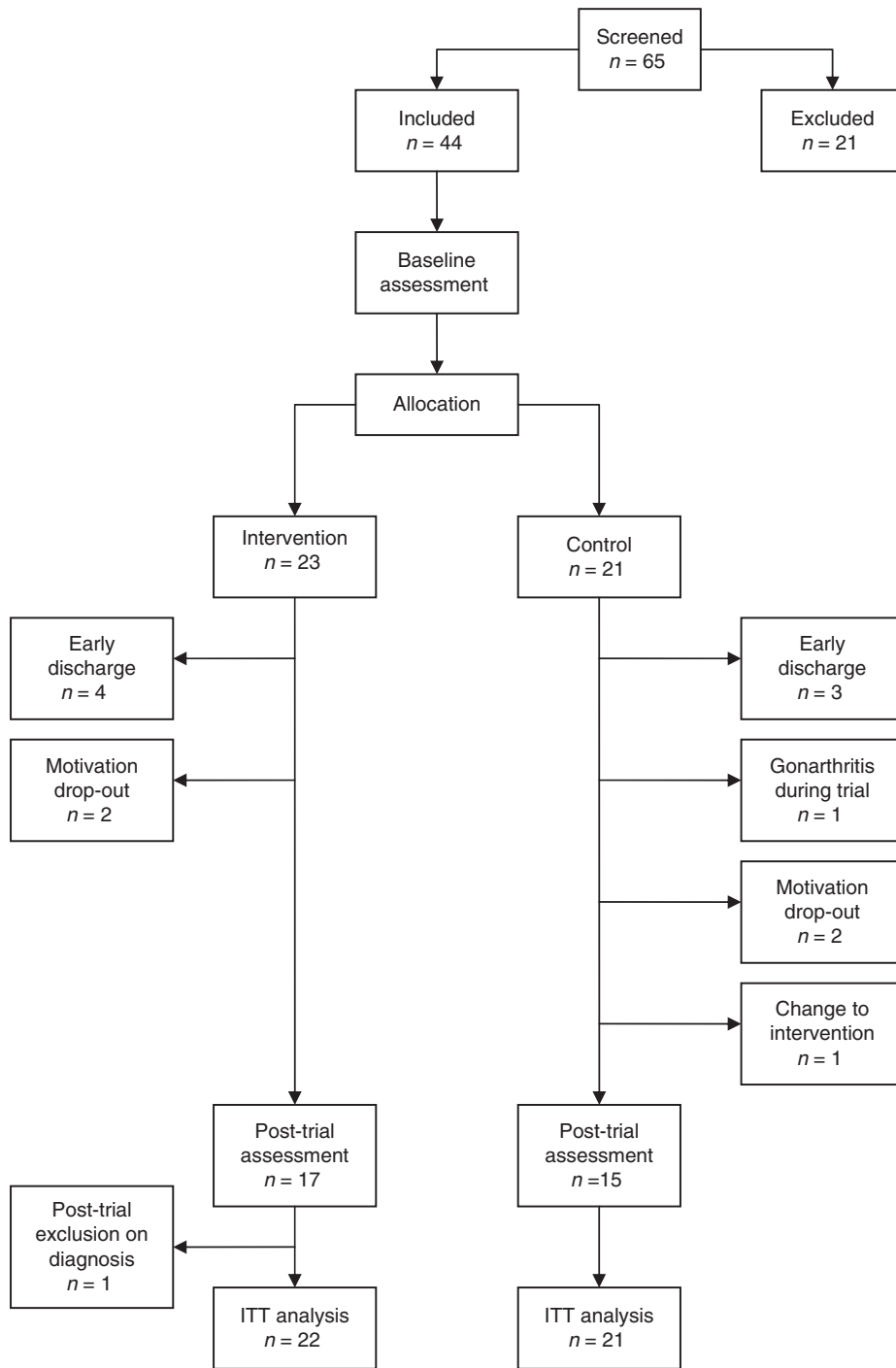


Figure 1 Patient flow and study design.

time. Also previous assessments were not available during post-test assessment and all instructions were standardized.

All eligible patients who were willing to participate signed an informed consent in which the project was explained as well as the use of their assessment data for analysis.

Intervention

All participants engaged in usual individual physiotherapy for half an hour each day. Information about intensity and content of the therapy beyond the trial were documented in a patient's record. Therapists were instructed not to depart from their usual care during the trial. This was monitored using the available documentation.

The high-intensity task-oriented training-programme incorporated 10 standardized workstations, focused on improving walking competency, similar to the study by Dean *et al.*¹⁹ Participants in the high-intensity training-group performed 45 minutes of circuit class training, held at the rehabilitation clinic three times a week for four weeks. All stations were practised for 2.5 minutes, followed by a 1-minute transfer to the next station. Afterwards the participants joined in walking relays and races for 10 minutes.

The high-intensity training-programme focused on improving postural control and gait-related activities such as stair walking, turning, making transfers, walking quickly and walking for specified distances. In line with the recommendations of the American Heart Association,²² cardiorespiratory workload started at 40–50% of heart rate reserve. Progression was attained by increasing the workload to a maximum of 70–80% of heart rate reserve,²⁵ and increasing the number of repetitions, both according to the observations and estimation of the therapists in charge and the patients perceived exertion. A 6–20 Borg Scale was used to rate subjects' perceived exertion.²⁶

The focus in the low-intensity physiotherapy-group was on improving motor control of the hemiparetic leg and balance. In contrast to the high-intensity training-group there were no components of physical fitness training such as strengthening exercises or cardiorespiratory training, indicating

that the training was set at a low-intensity profile aimed at learning gait-related activities. The participants in the low-intensity physiotherapy-group went through a 45-minute programme of group exercises, three times a week for four weeks, thus matching therapy time to the high-intensity training-group. The low-intensity physiotherapy-programme was also based on a 10 workstations circuit. All stations were practised for 2.5 minutes, followed by a 1-minute gap to transfer to the next station. Afterwards the participants joined in games, like passing through a ball, for 10 minutes.

Progression, according to the observations and estimation of the therapists in charge, was achieved by enhancing motor control challenge, not in enhancing the number of repetitions like the high-intensity training-group.

Data collection

All participants underwent a pretest baseline assessment during which subject characteristics age, Body Mass Index (BMI), gender, hemiplegic side, blood pressure and resting heart rate were determined as well as walking capacity, maximal gait speed and control of standing balance.

The outcome measures on walking distance and gait speed were selected in this trial according to the formal physiotherapy guidelines of the Royal Dutch Society for Physical Therapy, the Clinical Practice Guideline for Physiotherapy management of patients with Stroke.²³

The six-minute walk test (6MWT) was selected as a measure of walking capacity, being a general challenge to walking ability.²⁷ This test incorporates walking speed, dynamic balance and sub-maximal endurance, which are important requirements of ambulation. The 6MWT is valid and reliable in a stroke population.^{27,28} It was performed according to the American Thoracic Society Guidelines²⁹ on a 50-m course with 10-m increments marked discretely on the wall. Subjects were instructed to walk the course back and forth. The total distance covered was determined by adding the laps and the surplus, measured with a tape measure to the last marker, on countdown. Afterwards perceived exertion was evaluated using the 6–20 Borg Scale.²⁶ To ensure safe exercise and to objectify perceived exertion, heart rate was

recorded during the 6MWT using a Polar F1 heart rate monitor (Polar Oy, Kempele, Finland).

Maximal gait speed was assessed using the 10-metres timed walking test (10MTWT). The subjects were instructed to walk as fast as possible. To avoid the effects of acceleration and deceleration, gait speed was measured for 10 m on a 15-m course. This test was performed three times and the mean was used for analysis. The 10MTWT showed high intra-rater reliability (intraclass correlation coefficient (ICC)=0.95) and validity ($r_s=0.79$) in patients with stroke.³⁰ During 6MWT and 10MTWT the assessor remained behind the participant to avoid influencing performance, but still ensuring safety.

Control of standing balance was assessed with the Berg Balance Scale³¹ and the Functional Reach test.³² In stroke populations the Berg Balance Scale has shown good intra-rater reliability (ICC=0.97) and internal consistency Cronbach's alpha 0.92–0.98, but tends to show a ceiling effect,³³ therefore Functional Reach was also assessed. In a stroke population the Functional Reach test showed high intra-rater reliability (ICC=0.89) and validity ($r_s=0.71$).³⁴ The Functional Reach was measured beside a wall. Standing upright, the participant was asked to reach forward with the non-paretic arm as far as possible without touching the wall or taking a step.

Data analysis

Analyses in this study were performed using an intention-to-treat analysis to determine the effects of both interventions. Missing values were imputed using the assumption of a worst-case scenario in which the baseline value was carried forward.³⁵

Descriptive statistics were used for baseline characteristics, measures of central tendency and variability. Group comparisons at baseline and post intervention were analysed using a Mann–Whitney *U*-test, considering the small group sizes. An alpha level set at 0.05 determined significance in two-sided hypothesis testing. All analyses were performed using SPSS version 15.0 (SPSS Inc, Chicago, IL, USA).

Results

Sixty-five potential participants were screened for the present pilot study; 44 subjects satisfied the selection criteria and were included in the trial. Figure 1 shows the trial profile of patient recruitment and drop-outs during the study. Twenty-three participants were allocated to the high-intensity task-oriented training-group and 21 were allocated to the low-intensity physiotherapy-group. In the high-intensity training-group one participant was excluded afterwards due to a wrong diagnosis with respect to 'stroke', leaving 22 participants for analysis.

Due to an early discharge, four participants were lost before the post-trial assessment. One participant suffered from a recurrent stroke and was transferred to acute care, and two participants dropped out for motivational reasons. In the low-intensity physiotherapy-group 21 participants were analysed. Three participants were lost before post-intervention assessment due to early discharge. During the programme two participants dropped out for motivational reasons, a third participant did not receive treatment as allocated and a fourth dropped out because of acute gonarthrosis. Two participants in the intervention and three in the control group participated for less than 20 days, but could be assessed post trial. In neither group any adverse events occurred during the trial.

Baseline characteristics

Table 1 shows the patient characteristics of the both groups at baseline. No statistically significant differences between both groups were found with respect to patient characteristics such as age, body mass index, mean time since onset or mean participation duration. No statistically significant differences were found ($P>0.05$) with respect to measurement of 6MWT, 10MTWT, Berg Balance Scale and Functional Reach test.

Walking distance and maximal gait speed

The 6MWT showed an increment of 54.0 m (SD 65.1) to mean 518.7 m (SD 165.2) in the high-intensity training-group compared with an increment of 21.4 m (SD 43.2) to a mean 422.4 m (SD 127.9) in the low-intensity physiotherapy-group. Table 2 shows the mean scores for both groups post intervention.

A subsequent between-group analysis found a significant difference in favour of the high-intensity training-group ($Z = -2.26$, $P = 0.02$) (Table 2). The improvement on the 10MTWT was 0.3 m/s (SD 0.3) to a mean 1.7 m/s (SD 0.5) for the HiTT group compared with a post-trial mean of 1.4 m/s (SD 0.4) for the low-intensity physiotherapy-group. This difference in improvement was statistically significant in favour of the HiTT group ($Z = -2.13$; $P = 0.03$).

Balance

The scores on the Berg Balance Scale increased 1.0 points (SD 1.5) to a mean of 54.1 (SD 3.0) in

the high-intensity training-group. The low-intensity physiotherapy-group showed an increase of 0.9 points (SD 1.3) to a mean score of 54.1 (SD 1.7). An increase of 1.9 cm (SD 3.6) to a mean 27.0 cm (SD 7.9) in the HiTT group was found compared with an increase of 2.3 cm (SD 5.7) to a mean of 27.4 (SD 9.1) in the low-intensity physiotherapy-group. Table 2 shows between-group analysis on both balance measures, revealing a non-significant differences between both groups on the Berg Balance Scale ($Z = -0.07$, $P = 0.45$) and Functional Reach ($Z = -0.21$, $P = 0.84$).

Table 1 Baseline results

	HiTT group <i>N</i> = 22 Mean (SD)	LoPT group <i>N</i> = 21 Mean (SD)	<i>Z</i>	Significance (2-tailed)
Age (years)	56.8 (8.6)	56.3 (8.6)	-0.09	0.92
BMI (kg/m ²)	26.9 (9.3)	27.8 (4.9)	-0.47	0.64
Sex	19 male	17 male		
Hemi-side	11 left-sided	11 left-sided		
Time since onset (days)	22.5 (8.2)	23.5 (7.8)	-0.40	0.69
Intervention duration (days)	25.2 (5.2)	21.4 (9.7)	-1.10	0.27
6MWT (m)	459.8 (145.8)	401.0 (131.5)	-1.53	0.13
10MTWT (m/s)	1.5 (0.5)	1.4 (0.5)	-0.84	0.40
BBS	53.0 (3.3)	53.2 (2.3)	-0.21	0.83
FR (cm)	24.6 (9.2)	25.6 (7.4)	-0.24	0.81

HiTT, high-intensity task-oriented training programme; LoPT, low-intensity physiotherapy programme; BMI, Body Mass Index; 6MWT, six-minute walking test; 10MTWT, 10-metre timed walking test; BBS, Berg Balance Scale; FR, Functional Reach test.

Table 2. Post intervention results

	HiTT-Group <i>N</i> = 22 Mean (SD)	LoPT-Group <i>N</i> = 21 Mean (SD)	<i>Z</i>	Sig.(2-tailed)
6MWT (m)	518.7 (165.2)	422.4 (127.9)	- 2.26	0.02
Change score 6MWT	54.0 (65.2)	21.4 (43.2)		
10MTWT (m/s)	1.7 (0.5)	1.4 (0.4)	-2.13	0.03
Change score 10MTWT	0.3 (0.3)	0.0 (0.1)		
BBS	54.1 (3.0)	54.1 (1.7)	-0.07	0.45
Change score BBS	1.0 (1.5)	0.9 (1.3)		
FR (cm)	27.0 (7.9)	27.4 (9.1)	-0.21	0.84
Change score FR	1.9 (3.6)	2.3 (5.7)		

HiTT, High-intensity Task-oriented Training; LoPT, Low-intensity Physiotherapy; 6MWT, 6 minutes walking test; 10MTWT, 10 meter timed walking test; BBS, Berg Balance Scale; FR, functional reach test.

Discussion

The high-intensity task oriented training-programme in this pilot study implementing a high number of repetitions and a high cardiorespiratory workload, designed to improve hemiparetic gait was feasible and exceeds the effectiveness of a low intensity physiotherapy-programme in terms of walking capacity and walking speed. Since no adverse events occurred and dropout rate for motivational reasons was equally low in both groups, the high-intensity programme seemed to be feasible as well as safe and acceptable in the sample of the present pilot study.

The high-intensity task-oriented training programme in this study was based on the programme developed by Dean *et al.*¹⁹ Similar circuit class training programmes have been used in several other trials,^{21,36,37} although the low-intensity physiotherapy-programme in the present study was, contrary to the control interventions in above-mentioned studies, (1) matched for amount of spent time of practice and (2) also focused on improving locomotor function. In particular this latter fact suggests that the higher intensity of practice including a high cardiorespiratory workload is responsible for the favourable effects of the high-intensity training programme.

No significant effects on balance control were found as measured with the Berg Balance Scale. The lack of evidence for improved balance control on the basis of the Berg Balance Scale despite a higher dose of practice is in line with a previous meta-analysis of six RCTs on circuit class training showing no significant effects on balance control.²⁰ The lack of evidence for improved balance control may be related to lack of responsiveness of the Berg Balance Scale to change when relatively high scores on baseline are shown.³³ Most patients recruited in this study showed relatively high scores on the Berg Balance Scale at baseline, which limits further significant change on this scale.³⁸ On the other hand, balance control may be less influenced by a higher dose of practice when compared with more effort-related outcomes such as gait speed and walking distance.

There are a number of limitations of the present pilot study. First, the present pilot study lacks

adequate blinding procedures for the observer, suggesting that results may have been biased in favour of the high-intensity training-group.

Second, the study was aimed at exploring the feasibility, including safety, of the high-intensity training programme only in an early stage after stroke onset. In several other studies subjects were more severely impaired and in a chronic stage,^{19,36} therefore it requires further investigation to determine the feasibility of these programmes in other subpopulations and at different phases after stroke.

Third, the subjects recruited for this trial performed on a relatively high level of physical functioning at baseline. In most cases, gait performance measured with 10MTWT was within the 95% confidence limits of measurement error and comparable to scores observed in healthy populations.^{10,39} In contrast, the scores on the 6MWT remained at a 80% to observation in a healthy population,⁴⁰ suggesting that physical condition to walk long distances was more compromised than gait speed. On the other hand, still clinical significant improvement on both gait measures, considering a minimal clinical important difference of 54.1 metre on the 6MWT²⁷ and 0.3 m/s on the 10MTWT,^{2,30} proved to be attainable in the present patient sample despite the relatively high pre-test performance stressing the feasibility of the programme in this population. However, the generalization of this exercise program to more severely affected patients remains unclear.

Fourth, there was no follow-up in the present pilot study. With that, the long term effects of the high-intensity programme on ambulatory activity for walking competency in the community remain unclear.

Furthermore, the underlying mechanisms that drive the observed changes in gait performance following a high-intensity task-oriented training-programme remain unclear. Above findings are in agreement with the observation that improvement of walking ability is weakly associated with observed changes in strength and synergism of the paretic leg itself^{3,4,7} and suggest that improvements in gait could be associated with increased cardiorespiratory capacity and adaptations of the non-hemiplegic side rather than restoration of motor impairments on the hemiplegic side,⁷ enabling a decrease in energy expenditure.

Finally the findings in the present study suggest to be in line with observations in studies which used measures to evaluate cardiorespiratory capacity.^{17,41} However the measures in the present study were not feasible as to reveal underlying mechanisms in terms of cardiorespiratory capacity or energy expenditure.

Therefore, future research should emphasise on clarifying whether increased walking competency is due to a more efficient energy-expenditure induced by improved motor control during walking (i.e. restitution of function) or rather an increased cardiorespiratory capacity (i.e., compensation), or both.⁵

Clinical messages

- The effectiveness of a high-intensity task-oriented training programme seems related to higher intensity of practice and cardiorespiratory workload.
- High-intensity task-oriented training is beneficial early after stroke in mildly impaired stroke patients.
- A future evaluation of cardiorespiratory capacity and energy expenditure while walking is necessary to investigate underlying mechanisms explaining gait improvement following high-intensity task-oriented training.

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Competing interests

None stated.

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