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Robot-assisted gait training versus equal intensity treadmill training in patients with mild to moderate Parkinson's disease: A randomized controlled trial

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ABSTRACT

Background: There is a lack of evidence about the most effective strategy for training gait in mild to moderate Parkinson's disease. The aim of this study was to compare the effects of robotic gait training versus equal intensity treadmill training and conventional physiotherapy on walking ability in patients with mild to moderate Parkinson's disease.

Methods: Sixty patients with mild to moderate Parkinson's disease (Hoehn & Yahr stage 3) were randomly assigned into three groups. All patients received twelve, 45-min treatment sessions, three days a week, for four consecutive weeks. The Robotic Gait Training group (n=20) underwent robot-assisted gait training. The Treadmill Training group (n=20) performed equal intensity treadmill training without body-weight support. The Physical Therapy group (n=20) underwent conventional gait therapy according to the proprioceptive neuromuscular facilitation concept. Patients were evaluated before, after and 3 months post-treatment. Primary outcomes were the following timed tasks: 10-m walking test, 6-min walking test.

Results: No statistically significant difference was found on the primary outcome measures between the Robotic Gait Training group and the Treadmill Training group at the after treatment evaluation. A statistically significant improvement was found after treatment on the primary outcomes in favor of the Robotic Gait Training group and Treadmill Training group compared to the Physical Therapy group. Findings were confirmed at the 3-month follow-up evaluation.

Conclusions: Our findings support the hypothesis that robotic gait training is not superior to equal intensity treadmill training for improving walking ability in patients with mild to moderate Parkinson's disease.

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1. Introduction

Gait impairment is one of the primary movement disorders in Parkinson's disease (PD) [1–3]. It is characterized by a reduced gait speed, shortened stride length and longer double support phase [2]. Thus, one of the primary goals in PD rehabilitation is to improve walking ability [4]. The use of training programs focused on task-

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specific activities have been encouraged to improve walking ability, in line with the increased retention of motor skill learning observed in adults with mild PD after task practice [5]. On this basis, a wide range of conventional Physical Therapy (PT) approaches has been employed to treat PD, even though there is no consensus as to "best-practice" in the different phases of illness [4].

Forced use, task-specific, intensive, gait rehabilitation programs based on treadmill training (TT) have been reported to effectively improve gait speed, walking distance and stride length in mild to moderate PD [6]. In addition, robotic gait training (RGT) has been observed to improve gait speed, walking capacity, stride length and fatigue in patients with PD [7]. However, its effectiveness on walking impairment has been evaluated only in early stage PD [7,8], where it is not superior to TT [8]. Considering that gait hypokinesia

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Table 1
Protocol for treatment used in the Physical Therapy group.

Techniques	Sequence activities
Rhythmic initiation	
A	The command "relax and let me move
	you" was used first to move the pelvis
	through the available range of motion
	of anterior elevation and then to return the pelvis through the posterior
	depression pattern.
В	When the therapist could not feel
В	resistance during the movements,
	the command "now help me move
	you" was used to have the subject
	assist the movement for 3 to 4
	repetitions
С	Using the command "pull", the subject
	was asked to superimpose resistance
	upon the movement, with the therapist
	gradually increasing the resistance with
	the increase in subject's response. This
D	was repeated for 3 to 4 repetitions. The subject moved the pelvis actively
Б	through the anterior elevation pattern
	and returned to the starting position
	passively by relaxing.
Е	Sequences (C) and (D) were repeated
	for the remaining time.
Slow reversal	
A	The subject was moved to the lengthened
	range of the pelvis anterior elevation.
В	The therapist had the subject perform a
	contraction of the internal and external
	oblique abdominal muscles to anteriorly
	elevate the pelvis with maximal effort against
	resistance added by the physical therapist.
С	The therapist had the subject perform a
	contraction of the contralateral quadratus lumborum and iliocostalis lumborum muscles
	to posteriorly lower the pelvis against
	maximal resistance.
D	Sequences (B) and (C) were repeated for
	the remaining time.
Slow reversal	
A	The subject was moved to the lengthened
A	range of the pelvis anterior elevation.
В	The therapist had the subject perform a
	contraction of the internal and external
	oblique abdominal muscles to anteriorly
	elevate the pelvis with maximal effort
	against resistance added by the physical
_	therapist.
С	The therapist had the subject perform a
	contraction of the contralateral quadratus
	lumborum and iliocostalis lumborum
	muscles to posteriorly lower the pelvis against maximal resistance.
D	Sequences (B) and (C) were repeated for
D	the remaining time.

¹⁾ Patterns of movement: pelvic anterior elevation and pelvic posterior depression of left and right sides.

is the most important determinant of disability in mild to moderate PD [3], there is a lack of evidence about the more effective strategy for training gait in this phase of illness.

The main aim of this study was to evaluate whether a training program based on RGT could be more effective than equal intensity TT or conventional PT for improving gait speed and walking capacity in patients with mild to moderate PD. The secondary aim was to compare the effects of RGT versus equal intensity TT and conventional PT on spatiotemporal gait parameters, balance, fatigue and severity of disease in mild to moderate PD.

2. Methods

This study was performed in the Neurorehabilitation Unit of the Azienda Ospedaliera-Universitaria Integrata of Verona, Italy. Inclusion criteria: confirmed diagnosis of idiopathic PD according to the UK Brain Bank Criteria [9]; Hoehn and Yahr (H&Y) stage 3 determined in the "on" phase [10]; Mini Mental State Examination >24 [11]. Exclusion criteria: severe dyskinesias or "on-off" fluctuations; change of PD medication during the study; deficits of somatic sensation involving the lower limbs; vestibular disorders or paroxysmal vertigo; other neurological or orthopedic conditions involving the lower limbs (musculoskeletal diseases, severe osteoarthritis, peripheral neuropathy, joint replacement); cardiovascular comorbidity (recent myocardial infarction, heart failure, uncontrolled hypertension, orthostatic hypotension).

All participants were outpatients and gave their informed written consent for participation in the study, which was carried out according to the Declaration of Helsinki and was approved by the local Ethics Committee.

Prior to testing, we randomly assigned participants in a one-to-one ratio to three arms: a group that performed RGT, a group that underwent TT and a group that received PT. We allocated patients to one of the three treatment arms according to a restricted randomization scheme [12]. One of the investigators (F.O.) checked correct patient allocation according to the randomization list. After unmasking at the end of the study, we checked that no errors had been made in allocation. During the study, participants were instructed to take their normal PD medications: they were tested and trained during the "on" phase, 1–2.5 h after taking their morning dose. Participants did not perform any type of rehabilitation in the three months before the study, nor undergo any form of rehabilitation other than that scheduled in the study protocol.

2.1. Treatment procedures

Each patient underwent a training program consisting of twelve, 45-min sessions (including rest periods), three days a week (Monday, Wednesday, Friday) for four consecutive weeks.

2.1.1. Robotic Gait Training (RGT) group

Patients allocated to this group were treated with the Gait Trainer GT1 (Reha-Stim, Berlin, Germany) [7,13]. The GT1 machine is a static suspension system consisting of two motor-driven footplates positioned on 2 bars that provide a robotassisted propulsion with a planetary gear system (ratio of 60%-40% between stance and swing) [13]. Individuals on the GT1 machine are secured in a harness while movements of the center of mass are controlled in a phase-dependent manner by ropes attached to the harness [13]. The GT1 machine allows patients to be treated with a gait speed ranging from 0 to 2 km/h and a step length set from 28 to 48 cm. In this study, the step length of each patient was evaluated with the GAITRite system (CIR Systems, Havertown, PA) and individually defined. The maximum GT1 step length was chosen for patients with a step length >48 cm. Each training session consisted of three parts with a 5-min rest after each. First, we trained patients at 20% of body weight supported and 1 km/h of speed for 10 min; then, at 10% of body weight supported and 1.5 km/h of speed for 10 min; finally, at 0% of body weight supported and 2.0 km/h of speed for 10 min. Patients were instructed to "help" the GT1 gait-like movement during training. Patients unable to maintain the established pace were excluded.

2.1.2. Treadmill Training (TT) group

Patients allocated to this group performed TT without body-weight support with the Jog Now 500MD (Technogym, Cesena, Italy). Each training session consisted of three parts with a 5-min rest after each. First, we trained patients at 1 km/h of speed for 10 min; then, at 1.5 km/h of speed for 10 min; finally, at 2.0 km/h of speed for 10 min. Patients unable to maintain the established pace were excluded.

2.1.3. Physical Therapy (PT) group

Patients allocated to this group performed conventional gait training for 30 min according to the proprioceptive neuromuscular facilitation (PNF) concept, which defines the pelvis as a "key point of control" for maintaining a gait pattern [7,14,15]. Thus, we decided to facilitate pelvic motion and improve pelvis control during training [7,14,15]. Each training session consisted of 10 min each of rhythmic initiation, slow reversal and agonistic reversal exercises applied to the pelvic region (see Table 1 for treatment protocol) [7,14,15]. The same trained therapist treated all the patients in this group and standardized the duration and the intensity of each part of the treatment.

2.2. Testing procedures

Patients were evaluated before (T0), immediately after treatment (T1) (primary endpoint) and at three months of follow-up (T2). The same rater (C.M.), who was blinded to the group allocation, evaluated all patients. Asking the assessor to make an educated guess tested the success of blinding.

²⁾ Subject position: side-lying on the left/right side with both hips flexed to 100° and the knees flexed to 45° .

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