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ORIGINAL REPORT

EFFECTIVENESS OF ROBOTIC BALANCE TRAINING ON POSTURAL INSTABILITY IN PATIENTS WITH MILD PARKINSON'S DISEASE: A PILOT, SINGLE-BLIND, RANDOMIZED CONTROLLED TRIAL

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Objective: **To examine whether tailored robotic platform training could improve postural stability compared with conventional balance treatment in patients with mild Parkinson's disease.**

Design: **Randomized single-blind pilot study.**

Subjects: **Twenty-two patients with mild Parkinson's disease (Hoehn & Yahr scale; H&Y 1–2).**

Methods: **Patients were randomly assigned to an experimental group for robotic balance training and to a control group for conventional balance training. Each patient received 20 treatments (45 min/session, 5 times/week). Blinded evaluations were conducted before and after the treatment and 1 month post-treatment. Primary outcome measures were Mini BESTest, and Berg Balance Scale; secondary outcome measures were 10-Meter Walk Test, Five Times Sit to Stand Test, and Parkinson's Disease Questionnaire 39.**

Results: **Primary outcome measures in patients in both the experimental and control groups improved significantly after the balance treatment. Similar results were found for all the secondary outcome measures. The experimental group performed significantly better than the control group at both post-intervention and follow-up evaluation in the primary outcomes ($p < 0.05$). No significant differences between groups were found in secondary outcomes.**

Conclusion: **Robot-assisted balance training may be a promising tool to improve postural stability in patients with mild Parkinson's disease.**

Key words: robotic-assisted balance training; postural instability; neurorehabilitation; Parkinson's disease.

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LAY ABSTRACT

More than 10 million people worldwide are living with Parkinson's disease. Parkinson's disease is a slowly progressive neurodegenerative disorder that leads to balance problems. Balance is a major concern in patients with Parkinson's disease, and shows poor response to pharmacological treatment. It is known that exercise and physiotherapy can help. The best approach is to start exercising at the early stages of the disease with personalized rehabilitation treatment. This study explored the effectiveness of a new robotic platform treatment on balance compared with the conventional approach. Both trainings were found to improve balance, walking and quality of life. However, robotic balance training could have a major impact. The robotic device enables the training to be intense, fun, task-oriented, challenging and personalized, enhancing motor learning and neuroplasticity. This advance in rehabilitation technology could help to meet the challenges presented by Parkinson's disease.

Postural instability (PI), or impaired balance, is one of the cardinal motor symptoms that characterizes Parkinson's disease (PD). It is the inability to maintain equilibrium under both static and dynamic conditions, affecting balance control mainly in 4 domains: (*i*) balance during quiet stance, (*ii*) reactive postural adjustments to external perturbations, (*iii*) anticipatory postural adjustments, and (*iv*) dynamic balance (1).

PI is prominent in the advanced stage of PD, as reflected by the Hoehn & Yahr scale, where this problem appeared clinically only in the third stage. Nevertheless, PI is also present in the early stages of PD, before any clinically visible balance disturbance has appeared (2).

Early identification of instability and effective timely intervention is mandatory to limit the increasing burden of PI in the lives of patients with PD. In fact, PI leads to loss of mobility, falls, disability, and reduced quality of life (QoL). Among these, falls have a major economic burden, considerable morbidity, and high psychological impact. Limited responsiveness to dopaminergic therapy and deep brain stimulation implicates the need for alternative strategies to address balance disorder and prevent falls (3, 4). It is clear that exercise and physiotherapy play a beneficial role (5) and different studies have identified the beneficial effect on balance of a series of non-pharmacological approaches, such us treadmill training (6), robot-assisted gait training (7), tai chi (8), virtual reality (9), and movement strategy training (10). How-

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ever, which rehabilitation strategies are useful in practice in reducing balance problems and falls is a matter of debate. Patients with PD may benefit from a personalized exercise programme and a multidisciplinary approach (11) designed to help avoid falls and maintain mobility.

Recent technological advances in delivery of therapy (e.g. virtual reality and other gamification elements) have led to increasing interest in the field of neurorehabilitation in PD (12). A robotic device, hunova® (Movendo Technology, Genoa, Italy), has been developed recently to apply sensorimotor rehabilitation of the lower limbs and trunk in static and dynamic conditions. This robotic platform was introduced for post-stroke functional re-education, treatment of degenerative diseases of the central nervous system and lesions of the peripheral nervous system.

The robotic program enables personalized treatment with a challenging progression from simple to difficult tasks, attentional strategies, augmented visual and audio feedbacks, in a stimulating environment. Therefore, this study hypothesized that the robotic platform training (experimental robotic training group) would be more effective in improving postural control and in decreasing falls risk than conventional training (conventional training group).

To our knowledge, there are no published studies exploring the effects of this new technology in patients with PD. Therefore, the aim of this pilot study was to investigate the efficacy and feasibility of a 4-week hunova®-assisted training programme in patients with mild PD on postural control. The primary aim was to evaluate whether the robotic balance training is effective in improving postural stability. The secondary aim was to assess whether robotic balance training can also have a positive impact on risk of falls, walking ability, and QoL.

METHODS

A randomized, controlled, single-blind pilot study was designed. Patients with idiopathic PD were recruited consecutively from outpatients attending the Department of Physical Medicine and Rehabilitative Unit, Riuniti Hospital, Foggia, Italy, from October 2019 to January 2020. The study was approved by the ethics committee of University of Foggia (number 98/CE/2019 08.10.2019). All participants signed informed consent forms after receiving detailed information about the study's aims and procedures according to the principles of the Declaration of Helsinki.

Inclusion criteria were: confirmed diagnosis of idiopathic PD according to the UK Brain Bank Criteria; Hoehn & Yahr stage 1–2 determined in the "on" phase; Movement Disorders Society Unified Parkinson's Disease Rating Scale III (MSD-UPDRS III) score < 32; stable medication over the past 3 months; and a Mini-Mental State Examination (MMSE) score > 24. Exclusion criteria were current participation in any other behavioural or pharmacological study or instructor-led exercise programme, previous deep brain stimulation (DBS) surgery, debilitating conditions or vision impairment that would impede full participation in the study, balance impairment due to other disease (visual acuity or vestibular dysfunction), other neurological or orthopaedic conditions involving the lower limbs, severe cardiovascular comorbidity (e.g. recent myocardial infarction, heart failure).

Before being tested, participants were randomly assigned in a one-to-one ratio to 2 study arms (robotic balance training and conventional balance training) according to a simple (restricted) randomization scheme. An investigator determined the eligibility of the patient, but was blinded as to which group the subject would be allocated. Another investigator, using a randomization list (kept in sealed envelopes) checked that patient allocation was correct.

Treatment procedures

Each patient underwent a training programme consisting of 20, 45-min sessions (including warm-up, rest periods and cool-down), 5 days a week (Monday to Friday) for 4 consecutive weeks. Both groups underwent balance training consisting of exercises aimed at improving steady state (i.e., maintaining a steady position in sitting, standing and walking), proactive (i.e. anticipation of a predicted disturbance), and reactive (i.e. compensation of a disturbance) balance. During the study period, patients did not perform any other type of rehabilitation. Treatments were administered at the same time of day for each patient to avoid therapy-related motor fluctuations. Patients were in "on-phase" during the treatment, 1–2.5 h after their morning dose. During the whole training programme, the drug regimen was not changed.

Intervention group: hunova®

Patients allocated to this group were treated by means of the robotic device hunova® (Movendo Technology, Genoa, Italy) with the constant supervision of a trained physical therapist. hunova® (Fig. 1) is a "platform-based" end-effector robot that consists of 2 electromechanical platforms with 2 degree-of-

Fig. 1. hunova® (Movendo Technology). Left to right: platform and seat; bipodal standing position; and sitting position.

freedom: 1 placed under the feet and the other under the seat. The system integrates a central personal computer (PC), which computes the middle- and high-level robot control algorithms and runs the graphical user interface, which is displayed on the device monitor. The device also integrates an inertial measurement unit (IMU) body sensor, which allows the position of different body segments to be tracked, and a touch screen for biofeedback and touch interactive training. The robotic platform makes it possible to perform exercises in both standing and seated positions. It allows passive (mobilization), active (with elastic or fluid resistance), proprioceptive and assistive therapy (i.e. the device intervenes to complete the exercise when the patient needs it). The device can work in both static (no movement of the platforms) and dynamic modes (movements of the platforms). Indeed, due to its robotic modules, the device can control both the movement of the platform/seat, to induce continuous or random movements, thereby causing perturbation to the subject, and the resistance of the platform to the subject's movements. The training was divided into 2 phases, each lasting 10 sessions, which differed only in some exercises, since more complex tasks were inserted only in the second phase. All training sessions consisted of a sequence of 10 standing position exercises (bipodal mode exercises) followed by 10 sitting position exercises in both static and dynamic modes. During the exercises, the subject has to maintain the centre of pressure (CoP) in a defined area of confidence, or has to stabilize the upper trunk with both static and dynamic seat/base or during random perturbations offered by the device. Moreover, the subject has to mobilize the base or the seat for reaching targets on the screen in random directions or for drawing a vertical or horizontal line following a given path. The exercises are described in Table I.

Conventional balance training group

Patients allocated to this group performed a specific balance training with a trained physical therapist using common rehabilitation instruments (i.e. proprioceptive wooden board, Bobath ball) and techniques. Each session is divided into 3 10-min parts with a rest between them. The training was based on European guidelines (13) and consisted of a series of exercises on foam support bases, perturbations and destabilizing exercises, and weight-shifting exercises. Each training session consisted of 3 parts of 12 min with a 3-min rest between them and 2 min cool-down at the end. Each part consisted of 3 exercises (repeated 8 times) for a total of 9 exercises. The subject has to maintain stability as much as possible on a static or an unstable surface, perform trunk or head rotation while maintaining a correct postural alignment, move the upper limbs while sitting on unstable support, lean in different directions reaching their limits of stability. The training progresses and intensifies each week depending on the individual's performance. The same trained therapist treated all the patients in this group (also providing verbal instructions) and standardized the intensity of each part of the treatment.

Evaluation procedures

Patients were evaluated before treatment, immediately after treatment (primary end-point) and at 1-month follow-up. The same rater, who was blinded to the group allocation, evaluated all patients. Disease state was rated using the Hoehn & Yahr scale, and motor function was examined using the motor subscale of the MSD-UPDRS.

Primary outcomes.

- Mini-BESTest (MBT). This is a (scored 0–2) clinical test, commonly used to quantify balance impairments in people with PD, which measures 4 domains of dynamic balance: anticipatory postural adjustments; reactive postural control; sensory orientation; and dynamic gait. The higher scores indicating better performance (maximum score of 28) (14).
- Berg Balance Scale (BBS). This scale evaluates static and dynamic balance impairments. It is recommended in many neurological diseases including PD. It is a 14-item test scored 0–4 (maximum score 56). Higher scores represent a better balance (15).

Table I. Exercise list and descriptions

	Exercise	Phase	*n*	Task description	Position	Mode	Difficulty regulation
Steady state	Balance	1 2	8–4	The subject has to maintain his load in the centre of the seat as much as possible, maintaining a correct position of the trunk	Standing bipodal/sitting	Static/unstable base or seat	CoP area of confidence Trunk area of confidence Platform maximum workspace Platform oscillation area of confidence Type of instability (proprioceptive, elastic or fluid dynamic): Instability level
Proactive balance	Limit of stability	1 2	4	The subject has to lean in different directions reaching their limits of stability	Standing bipodal/sitting	Static/unstable base or seat	Amplitude of passive mobilization (degrees) Velocity of movement Trunk area of confidence Amplitude of active mobilization Target positions
	Control of dynamics	1 2	4	The patient moves the seat/base to replicate the patterns displayed on the screen	Standing bipodal/sitting	Static/unstable base or seat	Platform maximum workspace Platform oscillation area of confidence Amplitude of active mobilization
Reactive balance	Response to perturbation	1 2	4	The subject has to maintain balance reacting to perturbations offered by the device	Standing bipodal/sitting	Static/unstable base or seat	Amplitude of perturbations (degrees) Velocity of perturbations Trunk area of confidence
	Motor dual task	2	4	The subject has to maintain balance while reaching targets on the touch screen with the upper limbs	Standing bipodal/sitting	Static/unstable base or seat	Trunk area of confidence Amplitude of active mobilization Target positions

n: number of exercises.

Secondary outcomes.

- The 10-Meter Walk Test (10MWT) is a clinical measure to assess walking speed over a short duration. It is validated for mild–moderate PD (15). Patients walked a 10-m distance at comfortable speed and the middle 6 m was timed. The mean speed of 3 trials was analysed.
- The Five Times Sit to Stand Test (5TSTS) is a test to measure the ability to transfer between sitting and standing and to quantify functional lower extremity strength. It is valid and reliable for people with PD. Participants were instructed to sit with arms folded across their chest and stand up and sit down 5 times as quickly as possible. The time taken to complete the test was recorded (16).
- The Parkinson's Disease Questionnaire (PDQ-39) is a self-report QoL questionnaire to measure different dimensions: mobility, activities of daily living, emotional well-being, stigma, social support, cognition, communication, and bodily discomfort. The questions scored 0–4 (maximum dimension score of 100). The 8 dimensions scores were summed into the PDQ-39 summary index (PDQ-39-SI), with a higher score (range 0–100) showing a poorer QoL (17).

Statistical analysis

The collected data were coded and analysed using Statistical Package for Social Science (SPSS 26, Armonk, NY). Descriptive data were generated for all variables reported as mean (standard deviation; SD). According to a previous study (18), it was estimated that a sample of at least 10 subjects per group would detect a difference of 4.9 (SD 6.1) in BBS. For power analysis, a significance level of $\alpha = 0.05$ and 90% power were assumed (19).

Non-parametric tests were used, since assumptions of data normality and homogeneity of variance were not satisfied. The Mann–Whitney *U* test or Fisher's test (depending on type of data) were used to testing the homogeneity of the groups at baseline.

The Friedman test was used to compare the score in different evaluation sessions within each group. Wilcoxon signed-rank tests were carried out in each group of patients to determine within-group differences between pre-treatment/post-treatment (T0–T1) and between pre-treatment/follow-up (T0–T2) scores and the 95% confidence interval (95% CI) were reported. Effect size (r) was calculated to see the magnitude of group differences (20). The effect size, which was calculated as the z-score before–after and before–follow-up each intervention period divided by the root square of number of observations (N). We considered r=0.10 a small effect, r=0.30 medium effect, r=0.50 a large effect (21). To analyse group differences, a Mann–Whitney *U* test was used to determine between-group differences. The level of significance was set at $p < 0.05$. The Bonferroni correction was used in multiple comparisons, resulting in a significant $p < 0.016$.

RESULTS

Among the 58 patients eligible for the study, 22 were enrolled and the other 36 were excluded because they did not meet the inclusion criteria ($n = 30$) or because they declined to participate ($n = 6$). A total of 11 patients were allocated to each of the treatment groups. There were no drop-outs and no adverse events occurred during the trial in any of the groups. The study flow diagram is shown in Fig. 2. At baseline, no significant difference was observed between the 2 groups in the demographic data, disease duration and in all the outcome measures investigated ($p > 0.05$). Table II shows the characteristics of the study population and outcome measures score at baseline.

Primary outcomes

Table III shows mean (SD) within-group differences in outcomes in both groups. The participants in the experimental robotic training group (EG) and conventional training group (CG) improved significantly on the primary outcomes. The MBT and BBS scores changed significantly over 4 weeks of treatment in the EG (MBT: χ^2 (2)=39.45, $p < 0.001$; BBS: χ^2 (2)=21.53, $p < 0.001$) and CG (MBT: χ^2 (2)=19.53, $p < 0.001$; BBS: χ^2 (2)=19.00, $p < 0.001$). However, pairwise comparisons showed that only the EG improved significantly after 1-month follow-up on the primary outcomes ($p < 0.016$). A between-group comparison showed that the participants in the EG performed significantly better than those on the CG at both post-intervention and follow-up evaluation ($p < 0.05$).

Secondary outcomes

The participants in the EG and CG were significantly improved after robotic intervention (TUG: χ^2 (2)=17.63, $p < 0.001$ 5STS: χ^2 (2)=11.45, $p = 0.003$ 10MWT: χ^2 (2)=14.00, $p = 0.001$ PDQ: χ^2 (2)=15.04, $p = 0.001$) and conventional balance training (TUG: χ^2 (2)=12.63, $p = 0.002$ 5STS: χ^2 (2)=16.90, $p < 0.001$ 10MWT: χ^2 (2)=15.04, $p = 0.001$ PDQ: χ^2 (2)=13.81, $p = 0.001$) in all the secondary outcome measures. Furthermore, pairwise comparisons with Bonferroni

Table II. Demographic data and outcome measures at baseline

Parameter	Experimental robotic training group ($n = 11$)	Conventional training group ($n = 11$)	*p*-value*
Sex, F/M	5/6	4/7	0.529
Age, years, mean (SD)	68 (6.9)	67.27 (4.85)	0.846
Disease duration, years, mean (SD)	6 (1.7)	5 (2.3)	0.768
H&Y, mean (SD)	1.64 (0.5)	1.72 (0.46)	0.487
MSD-UPDRS III, mean (SD)	26.55 (5.77)	26.64 (7.27)	0.765
LEDD, mg/day, mean (SD)	512.12 (212.24)	525.28 (274.45)	0.682

H&Y: Hoehn & Yahr; MSD-UPDRS III: Movement Disorders Society Unified Parkinson's Disease Rating Scale III; LEDD: levodopa equivalent daily.

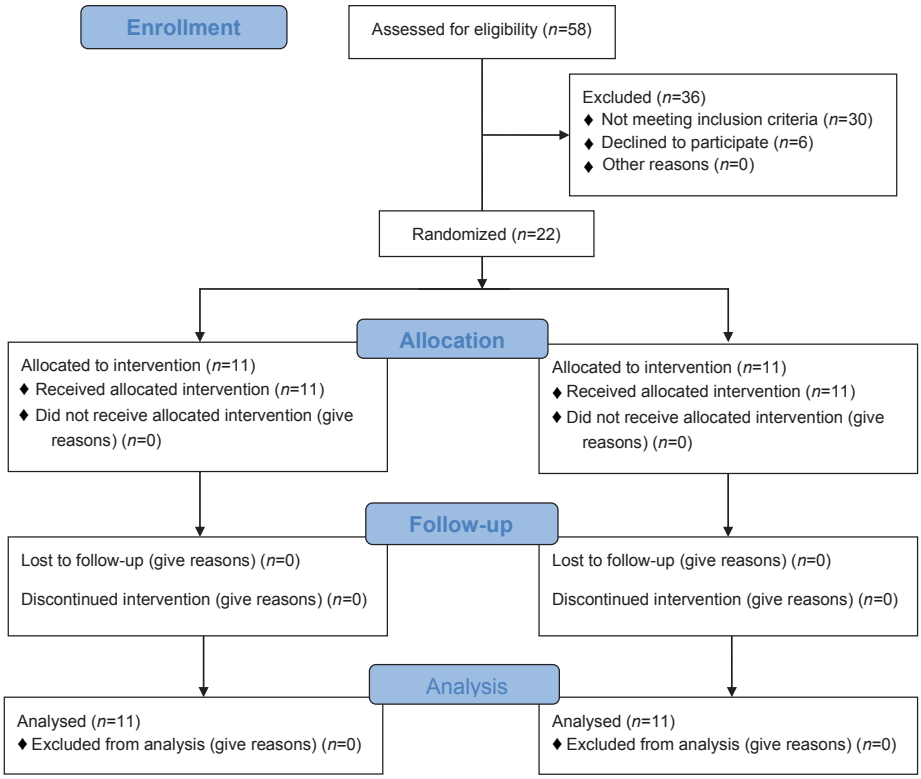

Fig. 2. Study flow.

correction indicated that the EG and CG improved significantly after treatment and after 1-month follow-up. No significant between-group differences were found at before–after intervention and before–follow-up treatment (see Table II for details).

Table IV shows the PDQ-39 scores (all dimensions and Score index) for both groups at T0, T1, and T2. Comparing the differences between T0 and T1, and T0 and T2, only mobility and activities of daily living dimensions were significant in EG and CG ($p < 0.016$).

Table III. Group data and within-group comparisons

	Group	Before Mean (SD)	After Mean (SD)	Follow-up Mean (SD)	After before mean difference (SD) [95% CI]	Effect size (WG)	*p*-value; effect size (BG)	Follow- up before mean difference (SD) [95% CI]	Effect size (WG)	*p*-value; effect size (BG)
Mini BEST	E	20.91 (1.3)	24.36 (0.67)	23.73 (0.79)	−3.45 (1.13) [−4.21; −2.7]*	−0.637	0.031–0.46	−2.82 (1.08) [−3.54; −2.09]*	−0.632	0.003–0.635
	C	20.73 (1.01)	23.09 (0.83)	22 (2.59)	−2.36 (1.21) [−3.17; −1.55]*	−0.631		−1.27 (0.9) [−1.88; −0.67]	−0.581	
BBS	E	49.45 (2.58)	54.91 (1.3)	53.36 (1.29)	−5.45 (1.97) [−6.78; −4.13]*	−0.629	0.009–0.56	−3.91 (2.07) [−5.3; −2.52]*	−0.633	0.035–0.45
	C	48.82 (4.02)	52.09 (2.79)	51.09 (3.53)	−3.27 (2.20) [−4.75; −1.8]*	−0.630		−2.27 (2.72) [−4.1; −0.44]	−0.541	
10MWT, m/s	E	1.01 (0.09)	1.19 (0.09)	1.17 (0.08)	−0.19 (0.12) [−0.27; −0.1]*	−0.598	0.2–0.273	−0.16 (0.11) [−0.23; −0.08]*	−0.588	0.061–0.4
	C	0.99 (0.04)	1.11 (0.07)	1.07 (0.06)	−0.12 (0.06) [−0.16; −0.08]*	−0.626		−0.08 (0.07) [−0.13; −0.04]*	−0.551	
PDQ-39	E	43.72 (23.52)	28.23 (21.72)	26.11 (22.65)	15.49 (11.97) [7.45; 23.53]*	−0.626	0.554–0.126	17.61 (14.26) [8.02; 27.19]*	−0.568	0.532–0.133
	C	45.09 (22.32)	32.87 (19.5)	31.64 (19.35)	12.22 (8.57) [6.46; 17.98]*	−0.626		13.45 (12.62) [4.97; 21.93]*	−0.550	
5STS, s	E	16.14 (3.29)	13.2 (2.03)	13.23 (1.69)	2.94 (2.31) [1.39; 4.49]*	−0.607	0.576–0.119	2.90 (2.88) [0.96; 4.84]*	−0.568	0.718–0.077
	C	18.14 (2.37)	15.83 (2.24)	15.23 (2.55)	2.30 (1.19) [1.51; 3.1]*	−0.626		2.90 (2.12) [1.48; 4.33]*	-0.626	

*Statistically significant ($p < 0.016$). E: experimental; C: control; BBS: Berg Balance Scale; TUG: Timed up and Go; 5STS: 5 Times Sit to Stand; 10MWT: 10-Metre Walk Test; PDQ-39: Parkinson's Disease Questionnaire - 39; SD: standard deviation; 95% CI: 95% confidence interval; WG: within-groups; BG: between-groups.

Table IV. Group data on the Parkinson's Disease Questionnaire-39 (PDQ-39) subsections

	Experimental robotic training group					Conventional training group				
	Before Mean (SD)	After Mean (SD)	Follow-up Mean (SD)	Before–after *p*-value	Before–follow-up *p*-value	Before Mean (SD)	After Mean (SD)	Follow-up Mean (SD)	Before–after *p*-value	Before–follow-up *p*-value
Mobility	14.77 (6.06)	8.4 (3.4)	8.18 (4.19)	0.011*	0.036*	14.77 (4.93)	8.18 (3.37)	8.64 (3.60)	0.003*	0.005*
Activities of daily living	8.57 (3.86)	3.35 (3.07)	3.35 (4.04)	0.016*	0.034*	10.44 (5.30)	5.22 (3.22)	5.59 (3.32)	0.016	0.017*
Emotional well-being	4.84 (3.075)	3.72 (2.87)	3.35 (3.07)	0.257	0.206	4.85 (3.08)	3.35 (3.08)	2.98 (3.22)	0.206	0.160
Stigma	3.40 (3.26)	2.27 (3.15)	2.84 (3.26)	0.157	0.564	5.11 (2.53)	3.41 (4.30)	3.97 (4.21)	0.180	0.317
Social support	6.03 (5.36)	3.01 (4.18)	4.52 (5.70)	0.102	0.480	5.28 (4.19)	3.01 (4.18)	3.02 (4.19)	0.086	0.180
Cognition	3.40 (4.29)	3.97 (3.15)	3.97 (4.21)	0.564	0.564	3.41 (4.30)	3.98 (3.15)	3.97 (4.21)	0.564	0.317
Communication	4.52 (4.33)	3.77 (4.33)	3.77 (4.33)	0.317	0.564	4.53 (4.33)	3.01 (4.18)	3.77 (5.71)	0.157	0.564
Bodily discomfort	3.01 (5.59)	3.01 (4.18)	3.75 (5.66)	0.317	0.785	3.02 (5.60)	2.26 (3.87)	4.53 (4.33)	0.317	0.317
PDQ-39 total	48.59 (13.01)	30.79 (8.92)	33.76 (12.17)	0.005*	0.033*	51.40 (14.58)	32.44 (9.82)	36.48 (12.90)	0.003*	0.004*
PDQ-39-SI	6.07 (1.62)	3.84 (1.11)	4.22 (1.52)			6.43 (1.82)	4.05 (1.22)	4.56 (1.61)		

*Statistically significant (p-value <0.05). PDQ-39-SI: Parkinson's Disease Questionnaire - 39 Summary Index; SD: standard deviation; p-value: significance in comparison within groups (before–after and before–follow-up).

DISCUSSION

All the outcomes showed that both robotic and conventional training could improve balance, motor performance and QoL in people with PD. A significantly greater improvement in postural stability (as measured by MBT and BBS) was found in the patients in the experimental robotic balance training group than in the control conventional balance training group. No significant differences were found between the 2 groups in all the other examined outcomes.

PD is commonly associated with gait impairments and disorders of posture and balance. Balance is considered a major concern in PD: a large survey showed that identifying what treatments help reduce balance problems and falls is the first need for patients with PD (22). In fact, balance impairments augment disease burden and reduce QoL in PD. Impaired balance in PD is a complex and multifactorial phenomenon and its pathophysiology is not well understood. It may result from faulty mechanisms in different processes: patients with PD lack of effective integration of sensory information and the generation of appropriate and effective motor response to maintain an upright posture, to initiate corrective response during walking and to face with balance perturbations. Moreover, impaired regulation of muscle tone, such as axial rigidity as well as an impaired cognitive information processing, impact on balance. In this context, exercise is accepted as an intervention that could ameliorate motor and non-motor PD symptoms and should be considered an essential component in the management of patients with PD (23). Several studies have investigated the effects of specific rehabilitation programmes in patients with PD. A recent meta-analysis (24) reported positive effects of exercise intervention on enhancing balance and gait performance, but there was no evidence that training decreased the number of people having falls over the short- or long-term.

The current study used a novel robotic device consisting of 2 degrees of freedom platform designed for the rehabilitation of lower limb, trunk and balance. Specifically, this robotic platform provides training focused on steady state, proactive and reactive balance with audio and visual biofeedback. Robotic balance training has already been used in frail older adults (25) and stroke patients (26) resulting in a better improvement of dynamic balance control than conventional treatment. Our results show a significant difference in MBT and BBS between the experimental and the conventional group comparing either before–after treatment or before–follow-up treatment. Differences are probably due to the different rehabilitation approaches. First, technology-based exercise interventions may improve adherence by stimulating patients to exercise in a personalized, motivating, fun, and engaging manner (27). Secondly, the robotic system provides objective measures of biometric parameters before and during treatment, making possible a personalized exercise programme and tracking of progress (28). Thirdly, it is well known that robotic rehabilitation may eventually enhance motor learning (29). Sensory feedback affects implicit learning, sensorimotor adaptation and reinforcement learning (30). hunova® provides proprioceptive, visual and audio feedbacks by means of a screen that receives information from sensors placed on the trunk and under platforms that record movements in the torso, distribution of load and the angle of the seat; this is essential to promote self-correction of the trunk as well as dual tasking.

Recent studies have demonstrated that motor learning occurs in patients with PD, in particular in the early stages of disease (31). However, in patients with PD cortical plasticity is reduced and so the retention of new skills is impaired. For this reason, a rehabilitation treatment should address the motor deficit and simultaneously enhance cortical plasticity. In order

to create the conditions for this to happen, the motor training needs to have some features that ensure the neuroplastic changes required to improve new motor skills. In the current study, the experimental training with the robotic platform could have offered this particular situation in contrast to the conventional training. The exercises proposed had appropriate intensity and repetition, difficulty, complexity and specificity. Moreover, the training was made more attractive thanks to the interactive monitor, feedback, rewards, cues that increased the patient compliance.

Individuals with PD are known to have deficits in trunk control and poorer pelvic control (32). Therefore, rehabilitation protocols should include exercises targeting the trunk and the core (32). In our experimental group, this has been made possible especially during the seated position: patients sit on the platform and control the movements of the seat with their pelvis while the platform exerts a resistance. Moreover, the robotic device is associated with a wireless inertial sensor (IMU) placed on the patient's trunk, allowing continuous audio and visual feedback about trunk control, and thus offering specific exercises to improve trunk mobility and trunk control. The robotic trunk training could have had an additional impact on higher balance improvement seen in the experimental group.

Consistent with the literature (33), our results show that enhanced balance performance was also linked to improved gait velocity (EG 0.19 m/s; CG 0.12 m/s) in both training groups. However, only the experimental group exceeded an MDC of 0.18 m/s, established by Steffen et al. for comfortable gait speed in PD (15), and reported a medium MCID (0.14–0.22 m/s) compared with a small one (0.06–0.14 m/s) in the control group, as indicated by Hass (34).

Existing evidence suggests that exercise, specifically exercise that challenges balance control, can prevent falls (35). When balance problems occurred, patients with PD are predisposed to fall. However, falls are not caused only by posture instability, but there had been identified several risk factors, such as freezing of gait (FOG), cognitive impairment, poor leaning balance, previous falls, lower limb weakness and slow gait speed (36). Indeed, postural instability is only one aspect that interferes with falls. In our view, the improvement in postural stability gained with the balance training could affect falls risk. In particular, considering that gait speeds less than 1.1 m/s are predictive of falls in PD (37), our patients at baseline could be considered at risk for falls in both groups. After the training, both groups exceed the previous cut-off potentially modifying their fall risk and at follow-up only the experimental group retained this gain. Moreover, patients at risk of falls could be identified also by FTSTS, setting a cut-off of >16 s (16). Our patients at baseline exceed the cut-off and are at risk of falls in both groups. After the training and at follow-up scores improve in both groups falling behind the cut-off. This result could be relevant, although future research should examine the direct effect of the robotic training on falls, analysing all the aspects related to the risk of falls, thus adding more evaluation.

Balance impairments are present in early disease stages and can even be detected in patients with *de novo* PD. It has been observed recently that all newly diagnosed patients with PD reported a minor balance impairment at their first visit and their balance worsened during the first 5 years (38). Moreover, patients in the early stages of PD (H&Y1–2), already exhibit signs of postural instability (2) and 25% of recently diagnosed patients had a fall in their first year of diagnosis (39). As a history of fall is itself a major risk factor for future falls, optimizing therapeutic strategies to prevent falls is crucial and requires identifying and treating patients with PD at risk for falling as soon as possible. Targeting the initial stages of PD is essential to delay clinically relevant symptoms.

Previous research has established that motor limitations, especially those related to a deficit in balance and a reduction in walking capacity, determine a worse overall QoL perception of individuals with PD (40). The current study found, as expected, an improvement in the overall QoL, as shown by the total score of PDQ-39 in both groups after treatment. Moreover, it was noted that mobility and daily living activities are the dimensions that mainly account for that improved perception of QoL in our patients. These results confirm that improving balance and mobility due to the treatment could indirectly provide a better QoL in patients with PD.

Study limitations

The current study has several limitations. First, these findings cannot be generalizable, given that the study was monocentric and the sample size was small. This is a pilot study and we aim to continue recruiting patients. Secondly, no long-term follow-up was considered. Thirdly, an instrumented evaluation of the balance deficit should have been added to better understand and quantify the deficit and the effects of both treatments. Fourthly, the study did not assess some important parameters related to PI, such as fear of falling, balance confidence, numbers of falls and other cognitive aspects of the patient with PD. Future studies should take all of these issues into account.

CONCLUSION

This study found that robotic balance training may achieve the same effect as conventional balance training on postural stability in patients with mild PD. Moreover, robotic training could have additional effects in retaining benefit, reducing risk of falls, and improving QoL. However, properly-sized randomized controlled trials are needed to further validate these findings. Finally, robotic training could provide a wider choice for delivering balance rehabilitation to patients with PD.

The authors have no conflicts of interest to declare.

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