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ORIGINAL RESEARCH

Wearable Sensor-Based Biofeedback Training for Balance and Gait in Parkinson Disease: A Pilot Randomized Controlled Trial

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Abstract

Objectives: To analyze the feasibility and efficacy of a novel system (Gamepad [GAMing Experience in PArkinson's Disease]) for biofeedback rehabilitation of balance and gait in Parkinson disease (PD).

Design: Randomized controlled trial.

Setting: Clinical rehabilitation gym.

Participants: Subjects with PD (N=42) were randomized into experimental and physiotherapy without biofeedback groups.

Interventions: Both groups underwent 20 sessions of training for balance and gait. The experimental group performed tailored functional tasks using Gamepad. The system, based on wearable inertial sensors, provided users with real-time visual and acoustic feedback about their movement during the exercises. The physiotherapy group underwent individually structured physiotherapy without feedback.

Main Outcome Measures: Assessments were performed by a blinded examiner preintervention, postintervention, and at 1-month follow-up. Primary outcomes were the Berg Balance Scale (BBS) and 10-m walk test (10MWT). Secondary outcomes included instrumental stabilometric indexes and the Tele-healthcare Satisfaction Questionnaire.

Results: Gamepad was well accepted by participants. Statistically significant between-group differences in BBS scores suggested better balance performances of the experimental group compared with the physiotherapy without biofeedback group both posttraining (experimental group−physiotherapy without biofeedback group: mean, 2.3±3.4 points; $P=.047$) and at follow-up (experimental group−physiotherapy without biofeedback group: mean, 2.7±3.3 points; $P=.018$). Posttraining stabilometric indexes showed that mediolateral body sway during upright stance was significantly reduced in the experimental group compared with the physiotherapy without biofeedback group (experimental group−physiotherapy without biofeedback group: −1.6±1.5mm; $P=.003$). No significant between-group differences were found in the other outcomes.

Conclusions: Gamepad-based training was feasible and superior to physiotherapy without feedback in improving BBS performance and retaining it for 1 month. After training, 10MWT data were comparable between groups. Further development of the system is warranted to allow the autonomous use of Gamepad outside clinical settings, to enhance gait improvements, and to increase transfer of training effects to real-life contexts.

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Balance and gait impairments are among the most disabling features of Parkinson disease (PD) and play a key role in the progressive deterioration of patients' autonomy.[1] For this reason, motor rehabilitation is now considered essential in the treatment of PD, as a complement to pharmacologic therapy and neurosurgery.[1,2]

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It has been shown that physiotherapy has small and short-term effects in PD[3] and that such effects can be improved by providing patients with real-time additional sensory information on their own motion during training (ie, biofeedback).[4,5] Biofeedback is therefore used by subjects to correct their movements, with increasing attentional engagement and motivation.[4] The working principles of biofeedback are extracting the appropriate variable from speciÞc body signals, coding this information into appropriate sensory signals, and feeding the sensory information back to the user in real time.[6] Several devices providing visual,[7-10] auditory,[6,11-13] and vibrotactile[14,15] biofeedback have been already applied on subjects with PD with encouraging results, but some aspects still need to be investigated to demonstrate its real added value.

First, most of the existing devices are devoted to a speciÞc aspect of motor rehabilitation (eg, balance,[7,8,12,14,15] gait[6,10,11,13]). Because biofeedback and cueing rehabilitation in PD have been shown to induce improvements speciÞc to the trained task and poorly transfer to other functional movements,[1,5,11] new devices integrating a wide set of personalized balance and gait tasks, similar to activities of daily living, should be developed.[2,5] Second, as discussed in a recent review,[3] more randomized controlled trials are needed to support the effectiveness of one physiotherapy intervention over another in PD and justify the inclusion of biofeedback as a training option.

Following these considerations, we developed a new biofeedback system (Gamepad [GAMing Experience in PArkinsonÕs Disease]) for balance and gait rehabilitation in PD. The system, based on wearable sensors, provided subjects with real-time visual and auditory feedback and included different motor exercises similar to activities of daily living and tailored to subjectÕs speciÞc deÞcits. The aims of this study were to test the feasibility of using the system in a typical rehabilitation gym and analyze balance and gait outcome measures comparing Gamepad-based training versus physiotherapy without biofeedback. We hypothesized that biofeedback provision through Gamepad can enhance the effects of balance and gait rehabilitation by complementing the impaired sensory inputs typical of PD,[16] and by increasing attentional engagement toward the motor processes, therefore enhancing motor learning[5] and bypassing defective basal ganglia.[2,16]

Methods

Participants

A consecutive sample of 54 subjects with PD from the Neurorehabilitation Department in Don Carlo Gnocchi Foundation (Milan, Italy) was assessed for eligibility from January 2013 to April 2015. Inclusion criteria were Hoehn and Yahr stage 2 to 4, ability to stand up > 10 seconds and inability to stand on 1 foot

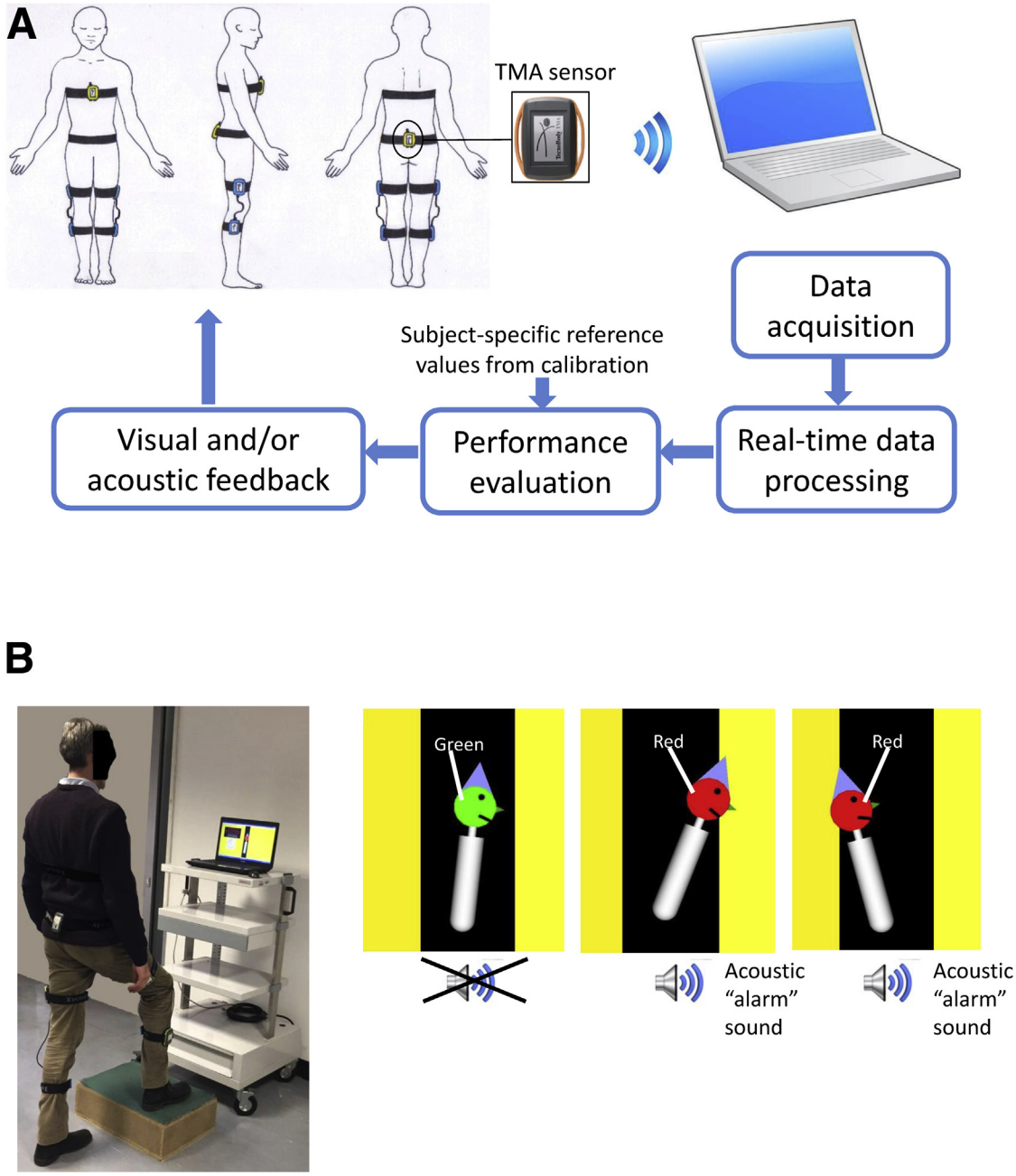

Fig 2 (A) Schematic representation of the Gamepad system. (B) Example of a subject controlling the AP inclination of his trunk while placing a foot on a step (left panel). The patient performs the task by looking at an avatar replicating the motion of his trunk on the PC screen (right panels). If the avatar is not maintained within the black bar (tailored reference target area), its head becomes red and an alarm sound is provided. Abbreviation: TMA sensor, Tecnobody Motion Analysis inertial sensor.

gradually reduces toward the end of treatment) was used to enhance learning.[23]

Physiotherapy without biofeedback group

Personalized exercises were defined by clinical staff following guidelines for physiotherapy in PD.[2,21] Each session included 5 minutes of muscle stretching (hamstrings, quadriceps, and calves) and mobilization exercises (eg, trunk rotation, hip abduction, flexion), followed by 40 minutes of balance and gait exercises similar to those performed by the experimental group, but without any instrumentation producing biofeedback or external cues. Subjects executed the tasks following verbal instructions and qualitative feedback from the physiotherapist.

Outcome measures

Assessments were taken by a trained examiner, unaware of group assignment, at baseline (t0), posttraining (t1), and 1-month follow-up (t2). Assessments and treatments were conducted when participants were in the "on" phase of medication.

Primary outcomes were balance and self-selected gait speed, assessed, respectively, with the Berg Balance Scale (BBS)[24-26] and 10-m walk test (10MWT).[26] Both tests are recommended tools for

Table 1 Demographic and baseline clinical characteristics of training groups

Characteristic	Experimental Group (n=17)	Physiotherapy Group (n=20)
Sex (male/female)	14/3	9/11
Age (y)	73.0±7.1	75.6±8.2
Time since diagnosis (y)	7.5±3.2	10.3±5.7
H-Y (0–5)*	2.7±0.7	2.9±0.5
BBS (0–56)†,‡	46.0±9.3	42.1±10.9
10MWT, gait speed (m/s)‡,§	1.04±0.25	0.78±0.29
UPDRS-III (0–56)*,§	16.6±6.8	22.3±7.3
TUG (s)*,†,§	14.7±6.3	23.9±16.3
ABC (0–100)‡,§	59.3±21.8	44.3±19.1
FOGQ (0–24)*	11.3±4.9	13.1±3.8
PDQ-39 (0–100)*	46.4±22.9	61.5±24.1
CoP ML sway (mm)*,†	5.7±2.9	6.7±3.5
CoP AP sway (mm)*,†	7.7±3.4	8.4±3.1

NOTE. Values are mean ± SD or number.

Abbreviations: ABC, Activities-specific Balance Confidence scale; FOGQ, Freezing of Gait Questionnaire; H-Y, Hoehn and Yahr stage; PDQ-39, Parkinson's Disease Questionnaire-39; TUG, timed Up and Go test.

* Lower scores indicate better performance.

† These variables did not meet assumptions of data normality and/or homogeneity of variances. In these cases, *t* test was performed on transformed data (Box-Cox transformation).

‡ Higher scores indicate better performance.

§ $P<.05$ (experimental group vs physiotherapy group, *t* test for independent samples).

clinical assessment of PD.[27] The BBS was chosen because it evaluates balance in static and transfer tasks, according to the proposed intervention. The 10MWT was selected because it represents a quick test (approximately 5min) to assess gait speed, which we expected to increase after training for gait and balance, the latter being an important factor affecting walking velocity in PD.[28]

Secondary outcomes included the following: disease-specific impairments (Unified Parkinson Disease Rating Scale – Motor Examination III [UPDRS-III]),[26,29] basic mobility function (timed Up and Go test),[26] perceived confidence during activities of daily living (Activities-specific Balance Confidence scale),[26] freezing severity (Freezing of Gait Questionnaire),[30] perceived quality of life (Parkinson's Disease Questionnaire-39),[31] and a stabilometric assessment using a force platform (Prokin-PK252).[a] In the latter assessment subjects were tested for 30 seconds during upright standing in 4 sensory conditions, according to Cattaneo et al[32]: eyes open, eyes closed, eyes open with foam pads under feet, and eyes closed with foam pads under feet. Center of pressure (CoP) sway in AP and ML directions was computed as the SD of the AP and ML CoP displacements recorded by the platform (sampling frequency: 20Hz). CoP AP (and ML) sway values, averaged among the 4 sensory conditions, were used for the analysis. Finally, at t1, the Tele-healthcare Satisfaction Questionnaire–Wearable Technology[33] was administered to the experimental group patients to assess user satisfaction regarding Gamepad. Further details about the clinical tests are provided in supplemental appendix S2 (available online only at http://www.archives-pmr.org/).

Statistical analysis

Between-group comparisons of baseline characteristics were performed using independent samples *t* tests. Differential effects of the 2 treatments were assessed using analysis of covariance with 1 between-group factor (group: experimental group or physiotherapy without biofeedback group) and 1 within-group factor (time: t1 or t2). For each outcome measure, the corresponding baseline score (t0) was used as covariate. In this model, between-group differences (experimental group vs physiotherapy without biofeedback group) at postintervention and follow-up were used to assess treatment effect because the baseline score was used as the covariate, as reported by Norman and Streiner.[34] After analysis of covariance, separate preplanned between-group comparisons at t1 and t2 were performed using independent samples *t* tests, also correcting for t0 score (contrasts analysis). Given the exploratory nature of this pilot study, the significance level was set to .05, and no corrections for multiple comparisons were applied. Between-group differences and effect sizes (Cohen *d*)[35] at t1 and t2 were also computed. Cohen *d* of 0.2, 0.5, and 0.8 represents small, moderate, and large effect sizes, respectively.[35] Some variables did not meet the assumptions of data normality and/or homogeneity of variances (Shapiro-Wilk test and/or Levene test, $P<.05$). In these cases, statistical tests were applied on transformed data (Box-Cox transformation).[36] Where explicitly indicated, results were presented as estimated from back-transformed data,[37] to facilitate interpretation. Statistical analysis was performed using STATISTICA.[d]

Results

Twenty-two participants were allocated to the experimental group, and 20 were allocated to the physiotherapy without biofeedback group (see fig 1). Five patients discontinued the training, and 5 were lost at follow-up. Dropout reasons (see fig 1) were unrelated to the study. All patients who received allocated treatment and underwent posttraining assessment were analyzed (experimental group: n=17, physiotherapy without biofeedback group: n=20). Missing follow-up values (5 subjects × 9 variables) were estimated using multiple regression.[38] For each outcome measure, the predictors were the corresponding pre- and posttreatment scores, age, disease duration, Hoehn and Yahr stage, and UPDRS-III baseline score. Table 1 shows the baseline characteristics of analyzed participants. The physiotherapy without biofeedback group showed statistically significant worse scores on the 10MWT, UPDRS-III, timed Up and Go test, and Activities-specific Balance Confidence scale. The 5 subjects who discontinued the training were excluded because they underwent <10 sessions. Baseline characteristics of these patients were comparable with those of analyzed experimental group participants ($P\geq.150$).

Primary outcomes

Table 2 reports between-group comparisons at t1 and t2. Analysis of covariance revealed a significant effect of group in BBS score ($F_{1,34}=6.29$; $P=.017$), showing better balance performances of the experimental group compared with physiotherapy without biofeedback group both at posttreatment (experimental group–physiotherapy without biofeedback group: mean, 2.3±3.4 points; $P=.047$, Cohen $d=.68$) and follow-up (experimental

Table 2 Outcomes characterizing the EG and CG at postintervention and follow-up

Outcome Measure	Posttreatment (t1)					1-mo Follow-Up (t2)				
	EG (n=17), Mean ± SD	CG (n=20), Mean ± SD	Between-Group Difference (EG−CG),* Mean ± SE	*P*	Cohen *d* Mean (95% CI)	EG (n=17), Mean ± SD	CG (n=20), Mean ± SD	Between-Group Difference (EG−CG),* Mean ± SE	*P*	Cohen *d* Mean (95% CI)
Primary										
BBS (0−56)†,‡	50.0±6.2	43.8±10.9	2.3±1.1	.047§	0.68 (0.02 to 1.34)	48.1±10.7	42.3±11.5	2.7±1.1	.018§	0.82 (0.15 to 1.49)
10MWT, gait speed (m/s)‡	1.17±0.23	0.87±0.33	0.06±0.06	.335	0.32 (−0.33 to 0.97)	1.17±0.29	0.87±0.33	0.05±0.06	.395	0.28 (−0.37 to 0.93)
Secondary										
UPDRS-III (0−56)‖	13.6±6.8	19.1±7.9	−1.1±1.8	.545	−0.20 (−0.85 to 0.45)	16.2±7.1	18.2±6.9	2.2±1.7	.196	0.43 (−0.22 to 1.08)
TUG (s)†,‖	13.7±5.6	24.3±18.0	−1.8± 1.6	.269	−0.37 (−1.02 to 0.28)	13.4±6.5	20.2±12.0	−1.2±1.4	.380	−0.29 (−0.94 to 0.36)
ABC (0−100)‡	67.2±22.3	47.8±22.2	7.6±5.6	.186	0.45 (−0.20 to 1.10)	60.6±22.7	45.3±19.2	2.3±4.1	.580	0.18 (−0.47 to 0.83)
FOGQ (0−24)‖	10.8±5.1	12.5±3.9	−0.4±1.1	.695	−0.13 (−0.78 to 0.52)	11.1±4.9	12.6±4.3	0.06±0.9	.947	0.02 (−0.63 to 0.67)
PDQ-39 (0−100)‖	44.6±24.7	59.2±23.3	−0.7±3.7	.844	−0.07 (−0.71 to 0.58)	48.4±27.2	56.8±22.4	5.0±4.7	.285	0.36 (−0.29 to 1.01)
CoP ML sway (mm)†,‖	4.8±2.7	6.7±2.1	−1.6±0.5	.003§	−1.06 (−1.75 to −0.37)	6.3±4.1	7.8±4.3	−0.7±0.7	.306	−0.34 (−0.99 to 0.31)
CoP AP sway (mm)†,‖	7.1±3.2	8.8±3.2	−1.2±0.6	.075	−0.61 (−1.27 to 0.05)	7.6±3.9	8.5±3.0	−0.7±0.8	.359	−0.31 (−0.96 to 0.34)

Abbreviations: ABC, Activities-specific Balance Confidence scale; CG, physiotherapy group; CI, confidence interval; EG, experimental group; FOGQ, Freezing of Gait Questionnaire; PDQ-39, Parkinson's Disease Questionnaire-39; TUG, timed Up and Go test.

* Adjusted for pretreatment score (t0) by analysis of covariance.

† These variables did not meet assumptions of data normality and/or homogeneity of variances. In this cases, statistical tests and Cohen *d* computation were performed on transformed data (Box-Cox transformation). Reported between-group differences were estimated from back-transformed results to facilitate interpretation.

‡ Higher scores indicate better performance.

§ $P<.05$ (EG vs CG, contrast analysis using independent sample *t* test).

‖ Lower scores indicate better performance.

Table 3 Descriptive statistics of the Tele-healthcare Satisfaction Questionnaire—Wearable Technology for benefit, usability, and wearing comfort of the Gamepad system

Area and Statement	Value
Benefit	
1. I can benefit from this technology	3 (1—4)
2. The effort of using this technology/method is worthwhile for me	4 (2—4)
3. I am confident I am getting the most out of this technology/method	4 (1—4)
4. This technology/method is helping me to achieve my goals	3 (1—4)
5. I would recommend this technology/method to other people in my situation	4 (1—4)
Usability	
6. The use of this technology/method requires effort	3 (0—4)
7. The technology/method is reliable according to my estimation and experience so far	3 (2—4)
8. This technology/method is easy to use	4 (2—4)
9. I feel safe when using this technology/method	3 (2—4)
10. I feel good while using this technology/method	3 (1—4)
Wearing comfort	
11. Wearing this device (parts of the device) is comfortable	4 (1—4)
12. I am pleased with the size of the device (parts of the device)	4 (2—4)
13. I would wish for another look and design of the device (parts of the device)	1 (0—2)
14. I am pleased with the weight of the device (parts of the device)	3 (2—4)
15. The body-worn parts of the device are difficult to adjust (fix, fasten)	1 (0—3)

NOTE. Values represent median (minimum—maximum) score given by patients to each statement on a 5-point Likert scale (where 0 is strongly disagree, 1 is mostly disagree, 2 is neither agree nor disagree, 3 is mostly agree, and 4 is strongly agree).

group—physiotherapy without biofeedback group: mean, 2.7±3.3 points; $P=.018$; $d=.82$). No significant group or time × group effects were found in the 10MWT; however, a small effect size favoring the experimental group was present (t1: $d=.32$; t2: $d=.28$).

Secondary outcomes

Analysis of covariance (see table 2) revealed a significant effect of group ($F_{1,34}=6.12$; $P=.018$) in CoP ML sway, which was significantly smaller in the experimental group than the physiotherapy without biofeedback group at t1 (experimental group—physiotherapy without biofeedback group: −1.6±1.5mm; $P=.003$; $d=-1.06$), but not at t2 (experimental group—physiotherapy without biofeedback group: −0.7±2.1mm; $P=.306$; $d=-.34$). No significant group or time × group effects were found in the UPDRS-III, timed Up and Go test, Activities-specific Balance Confidence scale, Freezing of Gait Questionnaire, Parkinson's Disease Questionnaire-39, and AP sway.

The Tele-healthcare Satisfaction Questionnaire—Wearable Technology (table 3) showed that all patients but one (statement 1 score: 1) found the device beneficial (statement 1 score: 3—4). Gamepad was considered reliable, easy to use, and safe by all patients (statements 7—9 scores: 2—4) and comfortable by 15 out of 17 subjects (statement 11 score: 2—4). Of patients, 65% found that using Gamepad required effort (statement 6 score: 3—4) and that such effort was worthwhile for them (statement 2 score: 2—4).

Physiotherapists were positive about Gamepad training, but they suggested to reduce the number of sensors and simplify the procedures for task calibration.

Discussion

In this study, a new system for biofeedback motor rehabilitation in PD (Gamepad) was developed and clinically applied in a pilot randomized controlled trial to test its feasibility and efficacy compared with physiotherapy without feedback. Compared with existing devices, to our knowledge, this is the first wearable system integrating both balance and gait tailored exercises similar to activities of daily living.

Between-group comparisons through analysis of covariance showed statistically significant higher scores on the BBS in the experimental group than the physiotherapy without biofeedback group at t1 (2.3 points) and t2 (2.7 points). These differences were in the range of those emerged in other studies using the BBS to compare physiotherapy methods (mean, 2.79; 95% confidence interval, 0.50—5.08),[39] highlighting the positive affect of the proposed intervention on balance performance in PD. Moreover, the mean posttraining increase in the BBS score by 4.0 points in the experimental group and 1.7 points in the physiotherapy without biofeedback group suggested that only the mean improvement of the experimental group was consistent with the minimal detectable change between 2.8 and 5 points found in previous studies on PD.[25,26] Noteworthy, no between-group differences were found in studies using biofeedback systems based on balance boards,[8,9] suggesting higher efficacy of wearable devices that allow the execution of more ecologic tasks.

This result is enforced by instrumental indexes describing static balance in different sensory conditions. In particular, the amplitude of CoP ML sway at posttraining was lower in the experimental group than the physiotherapy without biofeedback group, with a statistically significant large effect size favoring the experimental group ($d=-1.06$). This finding is particularly notable because ML sway amplitude (significantly increased in PD)[32] was found to be the best stabilometric parameter predicting future falls.[40] Although this improvement was not maintained at follow-up, this result corroborated previous studies[7,14] and suggested beneficial effects of biofeedback in increasing balance control in altered sensory conditions, which strongly affect postural stability in PD.[32]

Taken together, these findings about the BBS and ML body sway seemed to support the hypothesis that Gamepad-based training is superior to physiotherapy without feedback in improving balance in PD and increasing retention of some beneficial effects in the short term (1mo). As suggested by Nieuwboer et al,[5] the present findings can be ascribed to the contribution of biofeedback in enhancing motor learning, which is feasible in PD although impaired.[1] In particular, provision of additional sensory information could have helped patients not only during the first (cognitive) stage of learning, by focalizing their attention toward the task,[2,5] but also during the last (automatization) stage, as suggested by follow-up BBS scores showing higher retention in the Gamepad group.[5] In this context, a second possible explanation about the greater benefits attained by the experimental group could be related to the better baseline characteristics compared with the physiotherapy without biofeedback group, which can be potentially associated with higher learning abilities.[1] However, we think that this hypothesis can be excluded given the lack of correlation (see supplemental appendix S3, available online only at http://www.archives-pmr.org/) between change scores in the BBS and age, disease duration, and severity level (Hoehn and Yahr stage and UPDRS-III), suggesting that balance improvements were independent from these factors. Moreover, statistical analysis was conducted by adjusting for baseline scores.

Contrary to balance, no significant between-group differences emerged in walking speed and Freezing of Gait Questionnaire. Hence, our findings did not support the hypothesis that Gamepad-based training is superior to physiotherapy without biofeedback in improving gait in PD. This could be because of not only the need of a personal computer that restricted the use of Gamepad to rehabilitation gyms, but also to the training paradigms, which included tasks for the control of trunk posture and body-weight shifting during locomotion, but not exercises specifically devoted to the biofeedback-based regulation of spatiotemporal gait parameters typically impaired in PD[2] (eg, velocity, cadence, stride length), or to the reduction of freezing episodes.[11,13]

Finally, no significant between-group differences were found in the Parkinson's Disease Questionnaire-39 and Activities-specific Balance Confidence scale, suggesting that the beneficial effects of Gamepad training did not increase perceived quality of life and confidence in activities of daily living compared with physiotherapy without biofeedback. Although the rehabilitation paradigms implemented within Gamepad followed a functional approach,[2,4] these findings seemed to confirm previous results about limited transfer of training effects to activities of daily living and quality of life.[5,11] This also suggested further developments of Gamepad to extend its use outside clinical settings, making the training environment as close as possible to real-life contexts.[5,13]

Study limitations

This study had some limitations. First, the small sample size underpowered the study. A power analysis on posttreatment BBS scores revealed that 70 subjects (35 per group) are required to achieve a between-group effect size of .68, given $\alpha = .05$ and $1-\beta = 0.8$. Besides, the analysis of posttraining 10MWT scores showed that 152 patients per group are necessary to achieve an effect size of .32 with the same values of α and β. A second limitation is the randomization procedure used for patients' allocation, which resulted in unbalanced baseline characteristics between the 2 groups. Alternative methods (eg, block or stratified randomization), more suitable for small trials, would have reduced the occurrence of such unbalancing.[18] A third limitation is that the placebo effect resulting from increased motivation was not controlled for during Gamepad training. Application of sensors, without biofeedback, to the physiotherapy without biofeedback group would have acted as a sham-device, also providing objective measures of motor performances. Finally, some technical aspects of Gamepad should be further developed in future studies to improve system portability and gain more meaningful improvement in gait (eg, reduction of sensors, replacement of a personal computer with a wearable processing unit [eg, smartphone],[6,13] implementation of algorithms allowing online computation of spatiotemporal gait parameters to be used as biofeedback variables and objective measures of locomotion).[10,13]

Conclusions

Gamepad was proven feasible for clinical use on subjects with PD, was generally well-accepted by patients and physiotherapists, and seemed more effective than physiotherapy without biofeedback in improving balance. Future studies should be performed to include more sophisticated rehabilitation paradigms for gait training[10,13] and to realize a simplified, completely wearable system, potentially usable by patients in autonomy also outside hospital (eg, at home), to enhance the improvements, to prolong their retention, and to increase transfer of training effects to real-life contexts.

Suppliers

a. TecnoBody.
b. .NET; Microsoft.
c. MATLAB/Simulink; MathWorks.
d. STATISTICA; StatSoft.

Keywords

Gait; Parkinson disease; Postural balance; Rehabilitation

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Supplemental Appendix S1 Examples of Tasks Included Within the Gamepad System

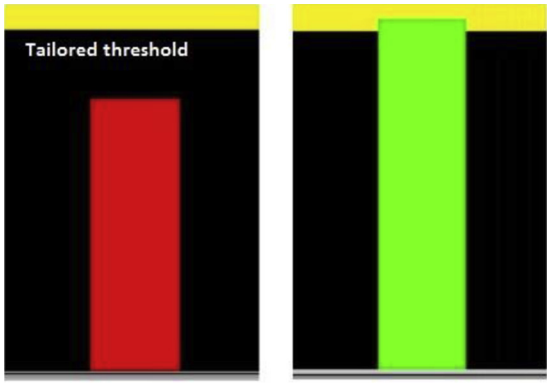
Static

Task

Upright standing by controlling the knee flexion and the ML (or AP) inclination of the trunk.

Instruction and feedback

The patient is asked to maintain upright balance trying to keep the knee extended and to control the ML (or AP) inclination of upper trunk. A visual feedback is provided about knee flexion/extension angle, represented by a vertical bar on the monitor (supplemental fig S1). If knee extension is below a threshold defined by the physiotherapist, the bar is red, otherwise, if the patient maintains a correct extension, the bar turns green. Simultaneously, an auditory feedback is provided about ML (or AP) trunk inclination. If this variable is within a tailored reference band defined by the therapist, no sound is provided, otherwise Gamepad produces alarm sounds (negative feedback): high-pitch sound in case of excessive right (or forward) inclination, low-pitch sound in case of excessive left (or backward) inclination.



Supplemental Fig S1 Example of visual feedback provided by Gamepad. The vertical bar represents the knee flexion/extension angle. The bar is red in case of excessive knee flexion (left panel), whereas it turns green in case of adequate knee extension (right panel).

Note that the exercise can be performed on firm surface or with foam pad under feet.

Quasi-dynamic

Task

Place a foot on a step after a correct shift of body weight toward the supporting limb.

Instruction and biofeedback

The subject is asked to transfer the body weight toward the supporting leg, keep this position for a time defined by the therapist, and then place the opposite foot on a step placed in front of him. The patient performs the task by looking at a circle replicating the motion of the center of mass on the computer screen (supplemental fig S2). The circle has to be moved from a starting position (white rectangle) toward a yellow target area, whose position and dimensions are defined by the therapist based on subjects' ability. If the circle is kept within the target area, its color is green, otherwise it turns red and an alarm sound is provided (negative feedback). After a given time, the patient places the leading foot on the step.

Dynamic

Task

Straight-line walking controlling the transfer of body weight between limbs.

Instruction and feedback

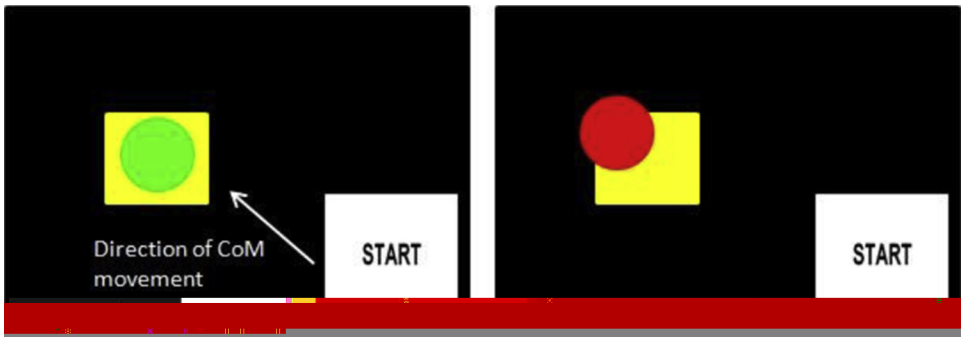
The subject is asked to walk while controlling the ML shift of body weight, estimated with the ML angular displacement of the lower trunk.[15] If this variable is above a tailored threshold, indicating the correct transfer of body weight toward the stance limb, Gamepad provides a sound (positive feedback).

Task

Walking over obstacles controlling the ML (or AP) inclination of the upper trunk.

Instruction and feedback

The subject is asked to walk over wooden sticks placed on the floor, maintaining the ML (or AP) inclination of the trunk within a



Supplemental Fig S2 Example of visual feedback provided by Gamepad. The circle represents the CoM that has to be moved from a starting position (START rectangle) to a final target position (yellow rectangle) toward the left (supporting) leg. The circle is green if the CoM in maintained within the target area, otherwise it turns red. Abbreviation: CoM, center of mass.

reference band defined by the therapist. If trunk inclination is outside the target band, Gamepad provides alarm sounds (negative feedback): high-pitch sound in case of excessive right (or forward) inclination, and low-pitch sound in case of excessive left (or backward) inclination.

Note that the exercise can be executed at a self-selected velocity or at a fast speed, as indicated by the physiotherapist.

Supplemental Appendix S2 Brief Description of the Outcome Measures

Primary outcomes

Berg Balance Scale

The BBS[24-26] rates balance from 0 (cannot perform) to 4 (normative performance) on 14 items exploring the ability to sit, stand, lean, turn, and maintain the upright position on 1 leg. Maximum score (ie, 56 points) indicates unimpaired balance.

10-m walk test

The 10MWT[26] measures, with a stopwatch, the time (T) taken by the subject to walk between 2 lines at the distance of 10m. Walking speed is therefore computed as $10/T$ (m/s). Both comfortable and fast gait speed can be measured. In this study only comfortable gait speed was assessed.

Secondary outcomes

Unified Parkinson's Disease Rating Scale

The Unified Parkinson's Disease Rating Scale[29] is the criterion standard instrument used to measure disease severity and disease-specific impairments in PD. It has 3 subscales: I (Mentation, Behavior, and Mood), II (Activities of Daily Living); and III (Motor Examination). Each item is rated on a 5-point ordinal scale from 0 to 4, with 4 representing the greatest level of dysfunction. In this study, only UPDRS-III was administered.

Timed Up and Go test

The timed Up and Go test[26] is a mobility test evaluating the time taken by the subject to rise from a chair, walk 3m, turn around, walk back to the chair, and sit down.

Activities-specific Balance Confidence scale

The Activities-specific Balance Confidence scale[26] is a questionnaire through which the subject rates his/her perceived level of confidence while performing 16 daily living activities. Scores range from 0% (not confident) to 100% (completely confident).

Freezing of Gait Questionnaire

The Freezing of Gait Questionnaire[30] evaluates freezing severity with a 6-item interview. Each item is rated on a 5-point ordinal scale from 0 (absence of freezing) to 4 (severe freezing).

Parkinson's Disease Questionnaire-39

The Parkinson's Disease Questionnaire-39 is a 39-item, self-report questionnaire,[31] which assesses PD-specific health-related quality of life over the last month. Scores are from 0 to 100, with 100 representing the maximum level of problems.

Tele-healthcare Satisfaction Questionnaire—Wearable Technology

The Tele-healthcare Satisfaction Questionnaire—Wearable Technology[33] consists of 6 areas (benefit, usability, self-concept, privacy and loss of control, quality of life, and wearing comfort) that evaluate the satisfaction of the subject with the wearable part of a system. Each area includes 5 statements rated by the user on a 5-point Likert scale between 0 (strongly disagree with the statement) and 4 (strongly agree with the statement). The questionnaire is described in supplemental table S1. In this study, only the benefit, usability, and wearing comfort areas were administered.

Supplemental Appendix S3 Correlation Analysis

Supplemental tables S2 and S3 showed the results of a correlation analysis performed on the entire sample of patients (n=37) between change scores of primary outcome measures (BBS and gait speed) and age, time since diagnosis, Hoehn and Yahr stage, and baseline score on the UPDRS-III scale. In particular, Spearman correlation coefficients (ρ) and related P values were computed.

It can be noticed from the results that, for both outcome measures, change scores (t1−t0 and t2−t0) are not significantly correlated with the selected variables, suggesting that, independently from the received intervention, the improvements attained after rehabilitation are not related to age, disease duration, and disease severity (Hoehn and Yahr stage and UPDRS-III score).

Supplemental Table S1 Tele-healthcare Satisfaction Questionnaire—Wearable Technology

Area	Statement
Benefit	1. I can benefit from this technology
	2. The effort of using this technology/method is worthwhile for me
	3. I am confident I am getting the most out of this technology/method
	4. This technology/method is helping me to achieve my goals
	5. I would recommend this technology/method to other people in my situation
Usability	1. The use of this technology/method requires effort
	2. The technology/method is reliable according to my estimation and experience so far
	3. This technology/method is easy to use
	4. I feel safe when using this technology/method
	5. I feel good while using this technology/method
Self-concept	1. The use of this technology/method is an interesting challenge for me
	2. This technology/method reminds me of losing my independence
	3. The use of this technology/method is making me feel older than I am
	4. I (would) feel embarrassed using this technology/method visible around others
	5. I like to use technologic products or systems like this technology/method
Privacy and loss of control	1. I feel there is too much supervision by this technology/method
	2. I use this technology/method by request of others (eg, physician, therapist, relatives)
	3. I am sure that my personal data are stored or processed in an appropriate way
	4. The use of this technology/method may have unpredictable negative consequences for me
	5. This technology/method forces me to disclose personal facts that I prefer to keep to myself
Quality of life	1. Using this technology/method improves my physical well-being
	2. This technology/method evokes unpleasant feelings
	3. This technology/method enhances my social contacts
	4. This technology/method helps me to maintain or increase my independence (eg, regarding mobility, communication, medication)
	5. The use of this technology/method has a positive effect on me
Wearing comfort	1. Wearing this device (parts of the device) is comfortable
	2. I am pleased with the size of the device (parts of the device)
	3. I would wish for another look and design of the device (parts of the device)
	4. I am pleased with the weight of the device (parts of the device)
	5. The body-worn parts of the device are difficult to adjust (fix, fasten)

Supplemental Table S2 Coefficient of correlation (Spearman ρ) between change scores (t1—t0 and t2—t0) in BBS and age, time since diagnosis, Hoehn and Yahr stage, and UPDRS-III score for the entire sample (n = 37)

	BBS Change Score (t1—t0)		BBS Change Score (t2—t0)	
Independent Variable	ρ	*P*	ρ	*P*
Age	−.082	.630	−.039	.818
Time since diagnosis	−.152	.369	−.191	.254
Hoehn and Yahr stage	.141	.406	−.017	.921
UPDRS-III baseline score	.099	.558	−.061	.721

Supplemental Table S3 Coefficient of correlation (Spearman ρ) between change scores (t1—t0 and t2—t0) in gait speed and age, time since diagnosis, Hoehn and Yahr stage, and UPDRS-III score for the entire sample (n = 37)

	Gait Speed Change Score (t1—t0)		Gait Speed Change Score (t2—t0)	
Independent Variable	ρ	*P*	ρ	*P*
Age	.074	.664	−.113	.505
Time since diagnosis	.140	.407	.089	.600
Hoehn and Yahr stage	−.005	.977	−.206	.222
UPDRS-III baseline score	−.031	.857	−.119	.482