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ORIGINAL ARTICLE

A wearable system for visual cueing gait rehabilitation in Parkinson's disease: a randomized non-inferiority trial

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ABSTRACT

BACKGROUND: Gait disturbances represent one of the most disabling features of Parkinson's disease (PD).
AIM: The aim of this study was to evaluate the non-inferiority of a new wearable visual cueing system (Q-Walk) for gait rehabilitation in PD subjects, compared to traditional visual cues (stripes on the floor).
DESIGN: Open-label, monocentric, randomized controlled non-inferiority trial.
SETTING: Outpatients.
POPULATION: Patients affected by idiopathic PD without cognitive impairment, Hoehn and Yahr stage II-IV, Unified Parkinson's Disease Rating Scale motor section III ≥2, stable drug usage since at least 3 weeks.
METHODS: At the enrollment (T0), all subjects underwent a clinical/functional evaluation and the instrumental gait and postural analysis; then they were randomly assigned to the Study Group (SG) or Control Group (CG). Rehabilitation program consisted in 10 consecutive individual sessions (5 sessions/week for 2 consecutive weeks). Each session included 60 minutes of conventional physiotherapy plus 30 minutes of gait training by Q-Walk (SG) or by traditional visual cues (CG). Follow-up visits were scheduled at the end of the treatment (T1) and after 3 months (T2).
RESULTS: Fifty-two subjects were enrolled in the study, 26 in each group. The within-groups analysis showed a significant improvement in clinical scales and instrumental data at T1 and at T2, compared to baseline, in both groups. According to the between-group analysis, Q-Walk cueing system was not-inferior to the traditional cues for gait rehabilitation. The satisfaction questionnaire revealed that most subjects described the Q-Walk cueing system as simple, motivating and easily usable, possibly suitable for home use.
CONCLUSIONS: Data showed that motor rehabilitation of PD subjects performed by means of the new wearable Q-Walk cueing system was feasible and as effective as traditional cues in improving gait parameters and balance.
CLINICAL REHABILITATION IMPACT: Wearable devices can act as an additional rehabilitation strategy for long-term and continuous care, allowing patients to train intensively and extensively in household settings, favoring a tailor-made and personalized approach as well as remote monitoring.

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KEY WORDS: Neurological rehabilitation; Parkinson disease; Gait; Wearable electronic devices.

Gait disturbances and postural instability are among the most disabling features of Parkinson's disease (PD), whose pathogenesis is probably multi-factorial depending on both dopaminergic and non-dopaminergic mechanisms as well as on sensory and cognitive aspects.[1, 2]

Gait disturbances in PD are classified as continuous, characterized by decreased stride length and gait speed, increased step frequency, increased double support time, stride-to-stride variability and left–right asymmetry or episodic (festination and freezing). Gait usually worsens over time as disease progresses, leading to an increased risk of falls and related injuries, loss of independence and a reduction in quality of life (QoL). Pharmacological treatments have proven to be effective in the early stages of the disease, producing a temporary relief of symptoms, but after 5 to 8 years of dopaminergic therapy, gait disturbances usually reemerge. In this frame, rehabilitative approaches play an important integrative role in ameliorating gait disturbances.[3]

It is well known the strict relationship between postural control and gait. Data from literature showed that postural adjustments due to anticipatory (feed-forward) postural adjustments (APAs) and compensatory (feedback) reactions guarantee both static and dynamic postural control, and their efficiency represents a prerequisite for walking.[4, 5] Moreover, postural control is under multisensory control with a prominent role of the visual system, and the adaptation of postural control to locomotion is learned through experience and the maintenance of high alert levels that allow us to activate context-dependent and task-specific postural muscle synergies.[6-8]

Some systematic reviews and meta-analysis have showed that conventional physical therapy might improve gait as well as balance, mobility and functional reach in subjects affected by PD.[9, 10]

In addition, several studies and reviews support the effectiveness of external sensory cueing, by means of rhythmic auditory or visual cues, in improving kinematic parameters of gait (gait cadence, stride length, velocity, and postural stability) and the functional performance in people with PD, at least in the short term.[10-14] The results of the RESCUE trial showed small but specific and significant improvements in short-term on balance after cueing training, at least for PD patients without cognitive decline[15] and a recent narrative review included cues training interventions, among the rehabilitation intervention that showed promising therapeutic effects in improving balance in people with PD.[16]

Specifically, cueing refers to the use of temporal or spatial stimuli to regulate movement and facilitate functional performance for individual with motor dysfunction. Basal ganglia act as internal triggers of neuronal activity in the supplementary motor area for well-learned, automatic movement sequences, such as locomotion. There is evidence that this mechanism is damaged in individuals with PD, and external cues may act as an attention resource to compensate the absent or deficient internal rhythm due to basal ganglia dysfunction. Subjects can be coached in concentrating their attention on gait by specific self-prompting instructions or by cues stimulation or a combination of these.[17] Movements generated by the presence of external sensory cues are prompted to use alternative (cortical, parieto-premotor) neuronal pathways which have not been damaged by neuronal degeneration of PD, bypassing the automatic basal ganglia network.[18-20]

Several devices have been proposed, based on various kinds of cues, to improve gait and balance in PD. In this regard, recent studies have provided preliminary evidence that visual cueing based on laser shoes and laser canes may reduce freezing, an established risk for falls, with improvement that can be observed for a variable period of time after rehabilitative intervention.[21-23] In light of the evidence of effectiveness of cueing, developing wearable devices able to generate cues that match with step and that are effective, easy to use and low cost, would be challenging but very appropriate.

The aim of this study was to evaluate the non-inferiority of a new wearable visual cueing device (Q-Walk system, QUICKLYPRO s.r.l., Bergamo, Italy) for gait rehabilitation in PD patients, compared to a conventional training based on the use of traditional visual cues (stripes on the floor). The secondary aim of the study was to evaluate the patients' satisfaction with the use of the new device as well as the ease of use of the instrument.

Materials and methods

Participants

All patients consecutively referred to the Neurorehabilitation Unit of HABILITA between 1st November 2019 and 31st December 2021 were screened. Patients with the following inclusion criteria were enrolled: diagnosis of idiopathic PD (defined by the UK Brain Bank Criteria);[24] absence of cognitive impairment (Mini-Mental State Examination score ≥24);[25] Hoehn and Yahr[26] stage II-IV; mild to severe gait disturbance with score ≥2 at the Unified Parkinson's Disease Rating Scale (UPDRS) motor section

III,[27] with or without freezing of gait; stable drug usage since at least 3 weeks.

Exclusion criteria were: past history or current presence of neurological conditions other than PD; orthopedic or visual disturbances severely impairing walking ability; previous deep brain stimulation or other neurosurgery; participation in a rehabilitation program within 2 months before the trial and previous use of cues for gait rehabilitation.

All the patients gave their written informed consent to take part in the study. All participants could withdraw from the trial at any time if severe adverse events occurred during treatment or by their request.

The study was approved by the Local Ethics Committee of Bergamo (Reg. Sper. n. 178/19, 11/10/2019) and was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. The clinical trial has been registered on Clinical Trials.gov: NCT05478187.

Study design and procedures

The study was conducted as an open-label, monocentric, randomized controlled non-inferiority trial.

At baseline (T0) all enrolled patients underwent clinical evaluation by means of the Performance Oriented Mobility Assessment (POMA).[28] At the same time, motor performance evaluation by instrumental gait analysis and balance evaluation were performed. Then subjects were randomly assigned to the study group (SG) or to the control group (CG) by means of a computer random number generator.

All the patients received the same amount and intensity of rehabilitative treatment in outpatient setting for a total of 10 individual sessions (5 sessions/week for 2 consecutive weeks). Each session consisted of 60 minutes of conventional physiotherapy plus an additional session of gait training (30 minutes), performed by means of the new wearable cueing system (SG) or by means of traditional visual cues consisting of stripes on the floor (CG). The conventional rehabilitation program was planned according to the European Physiotherapy guidelines for Parkinson's disease and focused on: endurance, strength, flexibility and balance with functional practice, motor learning principles.[29]

At the end of the rehabilitative treatment (T1) patients in the SG were asked to answer a brief satisfaction questionnaire relating to the use of the new wearable cueing system, which consisted of 7 questions answered on a 0-3 scale (0 = poor, 1 = average, 2 = good, 3 = excellent).

Patients were instructed to take their usual dopaminergic drugs 1 hour before their study appointment, allowing the evaluation and the intervention to occur in the ON-medication state, in order to optimize motor control and reduce fatigue.

Randomization and blinding

After enrollment, participants were randomly allocated to the study group (SG) or the control group (CG) in a ratio of 1:1. Randomization was performed by an independent statistician by means of a simple blocked randomization list generated by an online randomization service in Sealed envelope™ (free online at: https://www.sealedenvelope.com/simple-randomiser/v1/lists). All the clinical, functional and instrumental evaluations were performed by physiotherapists and/or neurologists blinded to the patients' allocation and not involved in the patients' care. All the statistical analyses were performed by an independent statistician, blinded to the patients' treatment.

The Q-Walk cueing system

The Q-Walk system (QUICKLYPRO s.r.l., Bergamo, Italy) consists in a pair of knee pads that patients can wear in the sub-patellar region of both lower limbs. Each device incorporates a LED spotlight with a lens that projects a customized circular light beam on the floor, right in front of the patient. A motorized stabilization system powered by battery (9 V, 800 mAh, Lithium-ion) allows the continuous adjustment on the sagittal plane (ankle, knee and hip flexion-extension) of the circular light beam at each step during the gait progression. The light beam is focused on a fixed point, at a distance previously defined by the physiotherapist and based on the subjects' individual anthropometric characteristics. In order to define the distance of the cue point on the floor, patients were invited to stay in quiet stance on a graded control mat (Figure 1); then the physiotherapist set up the LED spotlight at a distance of half of 80% of the body height. Then, patients were asked to walk so that the correctness of the position of the LEDs could be verified and mat coordinates recorded. Before starting the rehabilitation program, all the patients were trained in the use of the Q-Walk system and provided with the following indications: "You are wearing a pair of knee pads that projects visual cues to the floor, and you will have to try to follow them. The right device will provide a cue for the left step, and the left device will provide a cue for the right step. Walk naturally following the cues you will see on the floor in front of you."

The final version of the Q-Walk system, used in this study,

Figure 1.—Q-Walk system (QUICKLYPRO s.r.l., Bergamo, Italy).

was the result of a 5-step process that went through the following phases: 1) research: to understand the users' needs and the clinicians' suggestions in order to define the requirements of the device and the context of use; 2) design: to design preliminary projects according to the characteristics defined in the previous phase, under the supervision of end-users and clinicians; 3) development: to develop a prototype on the basis of the previous phases; 4) evaluation: to evaluate the prototype with end-users and clinicians to verify the fulfillment of the requirements, the functionality (if the prototype is working properly and in the way it is expected from a technical perspective) and the usability of the device; 5) clinical test (described in this study): to evaluate the clinical effectiveness of the device compared to conventional treatment, as well as users' acceptance and satisfaction.

Instrumental evaluation

Gait analysis

The gait analysis was performed by an optical infrared detection system (OptoGait®, Microgate, Bolzano, Italy). Briefly, the system consists of two optical detection bars (one transmitter and one receiver) defining a walking way and positioned on the two opposite sides. Each bar contains 96 LEDs communicating on an infrared frequency with LEDs on the opposite bar. The system detects the interruptions of the communication between the bars (recording parameters: frequency 1000 Hz; accuracy 1 cm), and a dedicated software measures in real-time the duration and position of each step, deriving spatial-temporal gait parameters. Subjects walked barefoot at a comfortable speed along the gait lab walkway. In order to observe natural locomotion, only general, qualitative instructions were provided. Before the recording session, the patients practiced for a few minutes to get familiar with the procedure. Six trials were recorded for each locomotor task: the first and last trial were discarded and the mean value of the other four trials was used for statistical analysis.

Balance evaluation

Postural assessments were performed using a force platform (Stabilometric balance by Khimeya®, Padua, Italy), and recordings were performed as described in a previous study.[30] Briefly, the quiet upright posture assessment was performed in order to detect the instant position of the center of foot pressure (CoP). The patients were examined without shoes, standing quietly on the force platform with their feet spaced 17 cm apart (distance measured between the heels) and with a 14° angle between the feet, with their arms at their sides, looking at a visual target positioned 40 cm in front of them at the height of their eyes.[31] All the patients received the same instructions: to keep their gaze fixed on the visual target, remaining standing for at least 40 seconds. Foot positions were marked on the platform to ensure consistency across trials. The eyes open (EO) and eyes closed (EC) conditions were recorded and six consecutive trials recordings (3 EO, 3 EC, randomly assigned) were collected. In order to avoid fatigue, patients were allowed to rest for one minute between trials. The force platform signals were recorded at 120 Hz, in a time window of 40 seconds. In order to avoid transient periods, the signals recorded during the first and last five seconds were discarded. The evaluations were performed in a quiet room with very low background noise and diffuse light.

Outcome measures

Step length (m) was considered as primary outcome measure for this study, on which the sample size calculation was based. As secondary outcome measures the following gait parameters were considered: mean speed (m/s), cadence (step/min), stance phase duration (%), double support phase duration (%); moreover, CoP sway length (statokinesigram) (mm), mean CoP position along the anteroposterior (A-P) and mediolateral (M-L) directions

were separately computed for both visual conditions (EO and EC) as measures of the patients' postural stability and asymmetrical weight distribution on the feet, respectively.

Clinical evaluation (POMA, UPDRS III), primary and secondary outcome measures were recorded at baseline (T0), after the intervention (T1) and at three months follow-up (T2) for SG and CG.

Sample size estimates

A total sample size of 52 (*i.e*. 26 subjects per group) achieves 80% of statistical power to detect non-inferiority of the Q-Walk cueing system device with respect to the traditional cues in increasing the stride length of patients, assuming a non-inferiority margin of -6.8 cm and a two-sample one-sided *t*-test significance level (alpha) of 2.5%. This margin can be considered a clinically acceptable limit, as it largely falls within the range of variability indicated for stride length in parkinsonian patients.[32] It was also assumed that the data are randomly drawn from a population in which the standard deviation of the increase in stride length after the treatment is 8.5 cm.[32]

Statistical analysis

Demographic, clinical and kinematic features of the study sample collected at baseline (T0) were reported as means and standard deviations, medians along with interquartile (i.e. first-third quartile) and min-max or as absolute and relative frequencies (percentages) for continuous and categorical variables, respectively. The difference in such characteristics between the two groups of patients was assessed by means of the standardized mean difference (SMD).[33] This measure quantifies the magnitude of the overall difference in terms of "effect size" (*i.e*. clinical relevance): for an SMD<0.20, there is a "negligible" difference between the groups, whereas an SMD between 0.20 and 0.49 results in a "small" effect size.[34] Check for symmetry and normality of the distribution of pre-post differences in the outcome variables (from T0 to T1 and T2) were assessed with the Skewness Index (S) and the Shapiro-Wilk Test, respectively.

For outcomes with a non-normal or asymmetric distribution (*i.e.* S>1 in absolute value) in the difference between the two time points (*i.e*. T1 *vs*. T0 and T2 *vs*. T0), changes in outcome values were assessed with the Friedman test, otherwise with the repeated-measures ANOVA model. The correlation of repeated measures within subjects was taken into account with an unstructured correlation matrix.[35] Tests for overall differences between the time points and *post-hoc* pairwise comparisons were performed using statistical least squares contrasts computed from the models. The p-values of the tests for overall differences were also corrected (*i.e*. inflated) for multiple testing, following Bonferroni method. Comparisons between the two groups were also performed with respect to the difference in outcome values after treatment (T1) and follow-up compared to baseline (T0) and P values were computed from statistical contrasts in least square means derived from the fitted models.

To assess whether the increase in stride length from T0 to T1 provided by the Q-Walk cueing system was not inferior to that provided by the traditional cues, a one-sided two-sample t-test on stride length difference was performed, under the null hypothesis that the mean difference was lower than or equal to -6.8 cm (denoting the presence of inferiority) and under the alternative hypothesis that the mean difference was greater than -6.8 cm (denoting the presence of non-inferiority).

A P value <0.05 denotes the statistical significance. All statistical analyses were performed using both R (v. 4.2.1, packages "arsenal", "tableone") and SAS 9.4 (SAS Institute Inc., Cary, NC, USA).

Data availability

The data associated with the paper are not publicly available but are available from the corresponding author on reasonable request.

Results

Sixty-seven patients were eligible for the study, and 52 of them were enrolled: 26 in the SG (17 male, nine female, mean age 73±7.3 years) and 26 in the CG (20M, 6F, mean age 70.3±11 years), respectively. Fifteen subjects not fulfilling the inclusion criteria were excluded, 10 because of cognitive impairment (MMSE <24) and five because of comorbidities including orthopedic disorders (three subjects with hip prosthesis) and previous neurological disorders (two subjects). There were no adverse events (*i.e*.: falls, dizziness, pain, instability) associated with the study interventions.

All patients completed the treatment and performed the evaluation at T1. There were two drop-outs in the SG and three in the CG, at T2. Therefore, the follow-up analysis included 24 and 23 patients in SG and in the CG, respectively. The comparison of the two groups showed no significant differences neither in the demographic and clinical features (Table I) nor in the instrumental data (Table II) at the baseline (T0).

TABLE I.—*Characteristics of the study sample at baseline (demographic and clinical features).*

Characteristics	Study group (N.=26)	Control group (N.=26)	Total (N.=52)	SMD
Age (years)				
Mean±SD	73.0±7.3	70.3±11.0	71.6±9.4	0.284
Median [IQR]	73.5 [69.0, 78.0]	69.5 [61.5, 82.0]	73.0 [66.5, 79.2]	
Min-max	54.0-84.0	52.0-86.0	52.0-86.0	
Gender				0.257
Female	9 (34.6%)	6 (23.1%)	15 (28.8%)	
Male	17 (65.4%)	20 (76.9%)	37 (71.2%)	
Years from diagnosis				0.124
Mean±SD	9.4±3.1	9.8±3.9	9.6±3.5	
Median [IQR]	9 [7, 12.25]	9 [6.75, 11.50]	9 [7.0, 11.75]	
Min-max	4.0-15.0	5.0-19.0	4.0-19.0	
Daily levodopa dose (mg/day)				0.114
Mean±SD	375±103.9	386.5±80.4	380.7±92.1	
Median [IQR]	400 [300, 462.5]	400 [375, 400]	400 [350, 400]	
Min-max	150.0-500.0	200.0-500.0	150-500	
Freezing of gait				0.000
Yes	7±26.9	7±26.9	14±26.9	
No	19±73.1	19±73.1	38±73.1	
MMSE				0.123
Mean±SD	27.0±1.9	27.3±2.4	27.2±2.2	
Median [IQR]	27.0 [25.2, 28.0]	28.0 [24.2, 29.0]	28.0 [25.0, 29.0]	
Min-max	24.0-30.0	24.0-30.0	24.0-30.0	
Hoehn & Yahr				0.060
Mean±SD	2.0±0.6	2.1±0.7	2.1±0.6	
Median [IQR]	2.0 [2.2, 2.0]	2.0 [2.2, 2.0]	2.0 [2.2, 2.0]	
Min-max	1.0-3.0	1.0-4.0	1.0-4.0	
UPDRS III				0.305
Mean±SD	30.8±8.2	28.1±9.4	29.4±8.9	
Median [IQR]	29.0 [25.2, 36.5]	27.0 [21.2, 33.8]	28.0 [23.8, 35.2]	
Min-max	18.0-49.0	13.0-53.0	13.0-53.0	
POMA balance				0.146
Mean±SD	13.0±2.6	12.5±3.2	12.8±2.9	
Median [IQR]	13.5 [11.0, 15.0]	13.5 [11.0, 15.0]	13.5 [11.0, 15.0]	
Min-max	7.0-16.0	6.0-16.0	6.0-16.0	
POMA gait				0.242
Mean±SD	8.8±1.7	9.3±2.1	9.0±1.9	
Median [IQR]	9.0 [8.0, 10.0]	10.0 [9.0, 10.8]	9.0 [8.0, 10.0]	
Min-max	5.0-12.0	4.0-12.0	4.0-12.0	
POMA total				0.009
Mean±SD	21.8±3.8	21.8±4.5	21.8±4.1	
Median [IQR]	22.5 [19.2, 24.8]	22.0 [20.0, 25.8]	22.0 [19.8, 25.0]	
Min-max	15.0-28.0	12.0-28.0	12.0-28.0	

MMSE: Mini-Mental State Examination; UPDRS: Unified Parkinson's Disease Rating Scale; POMA: Performance Oriented Mobility Assessment; SD: Standard Deviation; IQR: Interquartile Range (*i.e.* first-third quartiles). Quantiles are computed using the 7th algorithm defined by Hyndman and Fan.[36]
SMD: Standardized Mean Difference. It is defined as the difference between the two sample means, divided by the standard deviation of this difference. This effect size, known as Cohen's d, represents the mean difference in terms of its homogeneity.

Within-groups analysis

The within-groups analysis showed that both groups had a significant improvement in the clinical functional status at the end of the rehabilitation treatment (T1), as evaluated by the POMA (both the POMA-total score and the two POMA sub-scores: POMA balance and POMA gait) (P=0.000). At the follow-up (T2), values at POMA total scores and sub-scores were comparable to those detected at T1 for SG, while showed a slight but significant decrease compared to T1, although still better than the baseline for patients in the CG. UPDRS section III score significantly reduced at T1 and T2 compared to baseline for both groups, while no significant difference was detected between T1 and T2 for either the SG or the CG (Table III).

Gait analysis showed a significant improvement in dif-

TABLE II.—*Characteristics of the study sample at baseline (instrumental data).*

Parameter	Study group (N.=26)	Control group (N.=26)	Total (N.=52)	SMD
Gait analysis				
Right support phase duration				0.202
Mean±SD	66.4±3.9	67.3±5.5	66.8±4.7	
Median [IQR]	65.2 [63.9, 68.5]	65.8 [63.7, 69.4]	65.5 [63.9, 69.2]	
Min-max	60.9-74.8	60.5-83.1	60.5-83.1	
Left support phase duration				0.024
Mean±SD	66.5±4.5	66.6±4.1	66.5±4.3	
Median [IQR]	66.5 [63.9, 68.5]	65.7 [64.1, 68.1]	65.9 [64.0, 68.5]	
Min-max	60.0-79.2	61.0-81.9	60.0-81.9	
Double support phase duration				0.136
Mean±SD	32.3±6.1	33.3±7.6	32.8±6.8	
Median [IQR]	32.8 [28.8, 35.8]	31.2 [28.5, 36.4]	32.0 [28.6, 35.9]	
Min-max	21.4-45.3	21.4-54.3	21.4-54.3	
Cadence (step/min)				0.067
Mean±SD	101.7±12.6	100.7±17.0	101.2±14.8	
Median [IQR]	101.6 [95.5, 113.0]	102.1 [95.9, 110.7]	102.1 [95.4, 112.7]	
Min-max	78.8-126.7	47.5-121.3	47.5-126.7	
Step length (cm)				0.093
Mean±SD	99.0±15.5	100.4±16.2	99.7±15.7	
Median [IQR]	99.1 [90.1, 111.1]	98.9 [89.5, 114.7]	98.9 [89.3, 112.2]	
Min-max	58.1-126.2	68.2-129.3	58.1-129.3	
Mean speed (m/s)				0.067
Mean±SD	0.8±0.2	0.9±0.2	0.8±0.2	
Median [IQR]	0.9 [0.7, 0.9]	0.9 [0.7, 0.1]	0.9 [0.7, 1.0]	
Min-max	0.4-1.1	0.3-1.3	0.3-1.3	
Balance evaluation				
Eyes open				
Medio-lateral asymmetry (mm)				0.009
Mean±SD	2.1±3.6	2.1±1.3	2.1±2.7	
Median [IQR]	1.3 [0.8, 1.9]	1.5 [1.2, 3.0]	1.4 [1.0, 2.4]	
Min-max	0.4-19.2	0.6-4.8	0.4-19.2	
Antero-posterior asymmetry (mm)				0.090
Mean±SD	4.3±2.5	4.5±1.9	4.4±2.2	
Median [IQR]	3.7 [3.3, 4.6]	4.2 [3.2, 5.1]	3.9 [3.3, 5.0]	
Min-max	1.9-14.2	2.3-10.6	1.9-14.2	
Statokinesigrams (mm)				0.082
Mean±SD	538.0±405.7	511.4±213.8	524.7±321.3	
Median [IQR]	392.8 [348.1, 521.5]	456.3 [352.6, 550.5]	434.6 [350.6, 540.7]	
Min-max	271.8-2180.2	276.2-1096.9	271.8-2180.2	
Eyes closed				
Medio-lateral asymmetry (mm)				0.092
Mean±SD	2.2±2.6	2.4±1.6	2.3±2.2	
Median [IQR]	1.3 [0.8, 2.6]	1.7 [1.1, 3.4]	1.6 [0.9, 3.0]	
Min-max	0.6-13.8	0.7-6.4	0.6-13.8	
Antero-posterior asymmetry (mm)				0.099
Mean±SD	5.7±2.7	5.9±2.8	5.8±2.7	
Median [IQR]	4.8 [3.7, 7.1]	5.5 [4.5, 6.3]	5.2 [3.9, 7.1]	
Min-max	2.9-12.4	3.2-17.4	2.9-17.4	
Statokinesigrams (mm)				0.067
Mean±SD	639.6±381.0	663.5±328.1	651.5±352.3	
Median [IQR]	483.9 [397.6, 710.9]	622.1 [402.5,738.3]	503.3 [394.3, 728.2]	
Min-max	302.5-1545.1	320.5-1652.7	302.5-1652.7	

SD: standard deviation; IQR: interquartile range (*i.e.* first-third quartiles). Quantiles are computed using the 7th algorithm defined by Hyndman and Fan.[36] Standardized mean difference (SMD) is defined as the difference between the two sample means, divided by the standard deviation of this difference. This effect size, known as Cohen's d, represents the mean difference in terms of its homogeneity.

TABLE III.—*Within-group analysis (T0-T1-T2).*

Outcome measures	Study group			Control group		
	Baseline (T0)	After treatment (T1)	Follow-up (T2)	Baseline (T0)	After treatment (T1)	Follow-up (T2)
Clinical scales						
POMA balance	13.0 (2.6) [a, b]	14.6 (1.8)	14.3 (1.7)	12.5 (3.2) [a, b]	14.0 (2.7)	13.0 (2.9)
POMA gait	8.8 (1.7) [a, b]	10.3 (1.2)	10.1 (1.8)	9.3 (2.1) [a, b]	10.5 (1.8)	9.7 (1.8)
POMA total	21.8 (3.8) [a, b]	24.9 (2.7)	24.3 (3.2)	21.8 (4.5) [a, b]	24.5 (3.7)	22.6 (4.1)
UPDRS III	30.8 (8.2) [a, b]	23.1 (9.2)	23.3 (8.4)	28.1 (9.4) [a, b]	23.4 (9.0)	25.3 (9.9)
Gait analysis						
Right support phase duration (%)	66.4 (3.9)	64.1 (3.0)	65.4 (4.7)	67.3 (5.5)	65.7 (4.5)	66.2 (5.8)
Left support phase duration (%)	66.5 (4.5)	65.2 (4.3)	64.4 (3.4)	66.6 (4.1)	65.9 (4.4)	66.4 (5.4)
Double support phase duration (%)	32.3 (6.1) [a, b]	28.6 (5.3)	29.4 (5.1)	33.3 (7.6)	31.7 (8.3)	32.9 (9.4)
Cadence (step/min)	101.6 [95.5, 113.0]	112.2 [100.2, 119.0]	108.7 [96.9, 115.7]	102.1 [95.9, 110.7]	103.2 [96.5, 112.4]	102.0 [94.5, 113.6]
Mean speed (m/s)	0.8 (0.2) [a, b]	1.0 (0.2)	1.0 (0.2)	0.9 (0.2) [a, b]	1.0 (0.3)	0.9 (0.3)
Step length (cm)	99.0 (15.5) [a, b]	111.5 (18.1)	110.4 (19.0)	100.4 (16.2) [a, b]	111.4 (21.2)	105.9 (19.5)
Balance evaluation						
Eyes open						
Medio-lateral asymmetry (mm)	1.3 [0.8, 1.9]	1.1 [0.8, 1.5]	1.1 [0.9, 1.6]	1.5 [1.2, 3.0]	1.5 [1.2, 2.4]	1.9 [1.2, 2.6]
Antero-posterior asymmetry (mm)	3.7 [3.3, 4.6]	3.3 [2.8, 4.0]	3.3 [2.6, 3.9]	4.2 [3.2, 5.1]	4.0 [3.6, 5.3]	4.8 [3.6, 5.7]
Statokinesigram (mm)	392.8 [348.1, 521.5]	372.5 [333.1, 446.2]	371.8 [332.3, 448.8]	456.3 [352.6, 550.5]	434.2 [377.1, 542.9]	440.2 [378.9, 573.6]
Eyes closed						
Medio-lateral asymmetry (mm)	2.2 (2.6)	1.9 (2.4)	2.0 (2.4)	2.4 (1.6)	2.1 (1.3)	2.5 (1.4)
Antero-posterior asymmetry (mm)	4.8 [3.7, 7.1]	4.6 [3.3, 5.7]	4.5 [3.7, 5.1]	5.5 [4.5, 6.3]	5.4 [4.7, 6.5]	5.6 [4.1, 6.7]
Statokinesigram (mm)	483.9 [397.6, 710.9] [b]	445.3 [396.1, 583.0]	432.9 [371.1, 500.8]	622.1 [402.5, 738.3]	590.6 [423.1, 732.3] [c]	601.6 [423.2, 725.7]

POMA: Performance Oriented Mobility Assessment; UPDRS: Unified Parkinson's Disease Rating Scale; SD: standard deviation; IQR: interquartile range (*i.e.* first-third quartiles). Quantiles are computed using the 7th algorithm defined by Hyndman and Fan.[36]
Data were reported as mean and SD. If the distribution of the difference in outcome values from baseline was skewed, then the median and IQR were reported instead of the mean.
P values are computed from repeated measures ANOVA or Friedman test as appropriate.
[a] T0 *vs.* T1; [b] T0 *vs.* T2; [c] T1 *vs.* T2.

TABLE IV.—*Between-groups (non-inferiority) comparisons in the difference of outcome values after treatment (T1) and follow-up (T2) compared to baseline (T0).*

Parameter	Difference (T1-T0)		P value	Difference (T2-T0)		P value
	Study group	Control group		Study group	Control group	
Clinical scales						
POMA balance	1.7±1.3	1.5±1.4	0.6196	1.4±1.8	0.8±1.5	0.1678
POMA gait	1.5±1.1	1.2±1.2	0.3548	1.3±1.2	0.7±1.3	0.0801
POMA total	3.2±1.9	2.7±2.3	0.3955	2.7±2.1	1.5±2.4	0.0484
UPDRS III	-7.7±4.6	-4.7±4.1	0.0175	-7.4±4.5	-4.0±4.8	0.0174
Gait analysis						
Right support phase duration (%)	-2.2±2.9	-1.7±4.8	0.6053	-0.8±3.3	-1.7±6.1	0.6428
Left support phase duration (%)	-1.3±4.1	-0.7±2.0	0.5034	-1.8±3.1	-0.5±2.5	0.0743
Double support phase duration (%)	-3.7±2.7	-1.6±2.8	0.0074	-2.5±3.0	-1.1±5.4	0.138
Cadence (step/min)	5.4 [-0.1, 15.0]	1.1 [-2.1, 4.3]	0.0076	4.5 [-1.3, 8.2]	2.0 [-0.9, 5.0]	0.093
Mean speed (m/s)	0.2 (0.1)	0.1 (0.1)	0.2905	0.1 (0.1)	0.1 (0.2)	0.266
Step length (cm)	12.5 (9.4)	10.9 (7.5)	0.5165*	10.7 (11.3)	8.4 (11.7)	0.3925*
Balance evaluation						
Eyes open						
Medio-lateral asymmetry (mm)	-0.1 [-0.6, 0.1]	-0.1 [-0.6, 0.1]	0.2481	0.0 [-0.4, 0.1]	-0.1 [-0.3, 0.2]	0.4725
Antero-posterior asymmetry (mm)	-0.4 [-1.7, 0.3]	0.0 [-0.6, 0.8]	0.1643	-0.2 [-1.1, 0.6]	0.0 [-0.4, 0.3]	0.3853
Statokinesigram (mm)	-22.4 [-65.1, 2.6]	-3.5 [-35.3, 26.1]	0.0969	-8.5 [-50.9, 6.3]	-16.6 [-64.8, 0.9]	0.8831
Eyes closed						
Medio-lateral asymmetry (mm)	-0.3 (0.8)	-0.3 (0.7)	0.9176	-0.1 (0.8)	-0.1 (0.8)	0.4439
Antero-posterior asymmetry (mm)	-0.2 [-0.7, 0.3]	-0.2 [-1.1, 0.6]	0.1775	-0.1 [-1.2, 0.3]	-0.4 [-1.0, 0.1]	0.9777
Statokinesigram (mm)	-33.3 [-72.7, -5.7]	-5.8 [-117.7, 34.6]	0.0318	-27.2 [-43.2, -4.1]	-37.6 [-89.0, -4.8]	0.3013

Data were reported as mean and SD. If the distribution of the difference in outcome values from baseline was skewed, then the median and IQR were reported instead of the mean.
P values are computed from a statistical contrast in least-square means derived from repeated measures ANOVA or Friedman test as appropriate.
*Statistically significant difference.

ferent gait parameters (reduction of double support phase duration, increased speed and step length) for the SG, both at T1 and at T2, compared to baseline; CG significantly improved speed and step length, both at T1 and at T2, compared to baseline (Table III). Balance evaluation showed a reduction of the asymmetry and of the CoP displacement for both groups at T1, in both visual conditions (EO/EC) without reaching statistical significance. For both groups, at T2 balance outcome measures were comparable to T0 and T1 in both EO/EC conditions; the only statistical significance was detected for the CoP sway length that was significantly lower at T1 compared to T2 for CG and at T0 vs T2 for the SG, in EC condition (Table III).

Between-groups (Non-inferiority) analysis

As shown in Table IV, there was no statistical evidence that the mean increase in stride length from T0 to T1 in the Q-Walk cueing system (12.5 cm) was superior than that in the traditional cues (10.9 cm) (P=0.517). However, having set a non-inferiority margin of -6.8 cm, the P value from one-sided t-test was 0.0153, thus rejecting the null hypothesis of inferiority of the Q-Walk cueing system over the traditional cues.

Satisfaction questionnaire

All subjects in the SG completed the satisfaction questionnaire relating to the use of the Q-Walk system. Almost everyone found the tool easy to use (92% score 2-3) and the training motivating (88% score 2-3). In addition, most patients felt that they could also use the instrument at home (77% score 2-3). Table V summarizes all the ratings at the questionnaire.

Discussion

Findings from this study showed that the use of the Q-walk visual cueing system associated with conventional physiotherapy was not inferior to the traditional visual cueing modalities in improving gait and balance in people with PD. These results are consistent with previous studies showing that, in PD, cueing paradigms represent a useful modality for gait and posture rehabilitation, by improving the amplitude and timing of the intended movement, likely through an increase in body position/movement awareness.[13, 37]

It is well known that gait disturbances in PD are suggestive for basal ganglia dysfunction. The basal ganglia regulate the automatic maintenance of the scale of movement (motor set) and the running of each component of the motor plan in a timely manner (internal cue production). In PD, the loss of dopamine in these areas invalidates the expression of automatic control, causing behaviors to remain goal-directed as the associative networks of the basal ganglia, involved in goal-directed control are relatively preserved.[38] Our results confirm that the use of visual cues, increasing attention to gait performances and providing visual-spatial data to compensate for the motor set deficiency, may improve rhythmicity (stride-to-stride variability), increase left/right swing synchronization and walking speed.

Previous studies have reported that PD patients can develop a significant asymmetry in the CoP velocity and frequency characteristics compared to healthy subjects, since the early stage of the disease.[39] In this regard, Q-Walk showed to be effective in improving postural stability, as revealed by the tendency to the reduction of the length of statokinesigram and by the reduction of asymmetry in postural displacement parameters along the mediolateral (M-L) and anteroposterior (A-P) directions.

Although the effectiveness of visual cues is widely demonstrated, cues that provide positional information such as visible markers on the floor have the evident limitation of needing special floors which prevents the use of this strategy in a real-life context. To overcome this problem,

TABLE V.—*Ratings for the Satisfaction Questionnaire.*

Item	Score			
	0	1	2	3
1. Have you noticed any changes in gait using the Q-Walk cueing system? *	1 (3.8%)	3 (11.5%)	17 (65.4%)	5 (19.3%)
2. Did you feel safer walking with the use of cues?	5 (19.3%)	2 (7.7%)	18 (69.2%)	1 (3.8%)
3. Was it easy to follow the cues?	0	2 (7.7%)	14 (53.8%)	10 (38.5%)
4. Have you noticed greater confidence in gait following the cues?	2 (7.7%)	3 (11.5%)	17 (65.4%)	4 (15.4%)
5. Was it easy to follow the instructions provided by the physiotherapist?	0	0	14 (53.8%)	12 (46.2%)
6. Do you think you could also carry out this type of treatment at home?	1 (3.8%)	5 (19.3%)	13 (50%)	7 (26.9%)
7. Was it motivating for you to perform gait training with cues?	0	3 (11.5%)	12 (46.2%)	11 (42.3%)

Score 0 = poor/no; 1 = average; 2 = good; 3 = excellent.
*One missing.

various solutions have been proposed, including devices such as a walking stick placed where the next step should be or a visual laser beam stick that projects a line in front of the patient's feet.[22, 40] Devices called 'walking glasses' have been experimented as well. These devices provide visual cues during walking by means of LEDs that generate a virtual image of a horizontal line on the floor below the patient's main field of view. Signal is triggered by foot pressure and can be combined with auditory clicks in order to provide simultaneous rhythmic cueing.[41, 42] A similar device, tested by Espay *et al.*[43] demonstrated the effectiveness in improving walking of a pair of virtual (augmented) reality goggles containing a built-in LCD screen, which projects floor tiles when subjects are moving, and earphones that sound step-matched cues as determined by connected sensor strapped at belt. The present study is in line with these studies and provides further support to such preliminary experiences showing the benefit of a wearable custom-designed cueing system that provides visual cues to favor and improve walking. A priceless advantage of wearable technologies when compared to visual cues fixed on the floor is represented by the possibility to easily transfer cues paradigms outside hospitals and rehabilitation centers to patients' daily life. The Q-Walk system did not interfere with gait, showing good applicability. Furthermore, it received the approval of PD subjects and resulted easily wearable, usable, light and transportable. In fact, although out-patients enrolled in the present study performed the training in a clinical setting, in our opinion the Q-Walk system, due to all the above-mentioned features might represent an excellent starting point for using the device at home and in daily activities, also with the aim to potentiate the long-lasting effects reported at T2.

These considerations are also supported by the results of the satisfaction questionnaire. In this regard, 92% of the subjects stated that the cues were easy to use (53.8% score 2, 38.5% score 3), and 100% affirmed that following the physiotherapist's instructions was easy (53.8% score 2, 42.6% score 3). Moreover 77% of the individuals stated that they believed that the Q-Walk system could also be used at their home (50% score 2, 26.9% score 3).

The bio-psycho-social model of ICF[44] emphasizes the role of social factors like a degree of independence, integration to society and participation of disabled people. In this respect, although significant increases in gait parameters and clinical scales after training are relevant results, the primary goal of motor rehabilitation is to increase everyday life mobility, possibly also leading to improved participation and QoL.[45] Furthermore, patients can request to transfer rehabilitation interventions from clinical setting to community. In this respect, it is well known that training in more familiar environments, such as home, improves the effects of training.[46] Therefore, devices that allow performing training tasks and delivery rehabilitative interventions at familiar locations are particularly useful, also to support personalized approaches.[47] The Q-Walk system was developed keeping in mind the importance of designing applications that will effectively be transferred and generalized to the real world in an individualized manner.

Moreover, devices involving patients in sustainable and engaging exercise options in meaningful life activities play a beneficial role improving mood and confidence in everyday functional activities. About this, in the present study, 80% of the subjects declared that they felt more confident when walking with the cueing system (65.4% score 2, 15.4% score 3), and 88% of them found the use of the device motivating (46.2% score 2, 42.3% score 3).

Limitations of the study

Some limitations for this study must be mentioned. First, the small sample size that might have determined a limited statistical power and did not permit performing subgroup analysis (for example, to explore the impact of disease severity or the effect of cueing in relation to the type of dominant symptoms). Second, the intervention and the follow-up evaluations were delivered over a relatively short time frame. Finally, our sample included relatively high-functioning subjects with Parkinson's disease, therefore the findings cannot be generalized to people with advanced stages of the disease. However, starting from the encouraging results of this work, future studies on larger populations and longer follow-up will allow us to investigate these issues, clarifying the most suitable rehabilitative applications of the tool.

Despite physical activity and exercises represent important components of clinical management of chronic illness, particularly for the elderly who suffer from neurodegenerative disorders such as PD, the limited healthcare resources can hamper the continuity of care during the chronic stage. A new generation of wearable and not expensive technology can act as an additional rehabilitation strategy for long-term and continuous care, allowing patients to train intensively and extensively in household settings, while ensuring at the same time the treatment's quality, effectiveness and safety. The implementation of such system will nicely complement the remote management of PD (telerehabilitation).

By this way, the system could be used for programming exercises to be carried out at home with a tailor-made, personalized approach and for remote monitoring.

Conclusions

In conclusion, the Q-Walk visual cueing system associated with conventional physiotherapy resulted to be not inferior to the traditional visual cueing modalities in improving gait and balance of PD subjects. Q-Walk was simple and easy to use and patients' level of satisfaction was good. This new rehabilitative wearable device might be a promising tool for home rehabilitative intervention and extensive treatment in subjects with PD.

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Conflicts of interest

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Authors' contributions

Michelangelo Bartolo conceived and managed the study, interpreted data and wrote the paper. Alberto Castelli conceived the study, performed the enrollment and data acquisition. Marzia Calabrese and Gianpiero Buttacchio performed the enrollment and data acquisition. Chiara Zucchella interpreted data, wrote the paper. Stefano Tamburin reviewed the final draft of the paper. Andrea Fontana and Massimiliano Copetti performed data analysis. Alfonso Fasano reviewed the final draft of the paper. Domenico Intiso interpreted data, wrote the paper. All authors read and approved the final version of the manuscript.

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