

Outcome Evaluation of Highly Challenging Balance Training for People With Parkinson Disease: A Multicenter Effectiveness-Implementation Study

Breifni Leavy, PT, PhD, Conran Joseph, PT, PhD, Niklas Löfgren, PT, PhD, Hanna Johansson, PT, MSc, Maria Hagströmer, PT, PhD, and Erika Franzén, PT, PhD

Background and Purpose: In order for people with Parkinson disease (PwPD) to benefit from neurorehabilitation research, interventions tested in research settings require assessment in real-world clinical practice. There is little evidence for whether efficacious exercise interventions for PwPD remain effective when transferred to standard clinical settings. The aim of this study was to assess the clinical effectiveness of the adapted HiBalance program on balance control and gait among PwPD.

Methods: Participants ($n = 117$) with mild-moderate Parkinson disease were consecutively included into either the 10-week HiBalance group training ($n = 61$) or the control ($n = 56$) group. The main outcome was balance performance (Mini-BESTest). Secondary outcomes were comfortable gait speed (10-m Walk Test); functional mobility (Timed Up and Go [TUG] test) and dual-task interference (cognitive TUG test); physical activity level (steps per day); perceived balance confidence (Activities-specific Balance Confidence scale) and perceived walking difficulty (Walk-12G) and self-rated health (EQ-5D visual analog scale).

Results: In total, 98 people completed the trial. Compared with controls, the training group showed significant improvement in balance performance ($P < 0.001$), gait speed ($P = 0.001$), and dual-task interference ($P = 0.04$) following the intervention. No group differences were observed for physical activity level or any patient-reported measures.

Discussion and Conclusions: Highly challenging balance training is effective at improving balance, gait, and dual-task performance when delivered at a clinically feasible dose, in a range of rehabilitation settings, without direct involvement of the research group.

Video Abstract available for more insights from the authors (see the Video, Supplementary Digital Content 1, available at: <http://links.lww.com/JNPT/A299>).

Key words: *balance control, dual-task, effectiveness, exercise, clinical translation*

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INTRODUCTION

Parkinson disease (PD) is a highly disabling condition, involving motor and nonmotor symptoms, which culminate in balance and gait impairments and reduced quality of life. It is therefore important that people with PD (PwPD) can avail of specialized rehabilitation, which is in line with current best evidence. Evidence for the efficacy of exercise interventions on balance control and gait in PD is compelling.^{1–3} Systematic reviews report that facility-based balance training in particular provides the longest carryover effects.^{1,4} Additionally, studies investigating explanatory mechanisms for improved motor symptoms report positive trends in exercise-induced brain plasticity.^{5,6} For PwPD to benefit from neurorehabilitation research, the findings from randomized controlled settings require assessment in real-world clinical practice among typical patients and resources. To date, there is little evidence for whether the effects of efficacious exercise interventions for PwPD are maintained when transferred to clinical practice.

Efficacy trials are the gold standard for establishing the internal validity of an intervention by using selected populations under optimal conditions.⁷ The next step is to perform a clinical effectiveness trial to test whether effects are attenuated in less selective populations, under less controlled conditions, and without the direct involvement of program developers.⁸ The hybrid study design was proposed by Curran et al⁹ as a

Division of Physiotherapy, Department of Neurobiology, Care Sciences and Society, Karolinska Institutet, Huddinge, Sweden (B.L., C.J., N.L., H.J., M.H., E.F.); Stockholms Sjukhem Foundation, Stockholm, Sweden (B.L., E.F.); Department of Physiotherapy, University of the Western Cape, South Africa (C.J.); Function Area Occupational Therapy and Physiotherapy, Allied Health Professionals Function, Karolinska University Hospital, Stockholm, Sweden (N.L., M.H., E.F.); and Department of Health Promoting Science, Sophiahemmet University, Stockholm, Sweden (M.H.).

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Correspondence: Breifni Leavy, PT, PhD, Department of Neurobiology, Care Sciences and Society, Karolinska Institutet, Alfred Nobels Allé 23, 141 83 Huddinge, Sweden (breifni.leavy@ki.se).

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means to merge design features of clinical effectiveness and implementation research. The intended advantages of such a design are to facilitate more rapid translation from research to practice, and to inform the planning of more effective implementation strategies. Three types of hybrid designs are outlined—the Hybrid Type I is suitable for testing a clinical intervention with an “add-on” secondary evaluation of the process of program implementation (process evaluation).

We have previously shown beneficial effects of highly challenging group-based balance training (the HiBalance program) on balance and gait in mild-moderate PD.¹⁰ A hybrid implementation-effectiveness study of the HiBalance program was planned to assess program clinical effectiveness (outcome evaluation) as well examine contextual factors that either facilitate or hinder program uptake (process evaluation).¹¹ In line with implementation best practice, we adapted program aspects by replacing laboratory-based outcome assessments with clinical ones and by reducing the treatment dose from 30 × 1-hour group sessions to 20 × 1-hour group sessions in greater alignment with the reimbursement policy within Swedish outpatient rehabilitation, adaptations that are previously described.¹²

The aim of this article was to assess the effectiveness of the adapted HiBalance program in PwPD in a range of real-life clinical settings. A separate process evaluation has been conducted to examine multiple aspects of program delivery, which will inform future strategies for program implementation. Our primary hypothesis was that when delivered as a part of standard clinical care, the adapted HiBalance program would elicit positive effects on balance, gait, and physical activity level, and that effects would be attenuated from those observed during the efficacy trial stage. Our secondary hypothesis was that the intervention would positively affect patient-reported measures of walking ability and balance confidence.

METHODS

Rehabilitation Sites

Seven rehabilitation clinics of varying nature and geographical location were approached by the research group, regarding participation in the trial. Six clinics agreed to participate and were consecutively included. Two clinics commenced the training in spring of 2016 (a university hospital outpatient clinic and a primary care department of a nonprofit private hospital). A neurological rehabilitation clinic and a geriatric rehabilitation hospital, which had not previously held Parkinson-specific balance training groups, joined the trial in autumn 2016 and spring 2017, respectively. Two further primary care health centers with experience of PD rehabilitation assessed control participants only.

Physical therapist trainers had an average age 42 years and experience within neurology ranged from 2 to 18 years. Program training consisted of 2 half-day sessions covering aspects including theory of balance and gait impairments in PD, theory and practical training of the HiBalance program, and procedures for assessing and recording study outcome measures. Each clinic received a standardized program of reference materials concerning (i) theory and practice concerning the training program and (ii) outcome assessment procedures

and documentation. Trainers were advised to follow the general 10-week scheme outlining the nature and combination of balance components and dual-task components. Nonetheless, trainers were encouraged to develop their own exercises and adapt program delivery to best suit their respective facilities. Trainers were advised to contact the research team by phone or mail if problems arose in relation to training sessions or data collection methods. Apart from supplying and collecting materials relating to data collection, the research group did not play a part in program delivery at the clinics throughout the course of the trial.

Participants

Recruitment occurred through standard processes of referral within the clinics as well as advertisements in local newspapers. In Sweden, people have direct access to services provided by physical therapists, without the need for physician referral. All subjects had been diagnosed with idiopathic PD by a neurologist and were stable in their anti-PD medications. Phone interviews were conducted by clinicians to determine that participants (a) had perceived balance difficulty, (b) were ambulatory indoors without a walking aid, (c) had not been diagnosed with atypical Parkinsonism or other existing neurological/orthopedic conditions affecting balance, (d) could follow verbal instructions and had not been diagnosed with dementia, and (e) had not participated in a structured exercise program in the previous 6 months. Those at Hoehn and Yahr (H & Y) stages 2 and 3 were included.

All participants received verbal and written information and provided signed consent prior to inclusion. We attained ethical approval to increase the number of participants from 45 per group, outlined in our a priori power calculation,¹¹ by up to a maximum of 20 people in each group. This was due to a greater variance in balance performance and higher drop-out rates in the initial stages of the study than those observed in our pilot study.¹² The study was approved by the Ethical Review Board in Stockholm. The trial was registered on Clinicaltrials.gov, nr. NCT02727478.

Study Design

This study is the outcome evaluation of a nonrandomized clinical effectiveness trial, which had an effectiveness-implementation hybrid design type I⁹ (see study protocol¹¹). Use of the Hybrid Type I was advocated in the current study, as there is evidence for applicability of the HiBalance program in the planned setting, thus enabling the current effectiveness-implementation study to serve as a transition to future implementation studies.⁹ Nonrandomization was a design trade-off to enable clinics to commence and complete training groups during specific periods (spring and autumn) feasible within existing clinical practice. Participants were consecutively allocated by clinicians to fill firstly the training groups and then the control groups during each period.

Procedure for Testing and Training

Recruitment and training occurred during the period from spring 2016 to spring 2018. All participants were assessed by a physical therapist in the clinics during the “On” medication cycle 1 to 2 hours after taking their anti-Parkinson

medication. Participants in the training group were assessed 1 week prior to and 1 week following completion of the 10-week program. Physical therapist assessors and trainers were not blinded to group allocation. During the initial assessment, data were collected regarding, height, weight, and levodopa dosage. The Trail Making Test-B (TMT-B) was used to assess executive function/cognitive flexibility in shifting attention between 2 competing tasks at baseline.

Outcome Measures

The primary outcome measure was the Mini-Balance Evaluation Systems Test (Mini-BESTest) score, which consists of 14 items divided into 4 subdomains. Each item is scored from 0 to 2, maximum score is 28 points.¹³ The test is reliable and valid for use in PD, H & Y stages 2 and 3.¹⁴ Secondary outcome measures included: comfortable gait speed (10-m Walk Test); single- and cognitive dual-task functional mobility (Timed Up and Go [TUG] and cognitive TUG [TUG COG] test); physical activity level (steps per day); patient-reported balance confidence (Activities-specific Balance Confidence [ABC] scale) and walking difficulties (Generic Walking Scale [Walk-12G]); and self-rated health (EuroQol EQ-5D-3L).¹⁵

The 10-m Walk Test is a clinically feasible short-distance walking test, which is reliable and valid for use in mild-moderate PD.¹⁶ Participants were instructed to walk at their “normal, comfortable speed” over a 14-m distance, where the middle 10 m was timed to account for acceleration and deceleration. The average score of 3 tests was analyzed. The TUG test measures performance of a sequential locomotor task (rising from a chair, walking 3 m, turning and walking back to the chair), is reliable for PD, and can detect differences in performance.¹⁷ The TUG COG test involves performance of the TUG test while sequentially subtracting the number 3 from a start number. The time difference between the TUG and the TUG COG reflects dual-task interference during functional mobility.¹⁸ Dual-task interference can be used as a clinical measure of gait automaticity and can be expressed as a percentage: $TUG\ COG - TUG/TUG$.¹⁹ To assess steps per day, participants wore a waist-worn accelerometer (Actigraph GT3X+, Pensacola, Florida) during 7 consecutive days on 2 occasions—1 week prior to and following the 10-week intervention period. The Actigraph accelerometer records time-varying changes in acceleration in 3 planes of the axis, and data thresholds have been validated using criterion measures compared with total energy expenditure.²⁰ Data from at least 4 and at most 7 days were included, and when wear time was less than 540 minutes/day, data were excluded from the analysis according to recommendations.²¹ The Walk-12G is a patient-reported measure of perceived walking difficulties during 12 everyday activities and is reliable for use in PwPD.²² Balance confidence is a construct measuring fall-related self-efficacy during 16 activities and total ABC score is expressed as percentage of balance confidence. The psychometric properties have been shown satisfactory among PwPD.²³ The EQ-5D-3L measures self-reported health, is simple to use, designed for self-completion.¹⁵ The EQ vertical visual analog scale (EQ VAS) ranges from 0 to 100 (0 = worst health imaginable, 100 = best health imaginable) and was in clinical use at several of the participating clinics.

Balance Training Intervention

The HiBalance program is based on scientific principles of exercise training and postural control as well as research on exercise in PD and has been previously described.^{11,24} In brief, the program targets 4 main subsystems of balance control (stability limits, anticipatory postural adjustments, sensory integration, and motor agility) affected among PwPD, using principles of motor learning (ie, specificity, progressive overload, and variation) (see SDC Table 1, Supplementary Digital Content 2, available at: <http://links.lww.com/JNPT/A300>). The program also incorporates gradual integration of dual-task exercises, involving cognitive or motor tasks. To ensure highly challenging exercises, each task was individually adjusted by, for example, altering the base of support, increasing movement speed/amplitude, restricting vision, or varying the grade of multitasking and the difficulty level. The training is a group intervention (6-8 PwPD) performed for 1 hour, twice/week for 10 weeks, facilitated by 2 trained physical therapists. Progression of difficulty level occurred during 3 consecutive blocks A to C (see SDC Table 1, Supplementary Digital Content 2, available at: <http://links.lww.com/JNPT/A300>). The first 2 weeks (block A) focused on skills acquisition and quality of the exercises, which target each balance subsystem separately. In block B, dual-task exercises were introduced and alternated on a weekly basis (eg, motor dual-task during week 3 and cognitive dual-task during week 4). In block C, trainers chose freely between which balance components to combine, as well as the nature and timing of dual-task components. Additionally, participants were advised to perform an unsupervised 1-hour home exercise program focusing on aerobic capacity and strengthening of lower extremity/core muscles once a week. Control subjects were encouraged to continue to participate in their usual level of daily physical activity during the 10-week period, but were advised against commencing any new exercise programs during this period.

Statistical Analyses

Descriptive statistics were generated for all outcomes to test distributional assumptions. Homogeneity of the control and training groups at baseline was tested using Student's *t* test for continuous data and χ^2 test for categorical data. Significant group differences for gait speed ($P = 0.04$) and TMT-B ($P = 0.01$) were observed at baseline. Multiple linear regressions were performed using baseline gait speed and TMT-B as predictor variables for all outcomes. Whereas gait speed was a poor predictor of all outcomes, TMT-B appeared to predict change in Walk-12G scores alone and was therefore entered in the repeated analysis of variance (ANOVA) model as a covariate. A 2-factor repeated ANOVA was performed with time (pre- and post-) as the within-subject factor and group (training and control) as the between-subject factor. The repeated ANOVA was performed on complete cases. When interaction was found, post hoc tests were performed to establish the simple main effects.

A sensitivity analysis was performed to test for potential bias in the estimates of the complete case analysis. We first explored the missingness mechanism in the data by comparing subjects with complete and missing Mini-BESTest scores at posttesting using multinomial logistic regression. Whereas

missing data were unrelated to the baseline characteristics, age, sex, disease duration, group allocation, clinic or body mass index, missing data appeared related to TUG score. To test the robustness of the findings of the significant interactions from the ANOVA, chain equations of multiple imputation were used to obtain 10 imputed data sets that model missing data.

For nonnormally distributed data, Mann-Whitney U tests were performed to establish whether there was a between-group difference. The Wilcoxon signed rank test examined within-group difference between pre- and posttraining assessments. Effect size measures between the groups were calculated for normally distributed outcomes according to Cohen's d calculation²⁵ and as $r = Z/\sqrt{n}$ for nonnormally distributed data. Statistical analyses were performed using STATA, version 15.1 (StataCorp, College Station, Texas), while sensitivity analysis was performed in SAS/STAT 12.1.

RESULTS

Participant Characteristics

One hundred and seventeen participants were recruited and consecutively allocated into either the training ($n = 61$) or control group ($n = 56$) (Figure). The groups did not differ at baseline in relation to demographic, disease-related motor severity, or levodopa-equivalent dose (Table 1). However, significant baseline group differences were observed for gait speed ($P = 0.04$) and executive function ($P = 0.01$) (Table 1). Ten subjects in the control group and 8 subjects in the training group dropped out during the intervention period (Figure), resulting in a total attrition rate of 15.4%. The average compliance to the group training sessions was 84%, 12 adverse events occurred during the supervised training sessions, all of which were noninjurious falls.

Performance-Based Balance, Gait, and Physical Activity Outcomes

When compared with the control group at the 10-week follow-up, the training group had significantly improved their balance (Mini-BESTest score $F(1, 96) = 21.93, P < 0.001$; Table 2). This change represented an improvement over time in the training group of 2 points, which when expressed as a standardized mean difference represents a large effect size ($d = 1$). Analysis of effects on Mini-BESTest subdomains showed that improvements in balance were accounted for by improvements in *anticipatory postural adjustments* ($P = 0.005$) and *dynamic gait* ($P = 0.024$). Gait speed improved significantly in the training group $F(1, 94) = 11.25, P = 0.001$, representing an increase of 0.05 m/s. Although no between-group difference in functional mobility (TUG score) was observed at posttesting, the training group reduced their cognitive dual-task interference by 9% of baseline value. When expressed as a standardized mean difference, this change is considered small ($r = 0.11$). Results from the sensitivity analysis regarding the observed improvements in balance and gait speed indicated robust interaction effects, with significance in all 10 imputed datasets (see SDC Table 2, Supplementary Digital Content 3, available at: <http://links.lww.com/JNPT/A301>).

No improvements in physical activity level (average steps per day) were observed among the training group following the intervention (Table 2).

Patient-Reported Outcomes

When baseline differences in executive function were accounted for in the analysis, no significant improvement in perceived walking difficulty (Walk-12G) was seen (Table 2). This suggests that change in Walk-12G scores in the training group (Table 2) was influenced by baseline TMT-B. No improvement was observed in relation to balance confidence (ABC scale) or self-reported health status (EQ VAS).

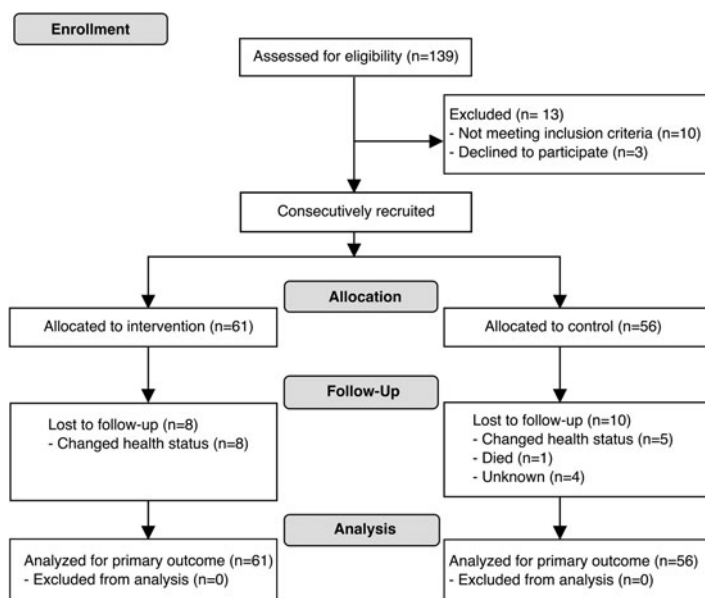


Figure. Consort flow diagram showing the course of the study.

Table 1. Demographic and Clinical Characteristics of Study Participants at Baseline^a

Characteristics	Training (n = 61)	Total	Control (n = 56)	Total
<i>Demographic measures</i>				
Sex, female, n (%)	33 (54)		22 (39)	
Age, y	70 (8.5) (45-87)	61	70 (6.5) (54-83)	54
Body mass index, kg/m ²	24.1 (3.7)	58	24.2 (3.1)	49
Years with PD	6.6 (5.1)	61	8 (5.8)	55
Hoehn and Yahr ^b (0-5), n (%)		61		56
2	28 (45.9)		20 (35.7)	
3	33 (54.1)		36 (64.3)	
<i>Clinical measures</i>				
Mini-BESTest ^c (0-28)	20.6 (3.2)	61	21.4 (4.2)	56
TUG test, s ^d	10.2 (9, 12.1)	61	10 (9, 12.3)	56
Cognitive TUG test, s ^d	14.9 (11.5, 20.2)	53	14 (11.6, 22)	55
Normal gait speed, m/s ^e	1.2 (0.19)	60	1.3 (0.22)	56
Trail Making Test-B, s ^{e,f}	122 (83, 204)	46	83 (65, 173)	43
Mean steps per day	4819 (2453)	53	5033 (2640)	48
<i>Patient-reported measures</i>				
ABC scale (0-100)	68 (16.9)	60	70 (18.2)	47
Walk-12G score (0-46) ^{e,g}	15.5 (7.5)	58	12 (7.3)	48
EQ VAS (0-100) ^h	69 (50, 75)	59	70 (62.5, 80)	48
People who fell in the past year, n (%)	34 (55)	61	27 (48)	56
Levodopa-equivalent dosage, mg	613 (318)	46	549 (252)	44

Abbreviations: ABC, Activities-specific Balance Confidence scale; EQ VAS, EuroQol visual analog scale; Mini-BESTest, Mini-Balance Evaluation Systems Test; PD, Parkinson disease; TUG, Timed Up and Go; Walk-12G, Generic Walking Scale.

^aMean (standard deviation), unless otherwise stated.

^bStages 1 to 5 of disease progression (1 = minimal disability, 5 = confined to bed/wheelchair).

^cMini-Balance Evaluation Systems test, 0 to 28 (higher score = better balance).

^dMedian (first quartile, third quartile).

^eSignificantly different at baseline gait speed ($P = 0.037$); Trail Making Test ($P = 0.05$), and Walk-12 ($P = 0.023$).

^fScore range = 0 to 300 seconds, higher score = greater difficulty.

^gHigher score = greater perceived walking difficulty.

^hEQ-5D visual analog scale (0 = worst health imaginable, 100 = best health imaginable).

DISCUSSION

This study investigated whether highly challenging balance training is clinically effective when delivered to PwPD, in a variety of clinical settings as a part of standard rehabilitative practice. Our choice of pragmatic clinical design is essential in

establishing the ecological validity of interventions previously proven efficacious. Our findings demonstrate significant improvements in balance control, gait speed, and motor-cognitive dual-task performance when the program was adapted to clinical practice and delivered at a dose feasible within Swedish

Table 2. Comparison of Between-Group Differences of Changes From Baseline for Primary and Secondary Outcomes

Outcome	Change Training		Change Control		Interaction Effect, P	Effect Size, d^a Effect Size
	Mean \pm SD	95% CI	Mean \pm SD	95% CI		
Mini-BESTest total score (0-28)	2.0 \pm 2.0	1.35, 2.57	-0.2 \pm 2.4	-0.82, 0.51	<0.001	1
Anticipatory postural adjustments	0.42 \pm 1.0	0.12, 0.70	-0.2 \pm 1.1	0.52, 0.12	0.005	0.57
Postural responses	-0.02 \pm 1.4	-0.41, 0.37	-0.26 \pm 1.5	-0.69, 0.16	0.398	0.18
Sensory orientation	0.25 \pm 1.2	-0.06, 0.55	-0.15 \pm 1.0	-0.48, 0.17	0.079	0.36
Dynamic gait	0.74 \pm 1.9	0.22, 1.26	-0.15 \pm 1.9	-0.73, 0.42	0.024	0.46
Gait speed, m/s	0.20 \pm 0.41	0.02, 0.11	-0.04 \pm 0.14	-0.73, 0.42	0.001	0.87
Balance confidence (0-100)	0.36 \pm 17.7	-4.38, 5.10	-4.0 \pm 15.5	-8.44, 1.84	0.301	0.26
Perceived walking difficulty (0-36)	2.57 \pm 6.78	-3.25, -0.15	1.72 \pm 8.38	-0.82, 2.42	0.887	0.03
Steps per day	-288 \pm 1428	-813, 236	-390 \pm 2016	-948, 167	0.792	0.06
		Median (Q1, Q3)			Mann-Whitney U, P (Z)^a	Effect size, r^b
TUG, s		-0.4 (-1.3, 0.5)		0 (-1.06, 1.2)	0.254 (1.14)	0.11
Dual-task interference, % ^c		-1.22 (-6.2, 0.66)		1.05 (-3.07, 3.51)	0.039 (2.06)	0.22
Self-reported health (0-100) ^d		5.5 (-5, 15)		0 (-10, 5)	0.065 (-1.84)	0.20

Abbreviations: CI, confidence interval; Q1, first quartile; Q3, third quartile; Mini-BESTest, Mini-Balance Evaluation Systems Test; SD, standard deviation; TUG, Timed Up and Go.

^aAccording to Cohen's d calculation (intervals: 0.2-0.3, small effect; 0.5-0.7, intermediate effect; ≤ 0.8 , large effect).²⁵

^b $r = Z/\sqrt{n}$ (intervals: 0.1-0.3, small effect; 0.3-0.5, intermediate effect; ≤ 0.5 , large effect).

^cCalculated as: cognitive TUG test time - TUG test time/TUG test time.

^dEQ-5D visual analog scale (0 = worst health imaginable, 100 = best health imaginable).

outpatient rehabilitation. No improvements in patient-reported outcome measures were observed.

In accordance with our hypothesis, we observed a 2-point average increase in the Mini-BESTest in the current study, for increase in balance previously reported in the efficacy trial of the HiBalance program.¹⁰ The average increase in balance performance exceeded the level of measurement error at group level previously reported for the Mini-BESTest.²⁶ Improvements in the Mini-BESTest subdomains *anticipatory postural adjustments* and *dynamic gait* may be explained by the specific structure of the HiBalance program in relation to targeting these balance subdomains (see SDC Table 1, Supplementary Digital Content 2, available at: <http://links.lww.com/JNPT/A300>). Nonimprovement in *sensory integration* aligns with our previous observations, and is plausibly explained by a ceiling effect of this domain whereby 48% of participants achieved the maximal score at posttesting. Unlike the aforementioned balance subdomains, *postural responses* were not specifically trained in the HiBalance program. Although program trainers were instructed to observe for the occurrence of balance reactions as an indicator for achieving a high level of balance challenge, consistently eliciting balance reactions in a group context among participants with differing balance capacity may not always be feasible and is rarely reported in the literature.²⁷ Our results show that 42% of people in the training group increased their Mini-BESTest scores by a minimum of 3 points, which exceeds the individual-level minimal detectable change reported for this test.

The observed increase in gait speed is in accordance with mean change in gait speed reported by a previous meta-analysis.²⁸ An improvement of 0.05 m/s is small and borders the small important clinical difference (0.06 m/s) for PwPD reported by Hass et al.²⁹ Gait speed not only is a strong predictor of health and mortality in the general elderly population but also reflects limitations in activities of daily living in PwPD.³⁰ Additionally, considering that gait speeds less than 1.1 m/s are predictive of falls in PwPD,^{31,32} the potential to modify fall risk by increasing gait speed is an especially relevant clinical goal of such exercise interventions.³³

We observed a significant reduction in dual-task interference while performing the cognitive task during the functional mobility (TUG) test. This finding is somewhat in contrast to the results from the HiBalance efficacy trial where the training group improved performance of the cognitive task, but did not significantly improve dual-task gait speed in comparison to controls.³⁴ Although reduction in dual-task interference in this study was small, this finding provides preliminary evidence that dual-task performance can be improved when delivered to a more heterogeneous group of patients in the clinical context.¹⁰ Improving the capacity to perform tasks during chair-rising, walking, and turning is especially relevant due to PD-related impairments in turning,³⁵ as well as the high exposure to performing these tasks.³⁶ This gain in dual-task performance could be partly attributed to increased postural stability of the training group, or improved attentional or executive processes through progressive motor-cognitive training in a group context. Although our sole use of clinical (TUG COG) as opposed to laboratory (instrumented walkway systems) testing procedures prevents us from determining

whether dual-task performance was improved through changes in task-prioritization of cognitive processes or gait performance, our results are promising for how dual-task capacity can be improved in everyday rehabilitation settings.

When baseline differences in executive function were controlled for, no improvement in reported walking difficulties were observed. Walking ability is perceived by PwPD as a primary concern in terms of treatment, but also as the motor symptom which PwPD consider least likely to improve through treatment.³⁷ Perceived walking ability is not solely a reflection of walking capacity,³⁸ but influenced by behavioral factors such as self-efficacy and fear of falling³⁹—constructs not specifically targeted by the HiBalance program. Our strategy to not base inclusion on cognitive cut-off points may also have introduced bias to the estimates in relation to patient-reported measures. However, this less restrictive approach likely resulted in more representative sample of PwPD and strengthens the ecological validity of our findings. Additionally, we have recently reported that PwPD with lower cognitive performance appear to have a greater likelihood for improvement from this balance training program.⁴⁰

In contrast to our hypothesis, we found no between-group differences in balance confidence. It is possible that a program wherein balance challenge is progressed over 10 weeks and integrated with dual-task components, as opposed to a program involving more repetitive tasks, inhibits building confidence in perceived balance. The literature concerning the effects of training on balance confidence is conflicting, with reports of no changes^{27,28} and small improvements.⁴¹⁻⁴³ Nonetheless, in light of our findings, it appears that the HiBalance program requires an additional component to positively affect balance perceptions in PD. One possible suggestion for strengthening balance confidence could be to add a reward-based feedback component to the training to increase participants' self-efficacy.⁴¹

Limitations

This study has several limitations. Our allocation of subjects to the groups was not randomized and allocation to the groups was not concealed, which increases the risk of selection bias. This design trade-off was a result of insufficient numbers of participants at study onset to enable randomization without delaying the commencement of cost-effective group training in line with existing clinical schedules. However, we accounted for the observed baseline differences in the statistical analysis. Neither trainers nor assessors in the current study were blinded to group allocation, which increases the potential for detection bias. The passive nature of the control group also increases the risk of bias and the inability to evaluate the effects of socialization alone on test results. Additionally, testing did not include a follow-up assessment, and a long-term analysis of the efficacy phase of the HiBalance program has however been published.⁴⁴

CONCLUSIONS

This study provides preliminary evidence for the clinical effectiveness of highly challenging balance training in improving balance control and gait speed when delivered to people with mild-moderate PD in everyday clinical settings. A major

strength of this study is its ability to demonstrate the ecological validity of highly challenging balance training when delivered in multiple clinical setting as a part of standard rehabilitation. Additionally, the sample size was relatively large and consisted of a less restrictive sample of PwPD. We also consider a drop-out rate of 13% in the training group to be representative of routine clinical practice among heterogeneous groups of PwPD. Lastly, training was planned and delivered by clinicians without direct involvement of the research team. Future analysis of the process of program implementation will provide information concerning the quality and quantity of what was delivered, which will, in turn, inform further refinement of the program. These insights will inform strategies, which enable the maximum uptake of evidence-based training programs for PwPD on a wider scale.

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