

In-Patient Multidisciplinary Rehabilitation for Parkinson's Disease: A Randomized Controlled Trial

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Parkinson's disease (PD) is a neurodegenerative disorder characterized by motor impairments such as resting tremor, rigidity, bradykinesia, postural instability, and gait disturbances.¹ Patients also may experience nonmotor symptoms, including neuropsychological (eg,

anxiety, depression, and cognitive decline), autonomic, and sensory problems.² Both motor and nonmotor disorders cause disability, reduce the quality of life (QoL), and prevent participation in domestic and social activities.²

Therapy of PD is based on treatment with dopaminergic medication to minimize motor symptoms. Pharmacotherapy presents limits, because it is incapable of alleviating all motor symptoms; few nonmotor symptoms are responsive to drug treatment, and its long-term use is complicated by the development of dose-limiting response fluctuations, including disabling dyskinesias.^{1,2} Despite optimal pharmacological treatment, as PD advances, motor symptoms worsen and, coupled with non-levodopa (L-dopa), responsive problems such as cognitive-behavioral disorders may become the dominating features of the disease.³

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A recent review showed several approaches employed in subjects with PD, including physiotherapy, exercise, treadmill training, cueing, and dance, but could not find differences in treatment effects, leaving a gap for evidence-based practice.⁴ Multidisciplinary programs combining pharmacological and nonpharmacological rehabilitative treatments have been increasingly shown to offer better control of PD than pharmacotherapy alone.^{5,6} However, evidence on their effectiveness is still limited.⁷⁻⁹ Nonrandomized controlled studies reported benefits on functional performances, transfers, walking abilities, mood disorders, and QoL.¹⁰⁻¹³ Randomized controlled trials reported benefits on functional status, activities of daily living (ADL), mood disorders, and QoL after the intervention, but long-term effects were not evaluated.¹⁴⁻¹⁶ Conversely, a recent large-scale nonrandomized study showed that an integrated care approach offered only small benefits, which disappeared after correction for baseline disease severity.¹⁷ Among these studies, only that conducted in an inpatient setting achieved a clinically significant improvement of functional status.¹² However, this study was performed through a nonrandomized design and did not include long-term assessment.

Based on these premises, our hypothesis was that subjects with long-duration PD experiencing more complex symptoms (eg, decline in function, frequent falls, and so forth) reduced motor impairment after participation in an inpatient multidisciplinary rehabilitative program of task-oriented exercises, cognitive-behavioral training, and occupational therapy. We expected that the observed improvements were clinically significant, maintained over the long term, and superior to those induced by general physiotherapy. To demonstrate these hypotheses, we conducted a randomized controlled study comparing the experimental program with general physiotherapy, both in addition to an unchanged pharmacological treatment.

Methods

Design

This randomized, controlled, parallel-group study was conducted at the Salvatore Maugeri Foundation Rehabilitation Center in Lissone.

Participants were randomized using a permuted-block randomization procedure. The list of treatment codes was previously generated in Matlab, and an automatic assignment system, also developed in Matlab, was used to conceal the allocation. The principal investigator performing the assessments and the biostatistician making the analyses were blinded to treatment allocation; care providers and patients could not be blinded.

The study was approved by the Institutional Review Board and conducted in conformity with ethical and humane principles of research.

Participants

To be eligible, patients had to have a diagnosis of idiopathic PD (modified Hoehn & Yahr scale, 2.5-4), a decline in function assessed by a psychiatrist (eg, worsening of transfers and walking ability, frequent falls, risk of losing their independence), an age of older than 50 y, a disease duration of longer than 10 y, and stable drug usage for more than 15 d before recruitment without unpredictable and long-lasting “off” periods. The exclusion criteria were dementia (Mini-Mental State Examination <24), other neurological diseases, systemic illness, psychiatric deficits, invasive drug treatments (eg, apomorphine infusion, intraduodenal L-dopa), and surgical interventions for PD (eg, deep brain stimulation, thalamotomy).

Inpatients consecutively attending the center were evaluated by two psychiatrists, and those who satisfied the entry criteria were asked to declare their willingness to comply with whichever treatment option they were randomly assigned. Those who agreed were asked to give their written informed consent.

To limit expectation bias and reduce the risk of crossover, patients were blinded to the study hypothesis by telling them that the trial was intended to compare two common approaches whose efficacy had not yet been established.

Interventional Programs

Two psychiatrists, a psychologist, an occupational therapist (OT), and four physiotherapists were involved.

Experimental Group

This program included motor training, cognitive training, and ergonomic education (Appendix). Motor training, performed by physiotherapists, involved task-oriented exercises, transfers, balance, and gait training. Task-oriented exercises were targeted at improvements in mobility and strength and involved exercises such as ascending/descending stairs, climbing obstacles, and acquiring the most important functional strategies for ADL. Transfers training was based on moving from sitting to standing position, and turning on a couch, implementing strategies such as movements’ breakdown into subcomponents to improve performance. Balance training included exercises such as turning, sudden starts and stops, standing on an unstable surface, and walking while changing speed and direction. Gait training was performed in association with different cue strategies so as to manage freezing; a treadmill training was performed to improve gait parameters and aerobic and resistance capacity.

The cognitive training, performed by the psychologist, included specific exercises devoted to attention/working memory, psychomotor speed, executive functions, visuo-spatial abilities, and calculation skills. Patients were educated to view PD as something that can be self-managed rather than a serious disease that may inevitably influence their life. They were helped to increase their level of activity by graded exposure to exercises and to common ADLs and by communication aimed at sharing the goals to be reached. Additional components regarding communication and interpersonal relationships in relation to carers, executive dysfunction, and elements of case management were also given.

Ergonomic education, performed by the OT, was aimed at facilitating the modification of ADLs at home, learning new skills for alternative or adaptive ways to perform activities, and providing advices on specialist equipment or resources.

Control Group

This program included neuromotor techniques, passive and active articular mobilization, strengthening and stretching of the spine and limbs, as well as balancing by means of proprioceptive training when standing, and walking exercises, mainly devoted to resistance and velocity training.

Treatment Administration

During the intervention, lasting 8 weeks, patients were followed individually. Two equally experienced physiotherapists were separately responsible for each group and arranged a daily 90-min session of physical training. Additionally, the experimental group met with the psychologist for two 30-min sessions per week, and with the OT for one 30-min session per week. To ensure no variability in treatment administration, a fidelity check was carried out at each session based on an exercise administration manual. Patients were discharged after the end of the intervention and recommended to continue their training program at home.

Each participant was checked during hospitalization by PD nurses, who were in charge of administering drugs, monitoring possible side effects (eg, dyskinesias, hallucinations), and controlling sphincter regularity, blood pressure, quality of sleep, diet, and ability to feed. The pharmacological treatment of each subject was maintained constant during the in-hospital stay to avoid confounding factors over the treatment effects. No other physical modalities and manual therapies were offered once the patient had been enrolled until the end of the training.

Relatives were asked to support patient's compliance during the study and to inform staff promptly if any difficulty was encountered, to strengthen treatment adherence and minimize dropout rates.

Outcome Measures

Motor Impairment (Primary Outcome)

Motor impairment was assessed by using the Italian Movement Disorder Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS), Part III, characterized by 33 questions based on 18 items; the total score ranges from 0 (normal motor ability) to 132 (severe motor impairment).¹⁸

Balance

Balance was assessed by using the Italian Berg Balance Scale (BBS), which ranges from 0 (high risk of falling) to 56 (no risk of falling).¹⁹ The BBS has been identified as one of the best discriminators between fallers and nonfallers in subjects with PD, with a cut-off score of 43.5.²⁰

ADL

Activities of daily living were evaluated by the Italian Functional Independence Measure (FIM), which describes 18 ADLs associated with motor, cognitive, and sphincteral problems and ranges from 18 (maximal limitation) to 126 (no limitation).²¹

QoL

Quality of life was assessed by using the Italian 39-question Parkinson's Disease Questionnaire (PDQ-39). This measure consists of 39 questions, distributed between eight multi-item domains: mobility, activities of daily living, emotional well-being, stigma, social support, cognition, communication, and bodily discomfort. Responses are mapped to a percentage scale (0 = no problem; 100 = maximum level of problem) for each domain.²²

Assessment Schedule

Participants were assessed during "on" state approximately 1 h after the first drug assumption in the morning at three points: before treatment, 8 weeks later (post-treatment), and 12 mo after discharge (1-y follow-up).

At post-treatment, patients were also asked to rate the global perceived effect (GPE) of treatment by using a 5-point scale (1 = helped a lot; 5 = made things worse). To allow for a comparison to be made between groups in terms of drug therapy, the daily medication use of each participant was recorded at baseline and converted in levodopa equivalent dose (LED).²³ Participants were given a specific form to record any serious symptoms or events they experienced during the study.

Statistics

A sample size of 30 patients per group was calculated to be capable of detecting a between-group difference of 12 in the primary outcome with a standard

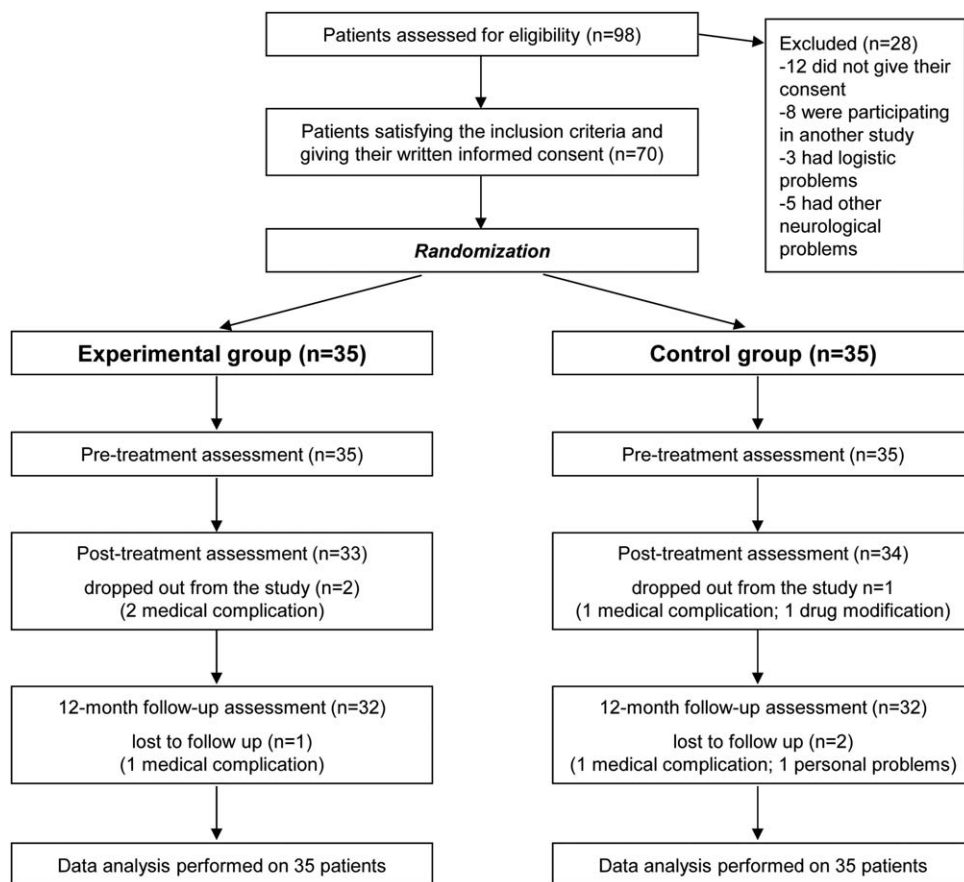


FIG. 1. Study flow chart.

deviation of 16.3, a type I error of 5%, and a power of 80%. Because the clinically important change for the MDS-UPDRS-Part III has not been evaluated, the between-group difference was estimated by computing the minimum detectable change from the standard error of measurement obtained in Martinez-Martin et al.²⁴ Thirty-five patients were included in each group to allow for a 15% dropout rate.

Baseline comparability was assessed by using the Student's *t* test for independent samples for age, disease duration, LED, and outcome measures. Linear mixed model analyses for repeated measures ($P < 0.05$) were made for each of the outcome measures, with group and time entered as fixed effects. The crossover effect of time and group was entered as an interaction term. The perceived differences in global effect were analyzed using the Mann-Whitney *U* test. Data were analyzed using SPSS 21.0.

Results

Of the 98 screened patients, 70 agreed to participate and were randomized between July 2011 and December 2012. Three subjects dropped from the study before the intervention ended, and a further three

were lost during follow-up, as shown in Figure 1. No crossover problems arose as no patient asked to swap groups.

The two groups were comparable at baseline (Table 1). The sample was characterized by a long disease duration (mean value of 15 y for both groups) and a mild-to-moderate level of disability, with most having a modified Hoehn & Yahr score of 3.

After training, both groups significantly improved their motor impairment (MDS-UPDRS-Part III score) and showed a significant between-group difference in favor of the experimental group of 25 points, which was maintained at follow-up (Table 2).

As for balance (BBS scores), significant effects of time ($P < 0.001$), group ($P < 0.001$), and time by group interaction ($P < 0.001$) were found, with the two groups showing a mean difference of 9 points at post-treatment assessment, which further increased to 16 points at follow-up because of a worsening in the control group.

Concerning FIM scores, the between-group differences were 19 and 25, respectively, after training and at follow-up, and significant differences (time, group, and time by group interaction) were found.

A more significant improvement was achieved by the experimental group, also concerning QoL, with all

TABLE 1. Patients' baseline characteristics (n = 70)

	Experimental Group	Control Group	P Value
Age, y*	74.1 (6.0)	73.4 (7.0)	0.662
Sex, male/female	24/11	22/13	
Body mass index, kg/m ² *	25.6 (3.8)	25.5 (3.8)	0.886
Disease duration, y*	15.7 (2.6)	15.3 (3.0)	0.495
Modified Hoehn & Yahr scale (ON), number of subjects (%)			
Score 2.5	8 (23%)	7 (20)	
Score 3	20 (57%)	22 (63)	
Score 4	7 (20%)	6 (17)	
Smokers, yes/no	2/33	3/32	
Married, yes/no	31/4	30/5	
Job, employed/retired	4/31	3/32	
Education			
Primary school	13	14	
Middle school	11	12	
High school	10	6	
University	1	3	
Comorbidity (principal)			
Cardiac diseases and hypertension	21	22	
Respiratory diseases	5	4	
Gastroenteric diseases	4	5	
Endocrine diseases	3	4	
Daily LED, ^a mg*	928.7 (86.7)	937.6 (91.1)	0.675
Use of drugs (%)			
Levodopa	85	80	
Dopamine agonist	77	70	
COMT inhibitor	12	17	
MAO β blocker	11	11	
Amantadine	14	11	
MDS-UPDRS-Part III ^b (0-132)*	83.0 (15.3)	83.0 (14.3)	0.987
BBS ^c (0-56)*	38.8 (9.0)	37.7 (10.0)	0.644
FIM ^d (18-126)*	68.8 (10.1)	70.1 (8.3)	0.562
PDQ-39 ^e			
Mobility (0-100)*	50.6 (23.2)	51.1 (20.5)	0.913
Activities of Daily Living (0-100)*	47.1 (19.2)	47.7 (17.2)	0.892
Emotional Well-being (0-100)*	43.0 (18.4)	41.0 (16.6)	0.631
Stigma (0-100)*	31.3 (19.4)	31.6 (16.6)	0.934
Social Support (0-100)*	30.7 (18.5)	31.9 (15.7)	0.773
Cognition (0-100)*	35.5 (19.5)	35.2 (14.4)	0.931
Communication (0-100)*	31.7 (18.6)	31.7 (16.3)	1.000
Bodily discomfort (0-100)*	36.9 (18.8)	36.9 (16.6)	1.000

*Mean values (standard deviation).

^aLevodopa equivalent dose.^bMovement Disorder Society Unified Parkinson's Disease Rating Scale, Motor subscale.^cBerg Balance Scale.^dFunctional independence measure.^eParkinson's Disease Questionnaire.

PDQ-39 subscales but communication showing a significant effect of time, group, and time-by-group interaction. Improvements were maintained or even further improved at follow-up.

A significant between-group difference was found for GPE ($P < 0.001$). Subjects in the experimental group believed that the intervention had helped them a lot (median = 1; interquartile range = 1), whereas no improvements were perceived by the control group (median = 3; interquartile range = 1).

Physiotherapists' systematic checking the exercise administration manual revealed excellent compliance rates in both groups (100%). Minor adverse effects of transient pain worsening (experimental group, 9; control group, 7), mood disorders (n = 5; n = 4), and autonomic and sensory problems (n = 8; n = 9) were easily managed by means of symptomatic drugs and brief periods of rest.

Discussion

Our findings showed that subjects with long-duration PD and a mild-to-moderate level of disability might benefit from an in-patient rehabilitative program, because a general improvement in terms of motor impairment, ADL, and QoL was visible in both groups after 2 mo of training. The daily practice of exercises might have helped the subjects of both groups to learn successful solutions.²⁵

Despite this general improvement, our findings demonstrated the superiority of the multidisciplinary rehabilitative program compared with general physiotherapy. A clinically significant between-group difference of 25 points was achieved for the MDS-UPDRS-Part III, strongly above that previously found in other studies. A between-group difference of approximately 14 points was found after 8 weeks of training comparing a group-based educational program with wait-listed controls.¹⁴ A recent randomized controlled study²⁶ and other nonrandomized trials^{10,11,17} showed even smaller between-group changes in terms of motor impairment. The difference between our results and the literature might be explained by the definition of a novel training program combining task-oriented exercises, cognitive training, and ergonomic education, which allow directly transferring the results achieved during rehabilitation sessions at home. Some of the previous studies were group-based to provide an opportunity for peer group support and encouragement^{12,14-16}; however, the definition of an individual training program ensuring an adequate process of cognitive and motor reconditioning, while giving enough time to the exchange of information between each patient and the care providers, might have increased rehabilitative outcomes. Furthermore, the inpatient setting allowed for the daily practice of exercise at a high-intensity rate (540 min/week), whereas most previous studies were conducted on an outpatient basis at low intensity rate (<120 min/week).^{13,14} The importance of the daily practice of exercise is confirmed by the only previous study that proposed an inpatient multidisciplinary program¹²: the authors achieved a pre-post change of approximately 32 points (FIM scores), comparable to the 40-point change obtained by the experimental group in our study.

TABLE 2. Changes over time within and between control and experimental groups (n = 70)

	Group	Pre-training*	Post-training*	Follow-up*	Mean Difference at Post-training†	Mean Difference at Follow-up†	F (P Value) Time Effect	F (P Value) Group Effect	F (P Value) Interaction Effect																																																																																																																																																																																
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MDS-UPDRS-Part III[§] (0-132)	Experimental	83.0 (15.3)	40.8 (13.4)	37.3 (12.7)	-24.5 (3.2)	-28.3 (3.4)	235.55 (<i>P</i> < 0.001)	40.16 (<i>P</i> < 0.001)	41.70 (<i>P</i> < 0.001)																																																																																																																																																																																
	Control	83.0 (14.3)	65.4 (12.5)	65.7 (14.8)						Secondary outcomes										BBS^b (0-56)	Experimental	38.8 (9.0)	50.2 (4.5)	51.5 (2.8)	9.3 (1.0)	15.6 (0.8)	23.27 (<i>P</i> < 0.001)	69.74 (<i>P</i> < 0.001)	29.05 (<i>P</i> < 0.001)	Control	37.7 (10.0)	40.8 (3.9)	35.8 (3.3)			FIM^c (18-126)	Experimental	68.8 (10.1)	109.2 (6.9)	115.4 (5.2)	18.9 (1.9)	24.8 (1.7)	378.92 (<i>P</i> < 0.001)	109.03 (<i>P</i> < 0.001)	58.09 (<i>P</i> < 0.001)	Control	70.1 (8.3)	90.3 (8.5)	90.6 (7.8)			PDQ-39^d										Mobility (0-100)	Experimental	50.6 (23.2)	26.8 (12.0)	20.2 (12.3)	-14.1 (3.4)	-15.4 (3.0)	34.36 (<i>P</i> < 0.001)	13.26 (<i>P</i> = 0.001)	4.72 (<i>P</i> = 0.012)	Control	51.1 (20.5)	40.9 (15.3)	35.5 (11.5)			Activities of Daily Living (0-100)	Experimental	47.1 (19.2)	21.3 (9.5)	11.7 (5.9)	-19.6 (2.2)	-24.9 (2.9)	44.20 (<i>P</i> < 0.001)	57.06 (<i>P</i> < 0.001)	12.23 (<i>P</i> < 0.001)	Control	47.7 (17.2)	40.9 (8.6)	36.6 (15.3)			Emotional Well-being (0-100)	Experimental	43.0 (18.4)	20.6 (12.1)	15.8 (8.4)	-14.8 (2.9)	-19.8 (2.5)	27.70 (<i>P</i> < 0.001)	20.76 (<i>P</i> < 0.001)	13.03 (<i>P</i> < 0.001)	Control	41.0 (16.6)	35.4 (11.8)	35.5 (11.5)			Stigma (0-100)	Experimental	31.3 (19.4)	11.0 (10.8)	10.7 (9.0)	-14.9 (3.4)	-15.8 (2.6)	18.34 (<i>P</i> < 0.001)	14.70 (<i>P</i> < 0.001)	7.50 (<i>P</i> = 0.001)	Control	31.6 (16.6)	25.9 (16.2)	26.6 (11.8)			Social Support (0-100)	Experimental	30.7 (18.5)	10.9 (16.5)	8.6 (12.6)	-10.2 (3.4)	-17.7 (3.1)	19.90 (<i>P</i> < 0.001)	17.06 (<i>P</i> < 0.001)	6.90 (<i>P</i> = 0.002)	Control	31.9 (15.7)	21.1 (11.3)	26.3 (12.2)			Cognition (0-100)	Experimental	35.5 (19.5)	21.2 (10.5)	15.6 (11.8)	-10.4 (2.6)	-15.4 (3.2)	12.99 (<i>P</i> < 0.001)	13.18 (<i>P</i> = 0.001)	5.19 (<i>P</i> = 0.008)	Control	35.2 (14.4)	31.6 (10.7)	31.1 (13.7)			Communication (0-100)	Experimental	31.7 (18.6)	23.0 (23.0)	21.6 (22.1)	-8.4 (4.8)	-9.4 (4.9)	2.91 (<i>P</i> = 0.061)	3.14 (<i>P</i> = 0.081)	2.57 (<i>P</i> = 0.084)	Control	31.7 (16.3)	31.4 (15.5)	31.0 (16.8)			Bodily Discomfort (0-100)	Experimental	36.9 (18.8)	15.7 (11.6)	10.9 (10.5)	-12.2 (2.8)	-20.3 (3.7)	21.70 (<i>P</i> < 0.001)	22.88 (<i>P</i> < 0.001)	7.32 (<i>P</i> = 0.001)	Control	36.9 (16.6)
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	Control	37.7 (10.0)	40.8 (3.9)	35.8 (3.3)						FIM^c (18-126)	Experimental	68.8 (10.1)	109.2 (6.9)	115.4 (5.2)	18.9 (1.9)	24.8 (1.7)	378.92 (<i>P</i> < 0.001)	109.03 (<i>P</i> < 0.001)	58.09 (<i>P</i> < 0.001)	Control	70.1 (8.3)	90.3 (8.5)	90.6 (7.8)			PDQ-39^d										Mobility (0-100)	Experimental	50.6 (23.2)	26.8 (12.0)	20.2 (12.3)	-14.1 (3.4)	-15.4 (3.0)	34.36 (<i>P</i> < 0.001)	13.26 (<i>P</i> = 0.001)	4.72 (<i>P</i> = 0.012)	Control	51.1 (20.5)	40.9 (15.3)	35.5 (11.5)			Activities of Daily Living (0-100)	Experimental	47.1 (19.2)	21.3 (9.5)	11.7 (5.9)	-19.6 (2.2)	-24.9 (2.9)	44.20 (<i>P</i> < 0.001)	57.06 (<i>P</i> < 0.001)	12.23 (<i>P</i> < 0.001)	Control	47.7 (17.2)	40.9 (8.6)	36.6 (15.3)			Emotional Well-being (0-100)	Experimental	43.0 (18.4)	20.6 (12.1)	15.8 (8.4)	-14.8 (2.9)	-19.8 (2.5)	27.70 (<i>P</i> < 0.001)	20.76 (<i>P</i> < 0.001)	13.03 (<i>P</i> < 0.001)	Control	41.0 (16.6)	35.4 (11.8)	35.5 (11.5)			Stigma (0-100)	Experimental	31.3 (19.4)	11.0 (10.8)	10.7 (9.0)	-14.9 (3.4)	-15.8 (2.6)	18.34 (<i>P</i> < 0.001)	14.70 (<i>P</i> < 0.001)	7.50 (<i>P</i> = 0.001)	Control	31.6 (16.6)	25.9 (16.2)	26.6 (11.8)			Social Support (0-100)	Experimental	30.7 (18.5)	10.9 (16.5)	8.6 (12.6)	-10.2 (3.4)	-17.7 (3.1)	19.90 (<i>P</i> < 0.001)	17.06 (<i>P</i> < 0.001)	6.90 (<i>P</i> = 0.002)	Control	31.9 (15.7)	21.1 (11.3)	26.3 (12.2)			Cognition (0-100)	Experimental	35.5 (19.5)	21.2 (10.5)	15.6 (11.8)	-10.4 (2.6)	-15.4 (3.2)	12.99 (<i>P</i> < 0.001)	13.18 (<i>P</i> = 0.001)	5.19 (<i>P</i> = 0.008)	Control	35.2 (14.4)	31.6 (10.7)	31.1 (13.7)			Communication (0-100)	Experimental	31.7 (18.6)	23.0 (23.0)	21.6 (22.1)	-8.4 (4.8)	-9.4 (4.9)	2.91 (<i>P</i> = 0.061)	3.14 (<i>P</i> = 0.081)	2.57 (<i>P</i> = 0.084)	Control	31.7 (16.3)	31.4 (15.5)	31.0 (16.8)			Bodily Discomfort (0-100)	Experimental	36.9 (18.8)	15.7 (11.6)	10.9 (10.5)	-12.2 (2.8)	-20.3 (3.7)	21.70 (<i>P</i> < 0.001)	22.88 (<i>P</i> < 0.001)	7.32 (<i>P</i> = 0.001)	Control	36.9 (16.6)	29.9 (11.1)	31.3 (18.3)																								
FIM^c (18-126)	Experimental	68.8 (10.1)	109.2 (6.9)	115.4 (5.2)	18.9 (1.9)	24.8 (1.7)	378.92 (<i>P</i> < 0.001)	109.03 (<i>P</i> < 0.001)	58.09 (<i>P</i> < 0.001)																																																																																																																																																																																
	Control	70.1 (8.3)	90.3 (8.5)	90.6 (7.8)						PDQ-39^d										Mobility (0-100)	Experimental	50.6 (23.2)	26.8 (12.0)	20.2 (12.3)	-14.1 (3.4)	-15.4 (3.0)	34.36 (<i>P</i> < 0.001)	13.26 (<i>P</i> = 0.001)	4.72 (<i>P</i> = 0.012)	Control	51.1 (20.5)	40.9 (15.3)	35.5 (11.5)			Activities of Daily Living (0-100)	Experimental	47.1 (19.2)	21.3 (9.5)	11.7 (5.9)	-19.6 (2.2)	-24.9 (2.9)	44.20 (<i>P</i> < 0.001)	57.06 (<i>P</i> < 0.001)	12.23 (<i>P</i> < 0.001)	Control	47.7 (17.2)	40.9 (8.6)	36.6 (15.3)			Emotional Well-being (0-100)	Experimental	43.0 (18.4)	20.6 (12.1)	15.8 (8.4)	-14.8 (2.9)	-19.8 (2.5)	27.70 (<i>P</i> < 0.001)	20.76 (<i>P</i> < 0.001)	13.03 (<i>P</i> < 0.001)	Control	41.0 (16.6)	35.4 (11.8)	35.5 (11.5)			Stigma (0-100)	Experimental	31.3 (19.4)	11.0 (10.8)	10.7 (9.0)	-14.9 (3.4)	-15.8 (2.6)	18.34 (<i>P</i> < 0.001)	14.70 (<i>P</i> < 0.001)	7.50 (<i>P</i> = 0.001)	Control	31.6 (16.6)	25.9 (16.2)	26.6 (11.8)			Social Support (0-100)	Experimental	30.7 (18.5)	10.9 (16.5)	8.6 (12.6)	-10.2 (3.4)	-17.7 (3.1)	19.90 (<i>P</i> < 0.001)	17.06 (<i>P</i> < 0.001)	6.90 (<i>P</i> = 0.002)	Control	31.9 (15.7)	21.1 (11.3)	26.3 (12.2)			Cognition (0-100)	Experimental	35.5 (19.5)	21.2 (10.5)	15.6 (11.8)	-10.4 (2.6)	-15.4 (3.2)	12.99 (<i>P</i> < 0.001)	13.18 (<i>P</i> = 0.001)	5.19 (<i>P</i> = 0.008)	Control	35.2 (14.4)	31.6 (10.7)	31.1 (13.7)			Communication (0-100)	Experimental	31.7 (18.6)	23.0 (23.0)	21.6 (22.1)	-8.4 (4.8)	-9.4 (4.9)	2.91 (<i>P</i> = 0.061)	3.14 (<i>P</i> = 0.081)	2.57 (<i>P</i> = 0.084)	Control	31.7 (16.3)	31.4 (15.5)	31.0 (16.8)			Bodily Discomfort (0-100)	Experimental	36.9 (18.8)	15.7 (11.6)	10.9 (10.5)	-12.2 (2.8)	-20.3 (3.7)	21.70 (<i>P</i> < 0.001)	22.88 (<i>P</i> < 0.001)	7.32 (<i>P</i> = 0.001)	Control	36.9 (16.6)	29.9 (11.1)	31.3 (18.3)																																								
PDQ-39^d																																																																																																																																																																																									
Mobility (0-100)	Experimental	50.6 (23.2)	26.8 (12.0)	20.2 (12.3)	-14.1 (3.4)	-15.4 (3.0)	34.36 (<i>P</i> < 0.001)	13.26 (<i>P</i> = 0.001)	4.72 (<i>P</i> = 0.012)																																																																																																																																																																																
	Control	51.1 (20.5)	40.9 (15.3)	35.5 (11.5)						Activities of Daily Living (0-100)	Experimental	47.1 (19.2)	21.3 (9.5)	11.7 (5.9)	-19.6 (2.2)	-24.9 (2.9)	44.20 (<i>P</i> < 0.001)	57.06 (<i>P</i> < 0.001)	12.23 (<i>P</i> < 0.001)	Control	47.7 (17.2)	40.9 (8.6)	36.6 (15.3)			Emotional Well-being (0-100)	Experimental	43.0 (18.4)	20.6 (12.1)	15.8 (8.4)	-14.8 (2.9)	-19.8 (2.5)	27.70 (<i>P</i> < 0.001)	20.76 (<i>P</i> < 0.001)	13.03 (<i>P</i> < 0.001)	Control	41.0 (16.6)	35.4 (11.8)	35.5 (11.5)			Stigma (0-100)	Experimental	31.3 (19.4)	11.0 (10.8)	10.7 (9.0)	-14.9 (3.4)	-15.8 (2.6)	18.34 (<i>P</i> < 0.001)	14.70 (<i>P</i> < 0.001)	7.50 (<i>P</i> = 0.001)	Control	31.6 (16.6)	25.9 (16.2)	26.6 (11.8)			Social Support (0-100)	Experimental	30.7 (18.5)	10.9 (16.5)	8.6 (12.6)	-10.2 (3.4)	-17.7 (3.1)	19.90 (<i>P</i> < 0.001)	17.06 (<i>P</i> < 0.001)	6.90 (<i>P</i> = 0.002)	Control	31.9 (15.7)	21.1 (11.3)	26.3 (12.2)			Cognition (0-100)	Experimental	35.5 (19.5)	21.2 (10.5)	15.6 (11.8)	-10.4 (2.6)	-15.4 (3.2)	12.99 (<i>P</i> < 0.001)	13.18 (<i>P</i> = 0.001)	5.19 (<i>P</i> = 0.008)	Control	35.2 (14.4)	31.6 (10.7)	31.1 (13.7)			Communication (0-100)	Experimental	31.7 (18.6)	23.0 (23.0)	21.6 (22.1)	-8.4 (4.8)	-9.4 (4.9)	2.91 (<i>P</i> = 0.061)	3.14 (<i>P</i> = 0.081)	2.57 (<i>P</i> = 0.084)	Control	31.7 (16.3)	31.4 (15.5)	31.0 (16.8)			Bodily Discomfort (0-100)	Experimental	36.9 (18.8)	15.7 (11.6)	10.9 (10.5)	-12.2 (2.8)	-20.3 (3.7)	21.70 (<i>P</i> < 0.001)	22.88 (<i>P</i> < 0.001)	7.32 (<i>P</i> = 0.001)	Control	36.9 (16.6)	29.9 (11.1)	31.3 (18.3)																																																																		
Activities of Daily Living (0-100)	Experimental	47.1 (19.2)	21.3 (9.5)	11.7 (5.9)	-19.6 (2.2)	-24.9 (2.9)	44.20 (<i>P</i> < 0.001)	57.06 (<i>P</i> < 0.001)	12.23 (<i>P</i> < 0.001)																																																																																																																																																																																
	Control	47.7 (17.2)	40.9 (8.6)	36.6 (15.3)						Emotional Well-being (0-100)	Experimental	43.0 (18.4)	20.6 (12.1)	15.8 (8.4)	-14.8 (2.9)	-19.8 (2.5)	27.70 (<i>P</i> < 0.001)	20.76 (<i>P</i> < 0.001)	13.03 (<i>P</i> < 0.001)	Control	41.0 (16.6)	35.4 (11.8)	35.5 (11.5)			Stigma (0-100)	Experimental	31.3 (19.4)	11.0 (10.8)	10.7 (9.0)	-14.9 (3.4)	-15.8 (2.6)	18.34 (<i>P</i> < 0.001)	14.70 (<i>P</i> < 0.001)	7.50 (<i>P</i> = 0.001)	Control	31.6 (16.6)	25.9 (16.2)	26.6 (11.8)			Social Support (0-100)	Experimental	30.7 (18.5)	10.9 (16.5)	8.6 (12.6)	-10.2 (3.4)	-17.7 (3.1)	19.90 (<i>P</i> < 0.001)	17.06 (<i>P</i> < 0.001)	6.90 (<i>P</i> = 0.002)	Control	31.9 (15.7)	21.1 (11.3)	26.3 (12.2)			Cognition (0-100)	Experimental	35.5 (19.5)	21.2 (10.5)	15.6 (11.8)	-10.4 (2.6)	-15.4 (3.2)	12.99 (<i>P</i> < 0.001)	13.18 (<i>P</i> = 0.001)	5.19 (<i>P</i> = 0.008)	Control	35.2 (14.4)	31.6 (10.7)	31.1 (13.7)			Communication (0-100)	Experimental	31.7 (18.6)	23.0 (23.0)	21.6 (22.1)	-8.4 (4.8)	-9.4 (4.9)	2.91 (<i>P</i> = 0.061)	3.14 (<i>P</i> = 0.081)	2.57 (<i>P</i> = 0.084)	Control	31.7 (16.3)	31.4 (15.5)	31.0 (16.8)			Bodily Discomfort (0-100)	Experimental	36.9 (18.8)	15.7 (11.6)	10.9 (10.5)	-12.2 (2.8)	-20.3 (3.7)	21.70 (<i>P</i> < 0.001)	22.88 (<i>P</i> < 0.001)	7.32 (<i>P</i> = 0.001)	Control	36.9 (16.6)	29.9 (11.1)	31.3 (18.3)																																																																																		
Emotional Well-being (0-100)	Experimental	43.0 (18.4)	20.6 (12.1)	15.8 (8.4)	-14.8 (2.9)	-19.8 (2.5)	27.70 (<i>P</i> < 0.001)	20.76 (<i>P</i> < 0.001)	13.03 (<i>P</i> < 0.001)																																																																																																																																																																																
	Control	41.0 (16.6)	35.4 (11.8)	35.5 (11.5)						Stigma (0-100)	Experimental	31.3 (19.4)	11.0 (10.8)	10.7 (9.0)	-14.9 (3.4)	-15.8 (2.6)	18.34 (<i>P</i> < 0.001)	14.70 (<i>P</i> < 0.001)	7.50 (<i>P</i> = 0.001)	Control	31.6 (16.6)	25.9 (16.2)	26.6 (11.8)			Social Support (0-100)	Experimental	30.7 (18.5)	10.9 (16.5)	8.6 (12.6)	-10.2 (3.4)	-17.7 (3.1)	19.90 (<i>P</i> < 0.001)	17.06 (<i>P</i> < 0.001)	6.90 (<i>P</i> = 0.002)	Control	31.9 (15.7)	21.1 (11.3)	26.3 (12.2)			Cognition (0-100)	Experimental	35.5 (19.5)	21.2 (10.5)	15.6 (11.8)	-10.4 (2.6)	-15.4 (3.2)	12.99 (<i>P</i> < 0.001)	13.18 (<i>P</i> = 0.001)	5.19 (<i>P</i> = 0.008)	Control	35.2 (14.4)	31.6 (10.7)	31.1 (13.7)			Communication (0-100)	Experimental	31.7 (18.6)	23.0 (23.0)	21.6 (22.1)	-8.4 (4.8)	-9.4 (4.9)	2.91 (<i>P</i> = 0.061)	3.14 (<i>P</i> = 0.081)	2.57 (<i>P</i> = 0.084)	Control	31.7 (16.3)	31.4 (15.5)	31.0 (16.8)			Bodily Discomfort (0-100)	Experimental	36.9 (18.8)	15.7 (11.6)	10.9 (10.5)	-12.2 (2.8)	-20.3 (3.7)	21.70 (<i>P</i> < 0.001)	22.88 (<i>P</i> < 0.001)	7.32 (<i>P</i> = 0.001)	Control	36.9 (16.6)	29.9 (11.1)	31.3 (18.3)																																																																																																		
Stigma (0-100)	Experimental	31.3 (19.4)	11.0 (10.8)	10.7 (9.0)	-14.9 (3.4)	-15.8 (2.6)	18.34 (<i>P</i> < 0.001)	14.70 (<i>P</i> < 0.001)	7.50 (<i>P</i> = 0.001)																																																																																																																																																																																
	Control	31.6 (16.6)	25.9 (16.2)	26.6 (11.8)						Social Support (0-100)	Experimental	30.7 (18.5)	10.9 (16.5)	8.6 (12.6)	-10.2 (3.4)	-17.7 (3.1)	19.90 (<i>P</i> < 0.001)	17.06 (<i>P</i> < 0.001)	6.90 (<i>P</i> = 0.002)	Control	31.9 (15.7)	21.1 (11.3)	26.3 (12.2)			Cognition (0-100)	Experimental	35.5 (19.5)	21.2 (10.5)	15.6 (11.8)	-10.4 (2.6)	-15.4 (3.2)	12.99 (<i>P</i> < 0.001)	13.18 (<i>P</i> = 0.001)	5.19 (<i>P</i> = 0.008)	Control	35.2 (14.4)	31.6 (10.7)	31.1 (13.7)			Communication (0-100)	Experimental	31.7 (18.6)	23.0 (23.0)	21.6 (22.1)	-8.4 (4.8)	-9.4 (4.9)	2.91 (<i>P</i> = 0.061)	3.14 (<i>P</i> = 0.081)	2.57 (<i>P</i> = 0.084)	Control	31.7 (16.3)	31.4 (15.5)	31.0 (16.8)			Bodily Discomfort (0-100)	Experimental	36.9 (18.8)	15.7 (11.6)	10.9 (10.5)	-12.2 (2.8)	-20.3 (3.7)	21.70 (<i>P</i> < 0.001)	22.88 (<i>P</i> < 0.001)	7.32 (<i>P</i> = 0.001)	Control	36.9 (16.6)	29.9 (11.1)	31.3 (18.3)																																																																																																																		
Social Support (0-100)	Experimental	30.7 (18.5)	10.9 (16.5)	8.6 (12.6)	-10.2 (3.4)	-17.7 (3.1)	19.90 (<i>P</i> < 0.001)	17.06 (<i>P</i> < 0.001)	6.90 (<i>P</i> = 0.002)																																																																																																																																																																																
	Control	31.9 (15.7)	21.1 (11.3)	26.3 (12.2)						Cognition (0-100)	Experimental	35.5 (19.5)	21.2 (10.5)	15.6 (11.8)	-10.4 (2.6)	-15.4 (3.2)	12.99 (<i>P</i> < 0.001)	13.18 (<i>P</i> = 0.001)	5.19 (<i>P</i> = 0.008)	Control	35.2 (14.4)	31.6 (10.7)	31.1 (13.7)			Communication (0-100)	Experimental	31.7 (18.6)	23.0 (23.0)	21.6 (22.1)	-8.4 (4.8)	-9.4 (4.9)	2.91 (<i>P</i> = 0.061)	3.14 (<i>P</i> = 0.081)	2.57 (<i>P</i> = 0.084)	Control	31.7 (16.3)	31.4 (15.5)	31.0 (16.8)			Bodily Discomfort (0-100)	Experimental	36.9 (18.8)	15.7 (11.6)	10.9 (10.5)	-12.2 (2.8)	-20.3 (3.7)	21.70 (<i>P</i> < 0.001)	22.88 (<i>P</i> < 0.001)	7.32 (<i>P</i> = 0.001)	Control	36.9 (16.6)	29.9 (11.1)	31.3 (18.3)																																																																																																																																		
Cognition (0-100)	Experimental	35.5 (19.5)	21.2 (10.5)	15.6 (11.8)	-10.4 (2.6)	-15.4 (3.2)	12.99 (<i>P</i> < 0.001)	13.18 (<i>P</i> = 0.001)	5.19 (<i>P</i> = 0.008)																																																																																																																																																																																
	Control	35.2 (14.4)	31.6 (10.7)	31.1 (13.7)						Communication (0-100)	Experimental	31.7 (18.6)	23.0 (23.0)	21.6 (22.1)	-8.4 (4.8)	-9.4 (4.9)	2.91 (<i>P</i> = 0.061)	3.14 (<i>P</i> = 0.081)	2.57 (<i>P</i> = 0.084)	Control	31.7 (16.3)	31.4 (15.5)	31.0 (16.8)			Bodily Discomfort (0-100)	Experimental	36.9 (18.8)	15.7 (11.6)	10.9 (10.5)	-12.2 (2.8)	-20.3 (3.7)	21.70 (<i>P</i> < 0.001)	22.88 (<i>P</i> < 0.001)	7.32 (<i>P</i> = 0.001)	Control	36.9 (16.6)	29.9 (11.1)	31.3 (18.3)																																																																																																																																																		
Communication (0-100)	Experimental	31.7 (18.6)	23.0 (23.0)	21.6 (22.1)	-8.4 (4.8)	-9.4 (4.9)	2.91 (<i>P</i> = 0.061)	3.14 (<i>P</i> = 0.081)	2.57 (<i>P</i> = 0.084)																																																																																																																																																																																
	Control	31.7 (16.3)	31.4 (15.5)	31.0 (16.8)						Bodily Discomfort (0-100)	Experimental	36.9 (18.8)	15.7 (11.6)	10.9 (10.5)	-12.2 (2.8)	-20.3 (3.7)	21.70 (<i>P</i> < 0.001)	22.88 (<i>P</i> < 0.001)	7.32 (<i>P</i> = 0.001)	Control	36.9 (16.6)	29.9 (11.1)	31.3 (18.3)																																																																																																																																																																		
Bodily Discomfort (0-100)	Experimental	36.9 (18.8)	15.7 (11.6)	10.9 (10.5)	-12.2 (2.8)	-20.3 (3.7)	21.70 (<i>P</i> < 0.001)	22.88 (<i>P</i> < 0.001)	7.32 (<i>P</i> = 0.001)																																																																																																																																																																																
	Control	36.9 (16.6)	29.9 (11.1)	31.3 (18.3)																																																																																																																																																																																					

*Mean values (standard deviation).

†Mean difference (standard error).

^aMovement Disorder Society Unified Parkinson's Disease Rating Scale, Motor subscale.^bBerg Balance Scale.^cFunctional Independence Measure.^dParkinson's Disease Questionnaire.

The use of task-oriented principles may have contributed to effective improvements in postural instability, eventually reducing the risk of falling: in the experimental group, 18 subjects (51%) increased their BBS scores above the cutoff of 43.5, which discriminates between fallers and nonfallers,²⁰ whereas the control group showed an unclear trend: seven subjects (20%) increased from less than 43.5 to more than 43.5, and the other six (17%) showed the opposite behavior.

The effect of treatment on PDQ-39 subscales confirms the benefits of the experimental training. No significant group effect was found in the communication subscale, but this was not surprising because no speech therapy was delivered. To provide an overall QoL index favoring future cost-effectiveness analyses, an estimate of the EuroQol EQ-5D index at 1-y follow-up was computed based on a previously defined function to map PDQ-39 to EQ-5D scores²⁷: mean values of 0.805 ± 0.117 and 0.566 ± 0.116 were achieved by the experimental and control group, respectively, with a between-group difference (95% confidence interval) of 0.239 (0.181; 0.297). However, nonmotor symptoms, such as dysautonomia, sleep, fatigue, or pain, having a strong influence on QoL, were not assessed and need to be taken into account in future studies.²⁸

The higher rates of treatment satisfaction in the experimental group indicate the superiority of the approach, because task-oriented exercises, education, and ergonomics were perceived as providing a better solution to the problems experienced.

Subjects were able to transfer their gains to home environments, and the experimental group achieved additional small improvements at follow-up, probably because they continued adhering to at least some elements of their allocated training program, as recommended at discharge. Because the experimental group showed a higher rate of treatment satisfaction, they may have been more prone to continue their training at home; however, frequency and duration of home training were not evaluated.

We had a limited number of dropouts, which suggests the patients were motivated and determined to adhere to treatment. The support of staff and relatives played a crucial role in establishing a controlled and protected situation. Patients tolerated the exercise programs well; only a few minor adverse events were registered.

This inpatient program costs approximately €20,000, which are provided by the Italian National Healthcare System, and therefore it is reserved for subjects with a mild to moderate level of disability.

This high cost might prevent its use in other countries, such as the United States, where inpatient rehabilitation admission usually has not been considered for PD unless an acute event has occurred.¹² However, we hope that our results might change the current management of PD; investments in inpatient interventions might prevent future costs attributable to disabling motor symptoms, including falls, fall-related injuries, and loss of independence. Outpatient settings might be considered for subjects with less severe symptoms to delay the progression of the disease.

This trial was internally valid, capable of distinguishing between-group effects, and adequately sized. It was based on concealed randomization, blinded data collection, and the effective masking of assessors and analysts. The data cannot be generalized to subjects in the early stage of PD and to most of PD treatments usually carried out on an outpatient basis.

This study has some limitations. Nonmotor aspects such as speech and swallowing were not addressed. We used measures based on questionnaires and did not investigate their relationships with physical measures; nonmotor symptoms, especially those exploring cognitive aspects, were not evaluated. Treatment expectations were not addressed, and this factor was partially limited by informing the patients during enrollment that the efficacy of both treatments had not yet been established. Questions may be raised concerning contact time differences between groups because of the psychological and occupational intervention, which potentially could have biased the results. Finally, despite recommendations relating to drug types and doses throughout the intervention, modifications were not investigated after discharge, influencing our interpretations of follow-up data.

In conclusion, our findings suggest that an inpatient multidisciplinary rehabilitative program is able to induce clinical significant improvements in subjects with long-duration PD and a mild to moderate level of disability. ■

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Appendix

The appendix provides a detailed description of the rehabilitative training program delivered to the experimental group.

Motor Training

List of task-oriented exercises (alphabetical order):

- Ascending and descending stairs
- Cleaning the house

- Cleaning the windows
- Climbing obstacles
- Doing gardening
- Doing housework
- Doing the dishes
- Doing the shopping
- Drinking
- Driving
- Engaging the reverse
- Ironing
- Jumping
- Lacing up one's shoes
- Making the bed
- Riding a bicycle
- Running
- Taking garbage can out
- Using the personal computer
- Washing one's face
- Washing one's hair

List of exercises for transfers training (alphabetical order):

- Assuming the lateral position
- Assuming the prone position
- Assuming the supine position
- Getting up from the bed
- Rising up from the chair
- Standing
- Standing in a queue
- Turning over on a couch

List of exercises for balance training (alphabetical order):

- Standing on an unstable surface
- Standing on a narrow base
- Exercise to improve coordination and balance in quadrupedal position
- Exercise in monopodal position
- Side walking
- Walking on predefined paths

List of exercises for gait training (alphabetical order):

- Sudden starts and stops
- Treadmill training
- Turning
- Walking
- Walking while changing speed and direction
- Walking between obstacles

Cognitive Training

List of exercises for neuropsychological training

- Attention/working memory: reaction time (visual tracking of a target), selectivity and concentration

(search for one or more target stimuli amongst a multiplicity of letters and symbols), storing information, sequences of words and numbers

- Psychomotor speed: rapid detection of visual stimuli, acknowledged with complex images
- Executive functions: solving problems, dilemmas, planning for unusual situations
- Visuo-spatial abilities: tasks of visual analysis and reproduction of images, labyrinths
- Calculation skills: resolution of mathematical operations in mind, operations in two digits, fast calculation with coins and money

Furthermore, specific questions were formulated to investigate patients' beliefs concerning causes of Parkinson's disease, characteristics of disabling symptoms, specific movements supposed to produce harm, capability of carrying out work duties, capability to perform daily activities (eg, home duties, driving, hobbies, and so forth), fear of not being believed or helped by other people (eg, family members, friends, co-workers, doctors), fear of hopeless and miserable future life.

Solutions were provided first by educating subjects on the nature of chronic conditions such as Parkinson's disease, to reduce the threat of the disease itself as well as to change how they see themselves and behave; subjects were encouraged to active and paced movement approaches to gradually increase physical capacity, reduce pain, and improve quality of life (eg, "get to know your disease and learn with patience and persistence how to move and to do things at home, during leisure time..."). Relaxation as well as attentional techniques such as distraction were shared with the subjects to facilitate graded exposure. Moreover, advice to develop helpful ways of thinking were provided to master disabling situations and to minimize the level of distress (eg, "stay calm, avoid extreme reactions, remind yourself you have had problems like this before and you know it will get better"); ways to challenge and change unhelpful ways of thinking were also encouraged to keep under control mood disorders (eg, when you get panicky, or you feel anxious, depressed, or irritable, stop and listen to what you have been saying to yourself and ask yourself: Is it helpful to think like that? Attempt to modify, with patience and practice, the way you look at your sensations). Finally, solutions on how to interact with people around patients were also given (eg, "ask family members, friends, or doctors for help they actually can give and offer appreciation in exchange, talk as openly as possible of your problems but try not to talk about Parkinson's disease all the time, encourage them to allow you to try things again, set goals to do things together...").

Ergonomic Education

List of Facilitations to Improve ADLs

- Carrying a bag
- Carrying a child in one's arms
- Lifting a weight correctly
- Doing one's hobbies
- Home and potential risks evaluation
- Changes at home
- Elimination of barriers

List of Alternative Skills to Perform Activities

- Adapted postures and alternative strategies useful to carry out independently and safely usual activities
- Caregiver's education to reduce the burden of care
- Strategies to conserve energy and reduce the demands of activities

Advice on Specialist Equipment or Resources

- Adapted cutlery, glasses, and other aids for feeding useful to favor an autonomous feeding
- Aids to enhance clothing and personal hygiene (eg, socks and stocking aids)
- Stools, chairs, grab bars for shower and bathtub
- Walking aids

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