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An evaluation of the Patient Education Program for Parkinson's disease in clinical practice

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Abstract

Aim: The Patient Education Programme for Parkinson's disease (PEPP) was assessed in a recent randomized controlled trial (RCT). In this study, a trend was identified towards significant improvement of patients' quality of life (Qol) as well as a significant reduction of caregivers' psychosocial burden and need for help. The present study is aimed at evaluating the effectiveness of the PEPP in clinical practice as compared to the RCT in an academic setting. The second aim is to assess its effectiveness in clinical practice at six-month follow-up.

Methods: Fifty-five patients and 50 caregivers from nine clinical settings participated in the PEPP consisting of eight weekly sessions of 90 minutes. Self-report questionnaires were used to assess patients' Qol (PDQ-39) and caregivers' psychosocial burden and need for help (BELA-A-k) at baseline, directly after the programme and at six-month follow-up. To compare the baseline data and short-term effects, data were used from an RCT study which included 64 PD patients and 46 caregivers.

Results: Compared to the RCT control group, significant effects, after Bonferoni adjustment, were found for patients' Qol as well as for caregivers' psychosocial burden and need for help. No significant changes were found between baseline scores compared to six-month follow-up. Scores returned to baseline levels at six-month follow-up.

Conclusions: Effects from the RCT study were replicated and the effect on patients' Qol was now significant. However, at six-month follow-up, scores returned to baseline levels, indicating the need for some form of a booster session.

Introduction

Parkinson's disease (PD) is one of the most common neurodegenerative diseases. It has an incidence over the age of 65 of about 160 per 100 000.[1] The symptoms of PD, including the physical, cognitive and psychiatric symptoms, often cause psychosocial stress in patients.[2,3] Psychosocial wellbeing has been found to be an important predictor of self-reported quality of life in PD patients.[4] Increased psychosocial problems and depressive symptoms are associated with greater decline in Qol over time and are therefore often recommended to be included in PD treatment.[4-6] As most PD patients live in the community, long-term responsibility of day-to-day management with PD has become a new challenge for patients and for their informal caregivers. Attention for the caring capacity of the caregiver is important because the wellbeing of the caregiver is an important factor in determining institutional placement and patients' quality of care.[7] The Patient Education Programme for Parkinson's disease (PEPP) is aimed at educating PD patients and caregivers and training them in the skills to cope with the psychosocial consequences of PD. The programme uses techniques from cognitive behavioural therapy. The programme has been evaluated on its feasibility in seven European countries[8,9] and is thereafter standardized in a manual, available in six languages, including Dutch and English.[10,11] In a recent randomized controlled trial (RCT), an effect was found towards significant improvement of quality of life in PD patients and significant reductions in caregivers' psychosocial burden and need for help.[12] In the RCT, the programme was provided in an academic setting and patients and caregivers were recruited for participation. They did not apply necessarily as a result of psychosocial help nor were they referred by a professional. Since the introduction of the programme in 2006, the PEPP manual if freely available and healthcare professionals are trained in a two-day special PEPP training course for providing this intervention in their own healthcare setting. Because of the positive results of the RCT, it is important to evaluate the effectiveness of the programme in daily clinical practice if participants are not recruited as study participants and if the programme is provided by trained health care professionals in "real world" uncontrolled clinical practice in the Netherlands. Therefore, the results of the present study will be compared to the results of the previous RCT. The second aim is to assess effectiveness in clinical practice at six-month follow-up.

Methods

Participants

Fifty-five patients and 50 caregivers were included in the clinical practice (CP) group, and completed baseline assessment (Figure 1). The inclusion criterion was a clinical diagnosis of Parkinson's disease by a neurologist. No exclusion criteria were used for participation in the study. All participants were recruited successively by the trainers of the sites within their own healthcare setting, or were referred by the physician or another healthcare professional of the organization, and through announcements on websites (e.g. of the patient organization) and leaflets. After baseline assessment, one group was cancelled because not enough participants had been recruited. All participants gave informed consent and the study was approved by the medical ethics committee of the LUMC. Participants' characteristics from the CP and RCT group are summarized in Table 1. Results from the RCT study were used (full description in A'Campo et. al).[12]

Figure 1 Flowchart of the Clinical Practice group

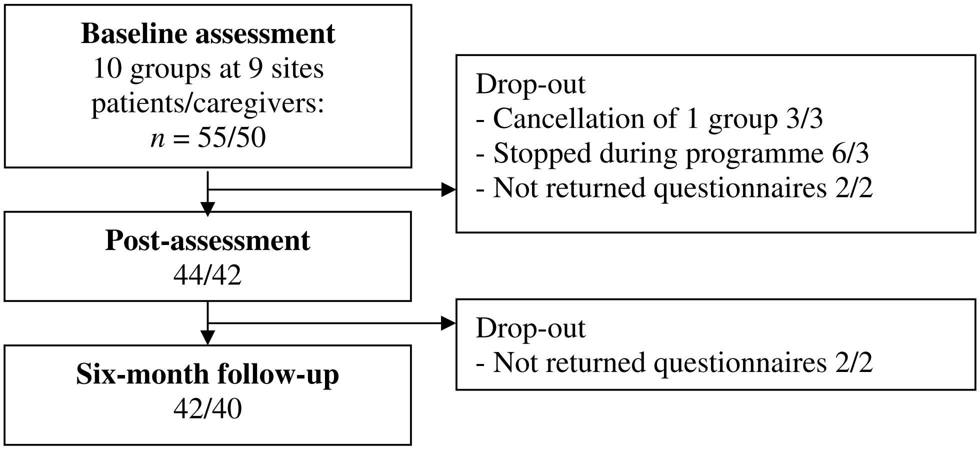


Table 1 Characteristics of the participants in the Clinical Practice and the Randomized Clinical Trial groups

	CP		*RCT-I*		*RCT-C*	
	Patients	Caregivers	Patients	Caregivers	Patients	Caregivers
	n = 55	*n* = 50	*n* = 35	*n* = 26	*n* = 29	*n* = 20
Men/women, *n*	37/18	15/35	20/15	9/17	15/14	8/12
Age (years), mean (SD)	68.0 (11.1)	66.6 (7.5)	65.5 (8.9)	63.4 (8.8)	64.2 (9.1)	61.5 (11.3)
Partner/no partner, *n*	52/3	50/0	30/5	26/0	24/5	20/0
Participation in PEPP						
With partner/alone, *n*	48/7	47/3	25/10	26/0	20/9	19/1
Education level						
Education till 18 yr/ higher, *n*	36/19	32/18	18/17	14/12	13/16	12/8
Working/not working, n	0/55	7/43	8/27	8/18	8/21	6/14
Duration PD, years, mean (SD)	8.6 (6.7)	-	6.0 (5.3)	-	5.5 (4.5)	
MMSE, mean (SD), range[1]	27.9 (1.8)	28.7 (1.7)	27.4 (3.4)	28.9 (1.1)	28.8 (1.1)	28.8 (1.7)
	24-30	23-30	17-30	26-30	27-30	24-30
H&Y, mean (SD)[2]	2.1 (1.1)	-	2.4 (1.0)	-	2.3 (0.7)	
Stage 1/2,3/4,5, *n*	21/30/4	-	11/18/4	-	7/20/0	
ADL, mean (SD)	75.2 (16.8)	-	76.0 (18.8)	-	78.9 (15.1)	-
PDQ-39 SI, mean (SD)[2,3]	35.4 (14.4)*	-	33.0 (13.5)	-	26.6 (12.1)	-
BELA-A-k, mean (SD)						
Bothered By[4]		14.8 (12.0)		12.7 (9.1)		9.9 (8.2)
Need for help[4,5]		21.9 (14.5)		18.9 (11.6)		15.5 (11.5)

Abbreviations: CP, Clinical practice; RCT-I, randomized controlled trial intervention group; RCT-C, randomized controlled trail control group; SD, standard deviation; PEPP, Patient Education Programme for Parkinson's disease; PD, Parkinson's disease; MMSE, Mini Mental State Examination; H&Y, Hoehn & Yahr; ADL, Activities of daily living; PDQ-39 SI, Parkinson's Disease Quality of Life Questionnaire Summary Index; BELA-A-k, Belastungsfragebogen Parkinson Angehörigen kurzversion.

[1] missing in 5 CP patients and 11 CP caregivers.

[2] missing in 2 RCT-I patients and 2 RCT-C patients.

[3] missing in 1 CP patient.

[4] missing in 2 RCT-C caregivers.

[5] missing in 1 RCT-I caregiver.

* $p < 0.05$ significantly different from RCT group.

Intervention

The Patient Education Programme for Parkinson's disease (PEPP) has a separate but parallel programme for patients and caregivers (4-7 persons per group). The PEPP is extensively described in a standardized manual,[10,11] which enables trainers to replicate the programme as in the RCT study. A summary of the contents can be found in A'Campo et al.[12] In short, the following coping strategies are trained during eight two-weekly sessions of 90 minutes duration: 1) taking a (pro-)active role in treatment, seeking information about PD; 2) self-monitoring of body, behaviour, cognitions and mood; 3) performing pleasant activities and relaxation; 4) stress management by replacing unhelpful and unrealistic thoughts with helpful and realistic thoughts; 5) dealing with or preventing depression and anxiety; 6) social competence such as communication and standing up for oneself; 7) ways to create and ask for social support. Session 8 is an overall practice and evaluation session. The programme was provided by healthcare professionals from nine different healthcare institutions (see acknowledgement). Trainers had followed the special two-day trainer course. Trainers were specialized (PD) nurses (n = 9), caregiver counselors (n = 2) social workers (n =2), psychologists (n = 2), occupational therapists (n = 2), a physiotherapist (n = 1), a patient activity leader (n=1), and a peer leader (n =1).

Assessments

All patients were evaluated by a trained research assistant on their disease severity with the Hoehn & Yahr (H&Y) scale,[13] on daily functioning with the Activities of Daily Living (ADL) scale,[14] and on global cognitive functioning with the Mini Mental State Examination (MMSE).[15] Quality of life (Qol) of the patients was assessed by the Parkinson's Disease Questionnaire (PDQ-39),[16,17] which provided a Summary Index. In the caregivers, psychosocial burden and need for help were assessed with the 'Belastungsfragebogen Parkinson Angehörigen kurzversion' (BELA-A-k).[18] During the programme, before and after each session, a 100-point Visual Analogue Scale[19] assessing current mood state (Mood-VAS) was administered. After the programme and at six-month follow-up, participants were asked to complete an evaluation questionnaire. Self-report questionnaires were filled out by the patients and caregivers at baseline, directly after the programme and at six-month follow-up at the site where the PEPP was provided, in the presence of a research assistant.

Statistical analysis

Statistical analyses were performed with the Statistical Package for the Social Sciences (SPSS 16.0). The significance level used for all analyses was $p < 0.05$. Participants from the CP group were compared with participants from the RCT group and completers were compared with drop-outs on characteristics, PDQ-39 and BELA-A-k (Pearson Chi-Square or independent t-tests). To assess differences in effectiveness between the present CP study and the RCT study, the effects on PDQ-39 and BELA-A-k were compared with effects found in the RCT data. Univariate tests (independent t-tests) were performed to compare the change scores (baseline minus post-intervention scores) between present CP group, the RCT-I and the RCT-C. The same Bonferoni adjusted p-value as in the RCT study was used to correct for multiple comparisons. To assess changes from baseline to six-month follow-up, one-way repeated measures ANOVA was used. Bonferoni adjustment for multiple comparisons was used for the post-hoc analyses. To compare pre/post –session mood ratings, a linear mixed model with random participant effect, fixed patient/partner, fixed time and a fixed before-after session effect was performed for patients and caregivers together. The data from the evaluation questionnaire were analyzed and compared with the RCT data descriptively.

Results

Participants

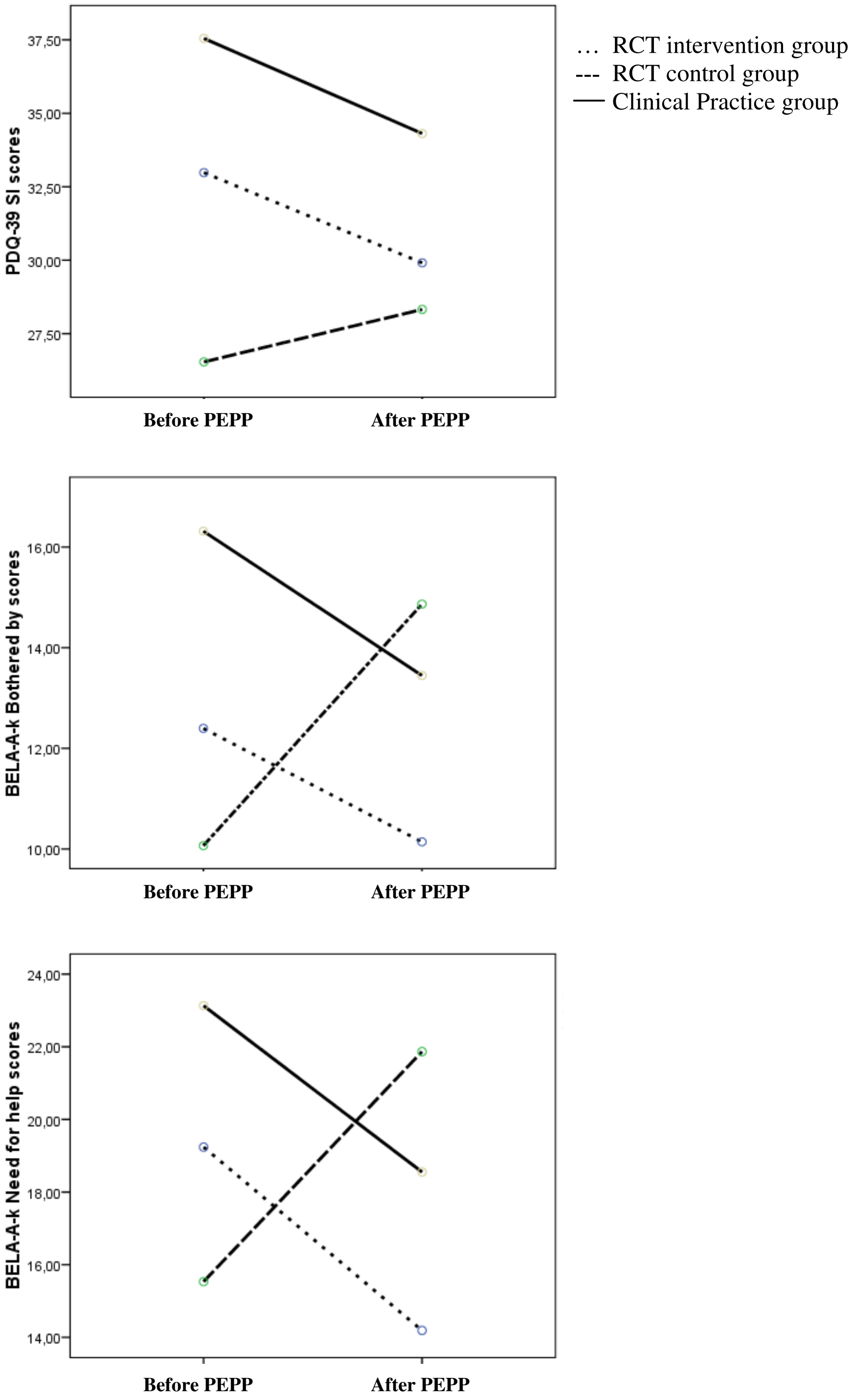
Forty-two patients and 40 caregivers completed all three assessments. At baseline, patients' scores on the PDQ-39 SI were significantly worse in the CP group as compared to the RCT group. Caregivers' scores did not differ between the groups.

Within the CP group, six patients and three caregivers dropped-out during the programme and another seven patients and seven caregivers dropped out before the programme or during follow-up. Patients who dropped out of the study, as compared to completers, had significantly better scores on the PDQ-39 SI (mean (SD) = 27.3 (15.7) versus 37.7 (13.4)). Regarding the caregivers, drop-outs as compared to completers had significantly better scores on the BELA-A-k Bothered By (mean (SD) = 8.2 (4.8) versus 16.5 (12.7)).

Short-term effects in CP compared to RCT

Significant CP short-term effects were found for the patients on the PDQ-39 SI ($p = 0.044$, after Bonferoni adjustment) as well as for the caregivers on the BELA-A-k Bothered by ($p = 0.005$, after Bonferoni adjustment) and Need for help ($p < 0.001$, after Bonferoni adjustment) scales. Patients reported a better quality of life after participation in the programme and caregivers less psychosocial burden and need for help. The short-term changes found in the CP group were not statistically different from the changes found in the RCT-I group (see Figure 2 and Table 2).

Figure 2 Scores before and directly after PEPP in the Clinical Practice and the Randomized Clinical Trial groups



Abbreviations: PEPP, Patient Education Program for Parkinson's disease; PDQ-39, Parkinson's Disease Quality of Life Questionnaire; BELA-A-k, Belastungsfragebogen Parkinson Angehörigen kurzversion; RCT, randomized controlled trial.

Table 2 Changes on outcome measures in the Clinical Practice and the Randomized Clinical Trial groups

	Mean change (SD)			Differences between groups p-value (p-value with Bonferoni)		
	CP	RCT-I	RCT-C	CP versus RCT-I	CP versus RCT-C	RCT-I versus RCT-C
Patients	*n* = 40	*n* = 29	*n* = 28			
PDQ-39 SI	3.8 (9.7)	3.1 (7.8)	-1.8 (6.7)	0.751 (1.00)	0.011 (0.044)*	0.015 (0.060)^
Caregivers	*n* = 34	*n* = 21	*n* = 15			
BELA-A-k						
-Bothered by	3.1 (7.4)	2.3 (5.4)	-4.8 (6.7)	0.656 (1.00)	0.001 (0.005)**	0.001 (0.005)**
-Need for help	5.0 (9.5)	5.1 (9.0)	-6.3 (8.4)	0.994 (1.00)	<0.001 (<0.001)**	0.001 (0.005)**

Values are Mean (SD), unless otherwise indicated. Abbreviations: CP, Clinical practice group; RCT-I, randomized controlled trial intervention group; RCT-C, randomized controlled trial control group; PDQ-39 SI, Parkinson's Disease Questionnaire Summary Index; BELA-A-k, Belastungsfragebogen Parkinson Angehörigen kurzversion. * significant $p < 0.05$, ** significant $p < 0.01$, ^ trend towards significance $0.1 < p > 0.05$.

Effects in CP at six-month follow-up

No significant changes were found between baseline scores compared to six-month follow-up. The scores returned to baseline levels at six-month follow-up. The significant improvement over time in CP patients' scores on the PDQ-39 SI (p = 0.045) was caused by the improvement from baseline to directly after the PEPP (Table 3). In the caregivers, significant changes over time were found in the BELA-A-k bothered by scale (p = 0.007) due to worsening of scores from directly after the PEPP to six-month follow-up.

Table 3 Changes in the Clinical Practice group on outcome measures from baseline to six-month follow-up

		Before PEPP	Directly after PEPP	6-month follow-up	p-value
Patients *n* = 42	PDQ-39 SI[1]	37.9 (13.4)	34.2 (13.1)	36.8 (13.0)	0.045*[a]
Caregivers	BELA-A-k				
n = 40	Bothered-by[2]	16.4 (13.1)	13.3 (11.5)	17.6 (13.1)	0.007**[b]
	Need for help[2]	23.6 (15.1)	18.6 (15.3)	23.3 (15.0)	0.889

Values are Mean (SD), unless otherwise indicated. Abbreviations: PDQ-39 SI, Parkinson's Disease Quality of Life Questionnaire Summary Index.; BELA-A-k, Belastungsfragebogen Parkinson Angehörigen kurzversion.

1 missing in 2 patients.

2 missing in 6 caregivers.

* significant p < 0.05, ** significant p < 0.01.

a: trend towards significant improvement between measurement 1-2.

b: significant worsening between measurement 2-3.

Mood-VAS

As in the RCT study, patients' and caregivers' scores on the Mood-VAS ($n = 77$) significantly improved during each session from mean = 68.1 at the beginning of the session to mean = 73.7 at the end of the session ($p < 0.001$, 95% CI: 4.6-6.7)) on the 100-point Mood-VAS. Mood also improved significantly from mean = 69.2 at the first session to mean = 73.7 at the last session ($p < 0.001$, 95% CI: 2.0-5.6). One site did not assess mood with the Mood-VAS. There was no difference in effects between patients and caregivers ($p > 0.05$).

Programme evaluation CP group

Regarding the programme evaluation directly after the programme, CP was comparable to RCT. At the six-month follow-up programme evaluation, about 45% of the patients and 70% of the caregivers reported some need for a follow-up session after the programme.

About 70% said they had benefited from the programme at six-month follow-up. Patients and caregivers were asked if they still used the learned coping strategies at six-month follow-up: relaxation training was still used in about 30% of the patients and caregivers; helpful and realistic thinking was used in about 40%; writing down questions for visit to a healthcare professional was still used in about 40%; planning pleasant activities was used in 50% of the patients and 65% of the caregivers; keeping a diary or records of problems was used in about 20% of the patients and 10% of the caregivers. According to 70% of the patients and 85% of the caregivers, communication had improved.

Discussion

This clinical practice study showed that the Patient Education Programme for Parkinson's disease (PEPP) is effective when provided in an uncontrolled 'real world' clinical practice within the Dutch healthcare system. A significant effect was found for patients' quality of life as compared to the control group of the recent randomized controlled trial (RCT), while in the RCT for this effect a trend towards significance was found.[12] Caregivers' significant improvements on psychosocial burden and need for help were replicated in clinical practice. These results indicate that the programme can be provided effectively by trained healthcare professionals in different kinds of clinical settings. Our findings are comparable with other clinical practice studies which also replicated RCT effects, namely Self-Management Intervention (SMI) research in chronic disease in general[20] and psychotherapy research.[21]

The finding that patients' Qol improvement was now significant indicates that the programme may be even more effective in clinical practice. However, improvements in the clinical practice group and RCT were comparable. Probably, the larger sample size created statistical significance. Furthermore, there was a difference in baseline Qol between the two study groups: clinical practice patients experienced a worse quality of life than the patients in the RCT. A worse Qol may have provided more opportunities for improvement, as has been found in other research.[22] This may also be indicated by the finding that completers as compared to drop-outs experienced a worse quality of life (patients) or more psychosocial burden (caregivers). More problems or a greater burden arising from the disease may increase the need for and possibility to benefit from the programme.

The baseline difference in Qol may be related to differences between the two groups regarding need for help. Clinical practice patients were often in treatment at a clinical setting or were referred for psychosocial treatment by a healthcare professional. In the RCT setting, participants often applied because of wanting to participate in research and less likely because of the psychosocial need for help.

Also, a common difference in clinical practice studies as compared to RCT studies is the lack of exclusion criteria.[21,23] In the present clinical practice study no exclusion criteria were used: trainers from the different sites were responsible for inclusion of participants. For example, at one site the study included a caregiver who was recently diagnosed with PD. In the RCT, this caregiver would have been excluded from the study.

At the six-month programme evaluation, a substantial proportion of the participants (70%) still confirmed they derived benefit from the programme. However, the short-term effects identified did not remain at six-month follow-up. Scores generally improved from baseline measurement to short-term measurement, and worsened again at six-month follow-up. However, a temporary improvement may be beneficial because it may lead to a deceleration of Qol deterioration. Qol deterioration is expected in PD as with the neurodegenerative character of the disorder, quality of life is increasingly challenged as the disease progresses. In a recent study, a 5% worsening of quality of life scores in PD after two years was found.[6] So, deceleration of Qol deterioration may be an important and economic beneficial effect of the programme.[24] Unfortunately we were not able to compare the CP six-month follow-up data with RCT control group data at six-month follow-up.
In most studies on self-management interventions and interventions regarding rehabilitation in PD, effects tend to disappear at long-term follow-up.[25-27] In the clinical practice study by Lorig, improvements did sustain at one-year follow-up on various outcomes measures.[20] To sustain effects of the PEPP for a longer period, a booster session for example after three months may be helpful to practise the knowledge and skills provided in the programme. The possible benefits of a booster session need further examination. In education in general, repetition is an important facilitator of learning.[28] Repetition may be especially important in Parkinson's disease where patients generally acquire procedural knowledge at a slower rate.[29]

A limitation of the study is that PEPP groups of trained health care professionals were included. The effects identified may not be replicated in groups of untrained trainers or trainers who did not apply voluntarily for participation in the study. The trainers included in this study may have applied feeling confident about their capacities as a trainer. PEPP groups with untrained trainers would be of interest for future research, as the manual is freely available. Another limitation is that the control group was derived from the RCT study. We corrected for baseline differences in Qol (by using difference scores), but more differences may be present between the two groups, making comparison with the RCT control group a limitation. In future research, the effects with a clinical practice control group should be assessed. Furthermore, a control group including the six-month follow-up assessment should be included, because of the expected decrease of Qol scores over time.

In conclusion, the Patient Education Programme for Parkinson's disease (PEPP) is effective in clinical practice. The effect on patients Qol was now found to be significant and the significant improvements in psychosocial burden and need for help for caregivers were replicated. Effects disappeared at six-month follow-up, indicating the need for a booster session.

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