

## **Evaluation of a psychoeducational intervention compared with education in people with Parkinson's disease and their informal caregivers: a quasi-experimental study**

### **ABSTRACT**

**Aim:** To evaluate the effects of a psychoeducational intervention compared with an education program to strengthen quality of life, psychosocial adjustment and coping in people with Parkinson's disease and their informal caregivers.

**Design:** A quasi-experimental study was performed with repeated measures at baseline, after the intervention and six months post-intervention.

**Methods:** The study was carried out at seven primary care centers from 2015-2017. A total of 140 people with Parkinson's and 127 informal caregivers were allocated to the experimental and the control groups. The experimental group received a 9-week psychoeducational intervention, whereas the control group received a 5-week education program. Repeated measures ANOVA were used to test differences in quality of life, psychosocial adjustment and coping between the experimental and control groups and over time.

**Results:** Patients and informal caregivers in both the experimental and control groups showed significantly better psychosocial adjustment at the post-intervention measurement compared with baseline data. We also found significantly greater quality of life in patients and coping skills in caregivers after the end of the interventions in the experimental and control groups. Nevertheless, no significant differences were identified on the outcomes at the six-month post-intervention measurement.

**Conclusion:** The effect of the psychoeducational intervention was not different from the effect of the education program. The strategies applied in both interventions followed a group approach led by a multidisciplinary team covering information about PD, healthy lifestyles and social resources. They might be easily

sustained in Primary Care to improve care for people with Parkinson's and informal caregivers.

## **IMPACT**

- This study addressed the lack of interventions with a psychosocial component that could influence the coping skills and quality of life of people with Parkinson's and informal caregivers.
- Positive effects on psychosocial adjustment, coping and quality of life in people with Parkinson's and their informal caregivers in the short term.
- Findings from this study could help to implement multidisciplinary and nurse led strategies in Primary care to reinforce patients' and informal caregivers' coping skills and ability and adjustment to Parkinson's disease, ensuring higher quality of care.

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**Key words:** adjustment, coping skills, informal caregivers, nursing, parkinson's disease, primary care, psychoeducational intervention, quality of life, quasi-experimental, multidisciplinary intervention

## **1. INTRODUCTION**

Parkinson's disease (PD) is a chronic neurodegenerative condition affecting around 10 million individuals worldwide. Currently, PD is generating great interest in society and health care institutions because it is causing a significant burden to the patients, families and health care systems (EPDA, 2019; Kowal et al., 2013; Mosley et al., 2017; Olesen et al., 2012). Bradykinesia, rigidity, resting tremor and postural instability, as well as sleep, emotional and cognitive disorders are some of the symptoms of PD. These motor and non-motor symptoms have a significant impact on the patients' quality of life (Antonini et al., 2012; Prakash et al., 2016; Simuni et al., 2018). As PD progresses, performing daily tasks becomes more difficult and frequently produces changes in patients' roles in their family and society (Haahr et al., 2011; Wressle et al., 2007). Most of these changes are perceived by patients with PD as losses (Charlton & Barrow, 2002; Haahr et al., 2011; Navarta-Sánchez et al., 2017). Hence, as with other long-term conditions (LTCs), people with PD must learn how to manage and live with their illness and how to find meaning and balance in their lives (Ambrosio et al., 2015; Boehmer et al., 2016). Therefore, health care systems should not only tackle the symptoms of PD, but also encourage patients with PD to develop their own process of psychosocial adjustment, coping and self-management (Kang & Ellis-Hill, 2015; Schipper et al., 2014; Shin & Habermann, 2017).

Informal caregivers of people with PD are deeply involved in daily care and it has been widely shown that fulfilling this caregiver role leads to social changes, as in the leisure activities with friends or relatives, in the household chores and in the family responsibilities (Lageman et al., 2015; Mosley et al., 2017). Many studies indicate that caregivers can also face uncertainty, burden, depression, stress and lower quality of life (Habermann & Shin, 2016; Hurt et al., 2017; Lageman et al., 2015; Lyons et al., 2004; Morley et al., 2012; Mosley et al., 2017; Theed et al., 2017). In addition, evidence supports the importance of helping informal caregivers manage the tension that arises from making care decisions and the social changes and losses they experience because of the new circumstances to improve their well-being and health (Mosley et al., 2017;

Shin & Habermann, 2017). Nevertheless, health care services do not generally address the social and psychological impact on informal caregivers of people with PD (Habermann & Shin, 2016; Mosley et al., 2017; Shin & Habermann, 2017).

### **1.1. Background**

Currently, the Chronic Care Model (CCM) has become an international benchmark to improve care for people with LTCs and their informal caregivers in the community. Many studies have reported positive outcomes in patients with LTCs with interventions based on components of the CCM (Flanagan et al., 2017). At present, the CCM has been applied in interventions focused on patients with diabetes, COPD or heart failure (Bodenheimer et al., 2002; Flanagan et al., 2017). However, the CCM has been scarcely used in interventions for patients with PD (Connor et al., 2015; 2019), despite its potential benefits to empower patients in the management of their condition.

According to the World Health Organization (2005), a recommended strategy in LTCs to address economic consequences and the impact on the patients' quality of life is the development of multidisciplinary health-care teams, centered on Primary health care. However, Primary care for patients with PD in many countries does not encompass a multidisciplinary team approach.

Most multidisciplinary interventions in patients with PD (Tan et al., 2014) were education programs focused on improving their self-management (in terms of symptoms, medication, healthy lifestyle) without considering the psychosocial challenges that PD may impose on patients (Suzukamo et al., 2006) and their family caregivers (Haahr et al., 2013; Hempel et al., 2008; Martin, 2016; Shin & Habermann, 2017). Only one multidisciplinary intervention (A'Campo et al., 2010) has been identified to improve the psychosocial adjustment to PD in both patients with PD and their family caregivers with promising results. The intervention showed a positive effect in caregivers' psychosocial problems and patients' and caregivers' mood.

However, this intervention (A'Campo et al., 2010) did not tackle the coping ability and this gap has been addressed in the present study.

It is particularly necessary to reinforce patients' and informal caregivers' ability to cope with PD. This may be through psychoeducational interventions, which help patients with PD and their informal caregivers to manage the stress of coping with their new social circumstances (Folkman & Moskowitz, 2004). In recent years, different studies have highlighted the potential benefits of psychosocial interventions to promote a comprehensive care plan for people with LTCs (Jiang et al., 2018; Kok et al., 2015). However, there is a lack of psychoeducational interventions to help patients with PD and their informal caregivers, mainly spouses, to facilitate their coping, adaptation to the new situation and reorganization of their life story (Lageman et al., 2015; Shin & Habermann, 2017).

Moreover, patients' ability to live with a LTC and manage it on their own is influenced by the support they receive from their friends and family (Boehmer et al., 2016; Kang & Ellis-Hill, 2015; Whitehead et al., 2018). A lack of empathy from family may prevent people who are living with a LTC from activating their ability to overcome changes and adapt to the new situation (Boehmer et al., 2016). In fact, family interventions are receiving greater attention to empower patients with LTCs to manage their condition (Smith et al., 2020). Thus, the present quasi-experiment focused on patients with PD and their informal caregivers simultaneously because family and personal support networks are paramount to achieving better outcomes in symptom management, coping and well-being (Deek et al., 2016; Smith et al., 2020; Vassilev et al., 2016).

Based on this evidence, this study has evaluated the effects of two multidisciplinary interventions based on the CCM to promote an active role in managing the PD in patients and their family caregivers. The intervention in the control group included an education program, whereas the experimental group received a

psychoeducational intervention to strengthen quality of life, psychosocial adjustment, and coping.

## **2. THE STUDY**

### **2.1. Aim**

To evaluate the short and long-term effects of a psychoeducational intervention compared with an education program to strengthen quality of life, psychosocial adjustment and coping in people with Parkinson's disease and their informal caregivers.

#### ***2.1.1. Hypothesis***

Patients with PD and their informal caregivers in the psychoeducational intervention will have higher levels of quality of life (primary outcome), psychosocial adjustment and coping skills (secondary outcomes), than those who will receive the education program over time.

### **2.2. Design**

A quasi-experimental study with control group and repeated measures at baseline (T0), just after the intervention (T1) and six months post-intervention (T2) was carried out as indicated in the study protocol (Navarta-Sánchez et al., 2018). This design was used to assess the effects of a psychoeducational intervention implemented in the experimental group compared with an education program delivered to the control group.

### **2.3. Participants and assignment**

In this study, patients with PD and their primary informal caregivers were recruited from seven primary care centers in the public health system in Northern Spain. All patients with PD and caregivers who potentially met inclusion criteria were invited to the study through a letter sent by healthcare professionals of the participating centers to the patients' homes. The letters contained information about the study and how to join it.

Participants were recruited through consecutive sampling after an interview with a member of the research team to evaluate if they met the inclusion criteria: patients with PD, at any stage, without cognitive impairment, who were receiving care as outpatients at the participating centers and were fluent in Spanish; informal caregivers over 18 years of age, who were fluent in Spanish, lived or maintained a close relationship with the patient and actively collaborated in his/her care.

In this study, randomization of patients was not feasible due to potential contamination between patients because they interacted with each other in their visits to the same primary care center. To avoid this contamination between the control and experimental groups, a coin was tossed to randomly assign the experimental intervention to three centers and the control group to four other centers (Lim & In, 2019).

Participants in the experimental and control groups received the intervention at different primary care centers between March 2015 - October 2017. After the psychoeducational or education program ended, there was a follow-up at six months for both groups. This procedure was repeated four times: in March 2015, October 2015, September 2016, March 2017. An additional control group was carried out in November 2017 with the corresponding follow-up to reach the calculated sample size for a total of seven centers participating in the study.

Participants were blinded to intervention assignment because they were aware only of the intervention they received at their primary care center. In other words, they did not know if they belonged to the control or experimental group. The professionals who helped the participants with quantitative data collection were blinded to intervention assignment.

#### **2.4. Sample size**

The sample size was calculated using the statistical program STATA 12.1 to detect a medium-large difference in the primary outcome (quality of life), based on data from previous studies which used the same quality of life scales. The size effect

(clinically relevant difference) was set at 10 in patients and 15 in caregivers and the mean and standard deviation on which the sample size was based was 29.03 (15.44) in patients (PDQ-39 scale) and 104.70 (25.04) in caregivers (SQLC scale) (Advocat et al., 2016; Martínez-Martín et al., 2005; Navarta-Sánchez et al., 2016). The statistical significance was set at  $p < 0.05$ . The assumed power was 0.80.

The calculated sample size was 52 patients and 53 family caregivers for the experimental group and the same number of patients and caregivers for the control group. This sample size was calculated to allow for a 25% patient dropout rate and a 20% caregiver dropout rate, according to findings from previous research (Lindskov et al., 2007; Rico-Blázquez et al., 2014).

## **2.5. The experimental intervention and the control group**

The experimental group received a psychoeducational intervention, whereas the control group received the education program, both led by a multidisciplinary team (Table 1).

The interventions for control and experimental group were developed based on the Chronic Care Model (CCM) (Coleman et al., 2009) and previous research. The philosophy of the CCM determined that participants in the present quasi-experiment were motivated to increase their abilities to enhance their autonomy and quality of life; and encouraged participants to use community resources.

The interventions already tested (A'Campo et al., 2010; Advocat et al., 2016; Hempel et al., 2008; Lindskov et al., 2007; Tan et al., 2014) were also analyzed to design both interventions. Finally, we conducted earlier research to identify specific needs of patients with PD and their informal caregivers in our context (Navarta-Sánchez et al., 2017) and addressed them in the interventions.

The specific approach in the experimental group was a psychoeducational intervention which provided support to better understand and cope with PD in patients with PD and their informal caregivers. It was characterized by encouraging participants to think about how they cope with PD and exchange their personal experiences with



other people in the group. This procedure was planned to help participants recognize their cognitive and behavioral coping skills, reflect on them and identify other coping skills that could help them adjust to PD even more. The promotion of coping and psychosocial adjustment to PD was delivered in four sessions led by professionals and an expert patient who only partook in the experimental group (Table 1). This approach was based on previous research (Suzukamo et al., 2006; Navarta-Sánchez et al., 2016), which highlight that psychosocial adjustment may contribute to improve quality of life in patients with PD and informal caregivers; and in evidence which associate coping and psychosocial adjustment (Folkman & Moskowitz, 2004; Navarta-Sánchez et al., 2016). Coping skills were understood as defined by Lazarus and Folman (Folkman & Moskowitz, 2004).

The education program for the control group included general information about PD, healthy lifestyles and different community resources. This program was designed to be similar to the education generally received by patients with PD and informal caregivers as part of standard care from social and health care professionals in our context.

## **2.6. Data collection**

The primary outcome was the improvement in quality of life of the patients with PD and informal caregivers in the experimental group compared with the control group. The secondary outcomes were the changes observed in coping skills and psychosocial adjustment in both groups.

Data were collected at T0 and T1 in the primary care centers from participants at an appointment. At T2, data were collected from a postal survey and, if participants did not send their survey data, they were collected through a telephone conversation.

Data were measured in the experimental group and control group with the following measuring instruments:

- The Parkinson's Disease Questionnaire-39 (PDQ-39): this scale was used to measure the quality of life in patients with PD. It is a 5-point Likert scale with 39

items and the scores can range from 0 (no problems) - 100 (many problems). It has been validated in Spanish and presents appropriate psychometric properties (Cronbach's  $\alpha$  ranged from 0.63-0.94 in all dimensions) (Martínez-Martín et al., 1998a). In the present study, Cronbach's  $\alpha$  ranged from 0.93-0.96 in the PDQ-39.

- The Scale of Quality of Life of Caregivers (SQLC): this scale assessed the quality of life of informal caregivers of PD patients through 16 items. The score is classified in four levels of impact on quality of life: none (141-149), mild (100-140), moderate (86-99) and severe (lower than 85) (Glozman et al., 1998). That is, high scores in SQLC show good quality of life, which is inverse to the scores of PDQ-39 in patients. The SQLC has been validated in Spanish and is a reliable instrument ( $\alpha > 0.80$ ) (Martínez-Martín et al., 1998b). Cronbach's  $\alpha$  ranged from 0.87-0.88 in the SQLC in our study.
- The Psychosocial Adjustment to Illness Scale (PAIS-SR): this scale with 46 items was applied to evaluate the psychosocial adjustment of patients with PD and caregivers to the new situation caused by PD. The highest score is 138, but a score above 62 indicates that the person has difficulties adjusting to illness. The specific version for patients has been validated in Spanish (Crespo Hervas & Ferre Navarrete, 1992), whereas the version for caregivers has not. Therefore, a process of back-translation was carried out to obtain a Spanish version with three bilingual people who were experts in psychosocial research and neurological disease (Bullinger et al., 1998). The PAIS-SR is used internationally and presents solid psychometric properties (Knafo et al., 2009). In the current research, Cronbach's  $\alpha$  ranged in the PAIS-SR from 0.90-0.92 in patients and 0.89-0.92 in caregivers.
- The BRIEF COPE Scale: it was used to measure coping skills in patients with PD and informal caregivers. It consists of 24 items and the score for each item can range from 1 (not doing the coping skills at all) - 4 (doing it very frequently) (Carver, 1997). The maximum score is 96 and the minimum is 24. High scores

indicate that the person uses coping skills very frequently. The scale has been validated in Spanish (Perczek et al., 2000). In this study, Cronbach's  $\alpha$  ranged in the BRIEF COPE scale from 0.81-0.88 in patients and 0.83-0.84 in caregivers.

Sociodemographic data were also collected at T0. On average, participants spent around 75 minutes completing the instruments described above.

## **2.7. Ethical considerations**

Ethical approval for this study was obtained from the Ethics Committee of the University of Navarre (ref 99/2013 mod 1). Participants were informed of the study details and signed an informed consent form that stated their decision to take part in the study was voluntary, did not affect to their healthcare and that they had right to leave the study at any time.

## **2.8. Data analysis**

Data are summarized as mean (SD) or counts and percentages, Chi-squared tests, Fisher's exact test and unpaired student *t* tests. Repeated measures ANOVA were used to compare the control and experimental groups and assess changes over time and the Time\*Group interaction effect. When comparing both groups at T1 and T2, ANCOVAs were performed to adjust for baseline differences. The statistical significance was set at  $p < 0.05$ . The smallest unit analyzed to assess intervention effects was the individual patient or caregiver with complete data. Analysis was performed in SPSS version 23.0.

## **2.9. Validity and reliability**

The repeated measures over time and the baseline comparison between groups have been applied to increase the rigor of this study. Also, we used validated scales that have shown reliability in previous research and in the present study to increase the validity and reliability of the data. The multidisciplinary team who delivered the interventions used a manual which contained a detailed description of the content and methodology of each session to improve adherence to intervention's characteristics of each group. The same team delivered the interventions in the seven primary care centers to ensure

intervention fidelity. This article is adhered to the CONSORT Statement (Schulz, Altman, & Moher, 2010).

### **3. RESULTS**

#### **3.1. Participant characteristics**

A total of 140 patients and 127 informal caregivers participated in the baseline measurement, 92.9% of patients and 89.0% of caregivers completed post-intervention measurement T1 and 83.6% of patients and 78.0% of caregivers participated in post-intervention T2 (Figure 1).

Based on the total number of patients and caregivers invited through letters to participate in the study, the participation rate was 25.6% in patients and 23.2% in caregivers. Regarding the percentage of dropouts, of the 140 patients and 127 caregivers who started in the experimental or control group, 7.1% (N = 10) of patients and 11% (N = 14) of caregivers were excluded to follow-up in measurement T1 because they did not attend 70% of the intervention sessions. In addition, 10% (N = 13) of patients and 12.4% (N = 14) of caregivers were lost in post-intervention measurement T2 because they did not send the questionnaire by postal service (Figure 1).

Patients in the experimental and control groups were on average 75.4 (SD 8.2) and 72.4 (SD 8.2) years of age, respectively. Most of patients in both groups were male (67.7% versus 70.7%). Most patients had PD at Hoehn & Yahr stages I, II and III. Caregivers in the experimental and control groups were on average 66.5 (SD 12.4) and 63.9 (SD 14.3) years of age, respectively. Most of caregivers in both groups were female (83.3% versus 80.8%). Most caregivers were the patients' spouses (70.4% versus 60.3%) (Table 2). The analyses of demographic and disease characteristics on lost-to-follow-up patients and caregivers revealed no significant differences with the participants who remained in the study.

#### **3.2. Comparison of group outcomes at baseline**

There were no significant differences between the experimental and control groups in the sociodemographic variables, except for the age and marital status of patients. As outlined in Table 1 patients in the experimental group were significantly older than in the control group (student  $t = 2.151$ ,  $p = 0.033$ ) and there were more single participants in the control group (student  $t = 10.352$ ,  $p = 0.014$ ).

Moreover, there were no significant differences at baseline between participants in the experimental and control group in terms of quality of life, psychosocial adjustment and coping skills, except in the case of patients in the “Health care orientation” domain of PAIS-SR (student  $t = -2.886$ ,  $p = 0.005$ ) with patients in the experimental group having more difficulties than those in the control group.

Regarding findings at baseline, patients and caregivers in the experimental and control groups noticed a mild impact on quality of life, revealed minor difficulties in their psychosocial adjustment to illness and used coping skills infrequently (Table 3).

### **3.3. Impact of the interventions on quality of life**

Findings showed that patients in both groups (experimental and control) improved their quality of life significantly after the intervention at post-test measure T1 (Table 3). This is observed in the statistically significant decrease ( $F_{2,107} = 8.49$ ,  $p < 0.001$ ) for the total PDQ-39 score at post-intervention measurement T1 (Figure 2). However, this benefit exhibited at T1 was not maintained at T2. In addition, there were no differences ( $F_{2,107} = 0.59$ ,  $p = 0.554$ ) between the experimental group and the control group in terms of patient quality of life (see Supplement 1 for findings on subscales).

Results in caregivers pointed out caregivers from neither group improved their quality of life after receiving the intervention ( $F_{2,86} = 0.96$ ,  $p = 0.386$ ). Moreover, the quality of life of the caregivers in the experimental group was similar to caregivers in the control group throughout the study because there were no significant differences ( $F_{2,86} = 1.89$ ,  $p = 0.157$ ).

### **3.4. Impact of the interventions on psychosocial adjustment to the illness**

Regarding patients, findings indicate considerable improvement in their psychosocial adjustment to PD after the intervention. This result is showed in the statistically significant decrease ( $F_{2,88} = 8.28, p = 0.001$ ) in the total PAIS-SR score at post-intervention measurement T1 in the experimental and control groups (Figure 2). However, this positive result was not found at post-intervention test T2. Additionally, there were no significant differences ( $F_{2,88} = 0.14, p = 0.868$ ) between the level of psychosocial adjustment expressed by patients in the experimental group and the control group.

The results of caregivers in psychosocial adjustment were in line with the findings in patients. As shown in Figure 2, caregivers in both groups improved their psychosocial adjustment to illness ( $F_{2,66} = 3.88, p = 0.026$ ) by the end of the intervention (T1). Nevertheless, this positive change was not repeated at the six-month follow-up (T2). There were no significant differences ( $F_{2,66} = 0.03, p = 0.967$ ) in the psychosocial adjustment achieved by caregivers in the experimental group and control group.

### **3.5. Impact of the interventions on coping skills**

Patients in both groups did not improve ( $F_{2,105} = 0.76, p = 0.471$ ) their coping skills after the intervention (Table 3). There were no significant differences ( $F_{2,105} = 0.01, p = 0.988$ ) between the coping skills displayed by patients in the experimental group and the control group (Figure 2).

In contrast, caregivers significantly improved ( $F_{2,87} = 5.95, p = 0.004$ ) their coping skills at post-test T1 after the end of the intervention in both groups. However, this improvement was not found at post-test T2 six months after the intervention. There were no significant differences ( $F_{2,87} = 0.25, p = 0.781$ ) in the coping skills displayed by caregivers in the experimental group and the control group.

## **4. DISCUSSION**

The findings from this study reveal that the psychoeducational intervention was not better than the education program in terms of the variables studied. Both

interventions improved quality of life and psychosocial adjustment in patients with PD and psychosocial adjustment and coping skills in caregivers. These benefits were found only in the short term and were not maintained six months after the intervention.

In both the experimental and control groups, better quality of life was noted in patients at post-intervention measurement T1. Although this finding seems promising as both educational interventions had a positive effect on quality of life, we need to be cautious in the interpretation of this as we did not have a non-treatment group to compare findings with in this study. However, previous research has also found improved quality of life in patients with PD when benefiting from an education program in different European countries (A' Campo et al., 2010; Chlond et al., 2016). These previous interventions provided information on Parkinson's disease, healthy lifestyles and social resources and the present study addressed these same topics in both interventions. It is therefore, necessary to establish guidelines to ensure that patients with PD and their informal caregivers receive comprehensive care to improve their quality of life that it is not focused only on symptoms, but also on healthy lifestyles and social resources.

Significant improvements were observed in the psychosocial adjustment and coping skills of informal caregivers in the present study. This was one of the study's relevant contributions, given the limited number of interventions focused on the needs of informal caregivers of patients with PD (Hempel et al., 2008; Shin & Habermann, 2017). Moreover, the promotion of psychosocial adjustment and coping skills in caregivers could prevent the development of feelings of burden, depression and uncertainty. Health care services should deal with the psychosocial needs of informal caregivers of patients with PD (Habermann & Shin, 2016; Mosley et al., 2017; Shin & Habermann, 2017).

The present study did not identify significant differences in any of the outcomes at the six-month post-intervention measurement. This result was found in previous research in different countries (A' Campo et al., 2010; Nelson et al., 2011; Sunvisson et al., 2001), though the long-term effect was not assessed in other studies (Lindskov et al.,

2007; Macht et al., 2007; Simons et al., 2006; Tan et al., 2014; Trend et al., 2002). This could be due to the difficulty of maintaining long-term positive behavior and attitudes without any external support. Moreover, the progressive nature of PD might be a barrier to achieving sustainable change. Nevertheless, benefits in patient quality of life have been found at three-month follow-up (Chlund et al., 2016) and six-month follow-up (Tickle-Degnen et al., 2010). These significant long-term results could be explained by the fact that both interventions (Chlund et al., 2016; Tickle-Degnen et al., 2010) encouraged patients to transfer the learning gained in the research to their daily lives by asking participants to do homework and even organizing an individual home session. We therefore recommend including homework, individual home sessions and booster sessions in future research to identify significant differences in long-term measurements in patients with PD and their informal caregivers. In clinical practice, it is necessary that health care professionals reinforce the knowledge of patients with PD and their caregivers about the illness over the time, because this knowledge can promote better self-management (Stenberg et al., 2016) and reduce uncertainty (Årestedt et al., 2015; Hurt et al., 2017).

The present research has proven that it is feasible to implement multidisciplinary interventions at different primary care centers for people with PD and their informal caregivers. It should be noted that the multidisciplinary team was involved in the sessions for the experimental and control groups. This approach may be partly responsible for the significant improvements in both groups in terms of quality of life, psychosocial adjustment to illness and coping. Consequently, as in other LTCs, encouraging multidisciplinary teams in Primary care in patients with PD and their informal caregivers is essential to deal with the multiple physical, social and psychological challenges of PD (Coleman et al., 2009).

In this study sessions in groups were used for both interventions at the participating primary care centers during the research period in the experimental and control groups. The improvements in the outcomes in both groups could therefore be partially



associated with the supportive groups, which were perceived as safe environments for people to freely express their opinions and worries with equals (Stenberg et al., 2016). According to Stenberg et al (2016), working in groups may create an atmosphere of mutual learning by showing how other people deal with a LTC and thus increase participants' hope and optimism. Furthermore, participants could also benefit from the socialization and social support involved in the groups and in relation to the experience of living with a LTC by relieving stress and increasing self-confidence in conflictive situations (Stenberg et al., 2016; Portillo et al., 2017; Theed et al., 2017). Consequently, it is important to establish educational interventions in groups for patients with PD and their informal caregivers at primary care centers. This approach could help improve health care services for this population group by dealing with the social changes and psychosocial impact associated with PD.

Finally, we must clearly state that the results did not support our hypothesis. On the contrary, we found that the psychoeducational intervention did not have better outcomes than the education program. Consequently, the education program with five weekly sessions in small groups led by a multidisciplinary team covering basic information about PD, healthy lifestyles and social resources proved to be useful to improve health outcomes in patients with PD and caregivers. This could be more feasible to implement in Primary Care involving nursing personnel as coordinators of the interventions. However, at this stage and considering the short-term effect of both interventions and the progressive nature of needs of patients with PD, further research is needed to compare the education program with usual care and determine if an educational reinforcement after 3 months has any further and sustainable outcome. Moreover, research about interventions with an increased length of the psychological component is necessary.

#### **4.1. Limitations**

Some participants completed the follow-up (Figure 1), but they did not answer all items in some subscales (mainly in the Sexual relationships subscale of the PAIS-

SR). Consequently, the sample size in the RM-ANOVA is lower than the number of participants who completed the follow-up due to missing data. Nevertheless, the sample size was appropriate for the RM-ANOVA because, taking into account those lost to follow-up, the calculated sample size for this study was 39 patients and 42 caregivers per group. This circumstance was met in all groups, except for the experimental caregiver group (N = 37), which did not affect the validity of these results due to the slight difference. The intention-to-treat (ITT) analysis was not performed because the complete outcome data were not available for all participants (Gupta, 2011) (see Figure 1).

## **5. CONCLUSION**

The effect of the psychoeducational intervention was not different from the effect of the education program. The strategies applied in both cases followed a group approach led by a multidisciplinary team covering information about PD, healthy lifestyles and social resources. They might be easily sustained in Primary Care to improve care for people with Parkinson's and informal caregivers.

## **CONFLICT OF INTEREST STATEMENT**

The authors declare no conflict of interest.

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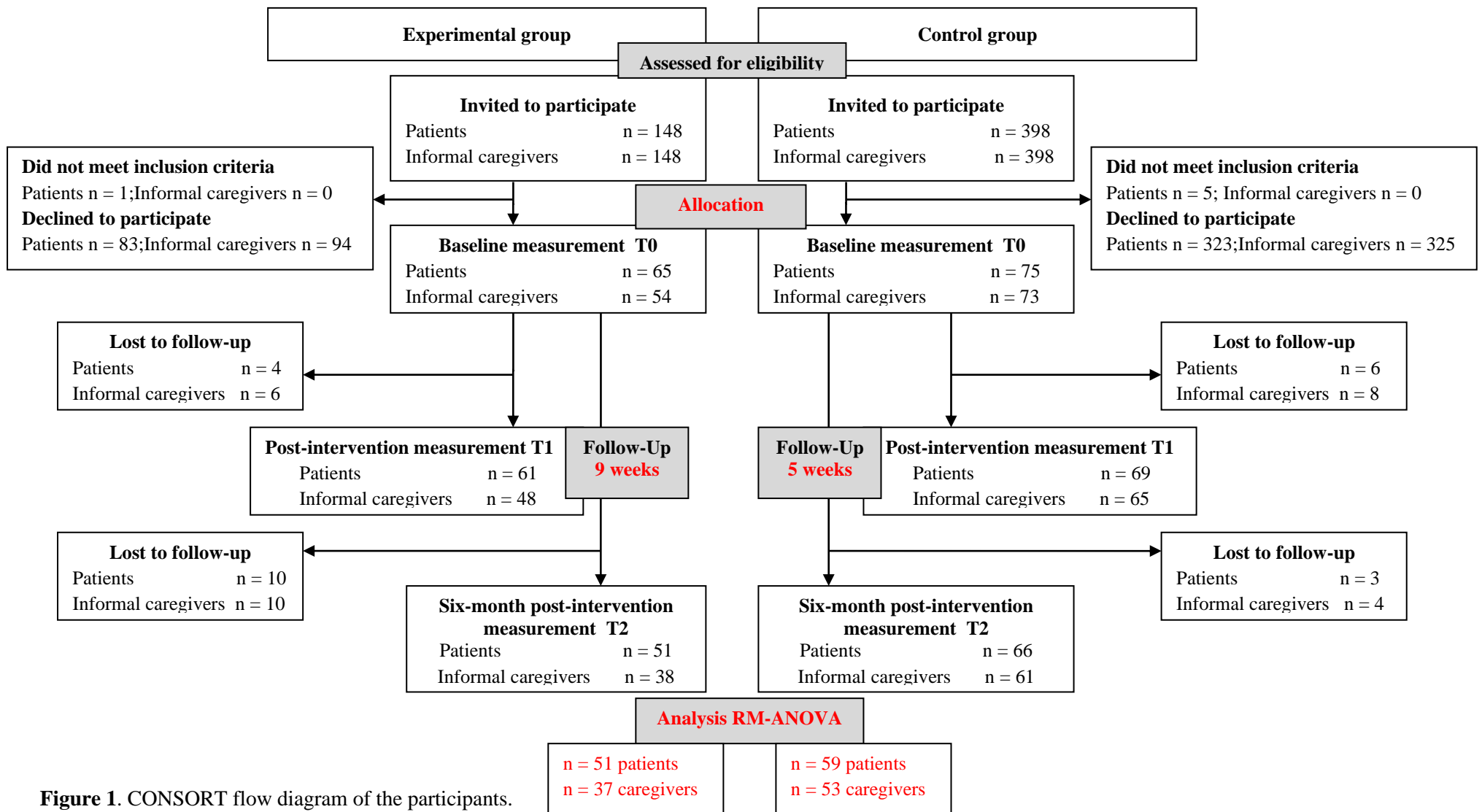


# CONSORT 2010 checklist of information to include when reporting a randomised trial\*

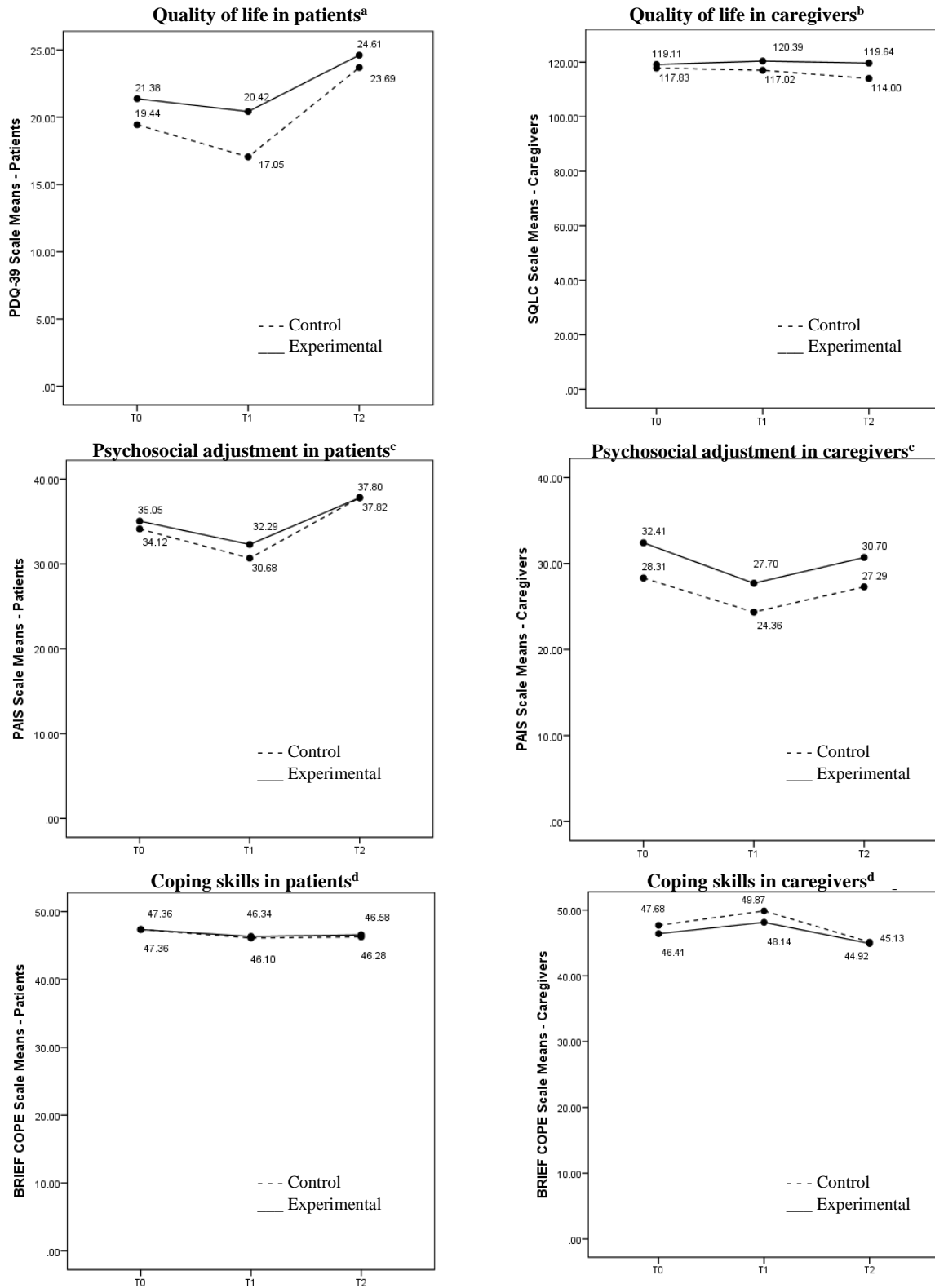
Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	3-4
	2b	Specific objectives or hypotheses	4
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5-6
Participants	4a	Eligibility criteria for participants	5-6
	4b	Settings and locations where the data were collected	5-6, 7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7, Table 1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-8, Figure 1
	6b	Any changes to trial outcomes after the trial commenced, with reasons	No
Sample size	7a	How sample size was determined	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	No
Randomisation:			5-6
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5-6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5-6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5-6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6

		assessing outcomes) and how	
Statistical methods	11b	If relevant, description of the similarity of interventions	6-7, Table 1
	12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	No
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1, 9-10
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1, 9-10
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	6
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 2, 9-10
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 3
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 3, 11-12
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	No
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	No
<b>Discussion</b>			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	13-16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13-16
<b>Other information</b>			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Title page

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming; for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).



**Figure 1.** CONSORT flow diagram of the participants.



**Figure 2.** RM-ANOVA results on quality of life, psychosocial adjustment and coping skills in patients and informal caregivers at T0 (Baseline), T1 (Post-intervention) and T2 (6 months Post-intervention).

<sup>a</sup> PDQ-39 scale, range 0 to 100, high scores show low quality of life; <sup>b</sup> SQLC scale, range 0 to 149, high scores show good quality of life, which is inverse to PDQ-39;

<sup>c</sup> PAIS scale, range 0 to 138, high scores show low psychosocial adjustment; <sup>d</sup> BRIEF COPE scale, range 24 to 96, high scores show frequent use of coping skills.



Outcome measure	Pre intervention Mean (SD)	Post, T1 Mean (SD)	Post, T2 Mean (SD)	Time effect, F (p)	Time*Group Interaction, F (p)
<b>PATIENTS</b>					
<b>PDQ-39 score</b>	Experimental, n = 51 Control, n = 59				
Mobility					
Experimental	30.0 (29.48)	27.34 (26.97)	37.45 (34.0)	12.63 (< 0.001)*	0.52 (0.594)
Control	27.07 (24.56)	21.50 (24.92)	34.10 (27.56)		
ADL's					
Experimental	26.47 (25.70)	24.93 (25.84)	33.17 (32.18)	7.62 (0.001)*	0.22 (0.801)
Control	23.28 (23.10)	19.74 (21.47)	29.73 (29.60)		
Emotional well-being					
Experimental	25.90 (23.38)	23.81 (21.69)	25.88 (24.45)	5.98 (0.003)*	0.89 (0.413)
Control	27.39 (21.61)	20.0 (17.76)	30.66 (20.97)		
Stigma					
Experimental	12.60 (16.77)	12.40 (15.57)	13.46 (18.50)	2.18 (0.118)	0.06 (0.941)
Control	13.67 (17.46)	9.90 (14.49)	13.90 (13.93)		
Social support					
Experimental	6.15 (13.36)	8.73 (17.29)	11.86 (17.49)	6.43 (0.002)*	0.12 (0.886)
Control	6.44 (11.26)	7.95 (13.77)	11.57 (15.95)		
Cognition					
Experimental	27.40 (19.79)	24.31 (19.25)	27.28 (20.60)	3.39 (0.037)*	0.26 (0.775)
Control	24.25 (20.21)	22.31 (20.40)	28.08 (19.50)		
Communication					
Experimental	15.0 (17.07)	19.63 (18.87)	18.27 (21.14)	2.24 (0.112)	0.40 (0.669)
Control	19.44 (19.58)	18.08 (21.38)	24.12 (22.27)		
Bodily discomfort					
Experimental	29.74 (27.60)	29.63 (24.67)	29.49 (24.83)	2.75 (0.068)	1.88 (0.157)
Control	28.11 (23.64)	22.95 (22.68)	34.20 (28.39)		
<b>PAIS-SR score</b>	Experimental, n = 51 Control, n = 59				
Health care orientation					
Experimental	9.51 (4.35)	8.16 (4.13)	8.43 (4.15)	2.07 (0.131)	1.07 (0.348)
Control	7.57 (3.58)	7.29 (3.47)	7.66 (3.63)		
Vocational environment					
Experimental	5.00 (3.56)	4.10 (3.90)	4.73 (3.62)	2.19 (0.117)	1.06 (0.349)
Control	5.08 (4.29)	5.08 (4.10)	5.66 (3.52)		
Domestic environment					
Experimental	5.34 (4.42)	4.59 (4.03)	4.73 (3.62)	5.05 (0.008)*	0.68 (0.509)
Control	4.73 (4.18)	4.03 (3.66)	5.66 (3.52)		
Sexual relationships (♂)					
Experimental	6.04 (4.49)	6.22 (4.75)	6.07 (4.06)	0.64 (0.532)	1.22 (0.299)
Control	4.83 (4.36)	4.16 (4.10)	5.27 (4.42)		
Extended family relation					
Experimental	1.28 (2.43)	1.38 (1.86)	1.37 (1.52)	1.88 (0.157)	0.62 (0.539)
Control	1.97 (2.97)	1.66 (2.05)	2.35 (2.56)		
Social environment					
Experimental	5.82 (5.47)	4.97 (5.37)	6.10 (5.44)	5.91 (0.004)*	0.65 (0.522)
Control	4.71 (4.97)	3.71 (4.22)	6.06 (4.64)		
Psychological distress					
Experimental	5.26 (3.62)	4.56 (3.71)	5.43 (3.49)	7.99 (0.001)*	0.32 (0.727)
Control	5.55 (3.75)	4.38 (3.46)	6.04 (3.44)		
<b>BRIEF COPE score</b>	Experimental, n = 51 Control, n = 58				
Active coping					
Experimental	4.75 (1.73)	4.87 (1.76)	4.51 (1.84)	0.16 (0.855)	1.01 (0.367)
Control	4.67 (1.93)	4.69 (2.11)	4.80 (1.68)		
Planning					
Experimental	4.57 (1.61)	4.25 (1.86)	4.35 (1.71)	0.41 (0.663)	0.80 (0.451)
Control	4.16 (1.92)	4.34 (1.95)	4.34 (2.03)		
Positive reframing					
Experimental	4.42 (1.50)	4.38 (1.85)	3.94 (1.69)	0.82 (0.443)	0.72 (0.488)
Control	4.24 (1.96)	4.15 (1.90)	4.25 (1.88)		
Acceptance					
Experimental	5.78 (2.00)	5.90 (1.86)	5.61 (1.89)	1.94 (0.149)	0.46 (0.632)
Control	5.91 (1.88)	5.38 (1.97)	5.27 (2.06)		
Humor					
Experimental	3.02 (1.65)	2.81 (1.56)	2.86 (1.56)	1.45 (0.240)	0.11 (0.900)
Control	3.36 (2.08)	3.28 (1.73)	3.02 (1.73)		
Religion					
Experimental	4.54 (2.29)	4.49 (2.31)	4.49 (2.31)	0.34 (0.711)	0.33 (0.721)
Control	3.99 (2.27)	4.31 (2.32)	4.31 (2.32)		

Using emotional support					
Experimental	5.29 (1.93)	5.17 (2.20)	5.02 (2.10)	1.47 (0.235)	0.19 (0.826)
Control	5.32 (2.08)	4.92 (2.04)	4.88 (1.93)		
Using self-distraction					
Experimental	3.86 (1.61)	4.11 (1.76)	4.14 (1.60)	2.46 (0.090)	0.90 (0.408)
Control	4.12 (1.79)	4.29 (1.94)	4.13 (2.10)		
Denial					
Experimental	2.97 (1.25)	2.84 (1.39)	3.08 (1.48)	1.27 (0.283)	0.54 (0.582)
Control	2.79 (1.15)	2.71 (1.26)	2.86 (1.39)		
Venting					
Experimental	3.34 (1.51)	3.24 (1.43)	3.25 (1.44)	0.25 (0.777)	1.35 (0.265)
Control	3.35 (1.66)	3.08 (1.19)	3.36 (1.41)		
Substance use					
Experimental	2.00 (0.0)	2.06 (0.40)	2.04 (0.28)	1.22 (0.299)	1.32 (0.272)
Control	2.05 (0.28)	2.14 (0.79)	2.20 (0.89)		
Behavioural disengagement					
Experimental	2.89 (1.20)	2.89 (1.19)	2.98 (1.44)	0.53 (0.469)	1.59 (0.209)
Control	2.79 (1.28)	2.69 (1.24)	2.89 (1.33)		
<hr/>					
<b>CAREGIVERS</b>	<b>Pre intervention Mean (SD)</b>	<b>Post, T1 Mean (SD)</b>	<b>Post, T2 Mean (SD)</b>	<b>Time effect, F (p)</b>	<b>Time*Group Interaction, F (p)</b>
<hr/>					
<b>SQLC score</b>	Experimental, n = 37 Control, n = 53				
<hr/>					
Professional activity					
Experimental	32.87 (4.36)	33.60 (4.47)	33.34 (5.11)	0.31 (0.736)	2.98 (0.056)
Control	32.88 (4.04)	32.23 (3.65)	31.92 (4.89)		
Social & leisure activities					
Experimental	44.19 (8.31)	44.25 (9.87)	45.11 (6.73)	0.05 (0.956)	0.86 (0.428)
Control	44.26 (8.08)	42.97 (9.13)	42.98 (9.80)		
Responsibilities to help					
Experimental	40.64 (14.45)	40.45 (14.88)	40.18 (14.36)	1.90 (0.156)	0.16 (0.849)
Control	38.66 (15.93)	39.23 (15.75)	37.54 (16.02)		
<hr/>					
<b>PAIS-SR score</b>	Experimental, n = 37 Control, n = 53				
<hr/>					
Health care orientation					
Experimental	9.30 (4.01)	7.44 (3.87)	8.29 (3.20)	4.90 (0.010)*	0.46 (0.632)
Control	8.04 (3.13)	6.78 (3.57)	6.69 (3.36)		
Vocational environment					
Experimental	2.64 (2.97)	2.65 (2.97)	2.71 (2.10)	0.43 (0.650)	0.06 (0.944)
Control	2.70 (3.17)	2.78 (2.77)	3.40 (3.31)		
Domestic environment					
Experimental	3.15 (3.11)	2.65 (3.03)	2.50 (2.74)	0.29 (0.748)	0.84 (0.436)
Control	2.99 (2.93)	2.65 (2.96)	3.54 (3.58)		
Sexual relationships (♂)					
Experimental	4.83 (4.51)	5.23 (5.02)	6.24 (3.87)	1.42 (0.249)	0.55 (0.579)
Control	4.54 (4.45)	4.35 (4.55)	5.20 (4.86)		
Extended family relation					
Experimental	1.62 (1.87)	0.98 (1.31)	1.29 (1.61)	2.11 (0.127)	1.11 (0.333)
Control	1.67 (2.00)	1.42 (1.77)	2.28 (2.52)		
Social environment					
Experimental	5.19 (5.20)	3.54 (4.73)	5.03 (5.24)	6.68 (0.002)*	0.11 (0.896)
Control	4.60 (5.38)	3.45 (4.16)	5.23 (5.70)		
Psychological distress					
Experimental	5.72 (3.49)	4.69 (3.02)	4.92 (3.48)	6.05 (0.003)*	0.43 (0.653)
Control	4.79 (3.40)	4.17 (3.15)	4.56 (3.36)		
<hr/>					
<b>BRIEF COPE score</b>	Experimental, n = 37 Control, n = 53				
<hr/>					
Active coping					
Experimental	5.19 (1.91)	5.04 (1.97)	5.37 (1.85)	4.69 (0.012)*	0.60 (0.552)
Control	5.25 (1.91)	5.50 (1.84)	5.15 (2.01)		
Planning					
Experimental	4.87 (2.10)	5.00 (1.91)	4.84 (1.52)	0.25 (0.782)	0.86 (0.428)
Control	4.97 (1.78)	5.23 (1.78)	4.72 (1.92)		
Positive reframing					
Experimental	4.42 (1.81)	4.90 (2.02)	4.34 (1.56)	0.24 (0.788)	1.04 (0.357)
Control	4.33 (1.76)	4.67 (1.75)	4.16 (1.56)		
Acceptance					
Experimental	6.04 (2.03)	6.31 (1.81)	6.24 (1.58)	0.62 (0.539)	0.96 (0.386)
Control	5.88 (1.86)	6.17 (1.72)	6.05 (1.94)		
Humor					
Experimental	2.58 (1.29)	3.00 (1.74)	2.53 (1.18)	2.42 (0.095)	0.21 (0.808)
Control	3.04 (1.61)	2.92 (1.50)	2.54 (1.07)		

Religion					
Experimental	4.98 (2.40)	4.94 (2.09)	4.87 (2.22)	0.52 (0.599)	0.09 (0.916)
Control	4.52 (2.26)	4.73 (2.39)	4.57 (2.35)		
Using emotional support					
Experimental	4.32 (2.16)	4.40 (2.18)	3.82 (1.86)	6.40 (0.003)*	1.03 (0.363)
Control	4.33 (2.01)	4.93 (2.10)	4.46 (1.99)		
Using self-distraction					
Experimental	3.64 (1.76)	3.69 (1.74)	3.29 (1.29)	6.76 (0.002)*	0.31 (0.736)
Control	3.70 (1.72)	4.27 (2.02)	3.39 (1.58)		
Denial					
Experimental	2.66 (1.30)	2.27 (0.69)	2.45 (0.83)	1.48 (0.235)	0.71 (0.493)
Control	2.47 (0.99)	2.70 (1.23)	2.59 (1.16)		
Venting					
Experimental	3.34 (1.58)	3.62 (1.69)	2.97 (1.26)	5.16 (0.008)*	2.60 (0.080)
Control	3.55 (1.33)	3.77 (1.37)	3.33 (1.26)		
Substance use					
Experimental	2.23 (1.15)	2.06 (0.42)	2.03 (0.16)	0.47 (0.626)	0.06 (0.942)
Control	2.01 (0.12)	2.03 (0.26)	2.03 (0.26)		
Behavioural disengagement					
Experimental	2.53 (1.30)	2.56 (1.27)	2.37 (0.85)	0.45 (0.641)	1.81 (0.170)
Control	2.52 (1.04)	2.48 (1.20)	2.41 (0.78)		

**Supplement 1.** Repeated measures ANOVA on subscales of quality of life, psychosocial adjustment and coping skills in patients and informal caregivers at Baseline (Pre-intervention), T1 (Post-intervention) and T2 (6 months Post-intervention).

(\*)  $p < 0.05$

(⊘) Missing data in 10 cases in the experimental group and 9 cases in the control group.

(●) Missing data in 10 cases in the experimental group and 11 cases in the control group.

Interventions' details		Experimental group	Control group
Deliverer and content	<ul style="list-style-type: none"> <li>• <i>General practitioner</i>: introduction to the intervention.</li> </ul>	✓	✓
	<ul style="list-style-type: none"> <li>• <i>Neurologist</i>: motor and non-motor symptoms of PD; pharmacological and surgical options of treatment.</li> </ul>	✓	✓
	<ul style="list-style-type: none"> <li>• <i>Nurse</i>: healthy lifestyles (diet, physical exercise, fall prevention, sleep/rest and social life).</li> </ul>	✓	✓
	<ul style="list-style-type: none"> <li>• <i>Social worker</i>: information about how to apply for the resources for people with disabilities and their families.</li> </ul>	✓	✓
	<ul style="list-style-type: none"> <li>• <i>General practitioner and expert patient</i>: the psychosocial adaptation to PD and coping skills in everyday life.</li> </ul>	✓	
	<ul style="list-style-type: none"> <li>• <i>Psychologist</i>: benefits of practicing positive self-esteem, empathy and patience in their everyday life.</li> </ul>	✓	
	<ul style="list-style-type: none"> <li>• <i>Psychologist</i>: relaxation techniques for the management the stress.</li> </ul>	✓	
	<ul style="list-style-type: none"> <li>• <i>Psychologist</i>: advantages of looking for information, living in the present, partaking in activities, searching for the normalization of the situation.</li> </ul>	✓	
	<ul style="list-style-type: none"> <li>• <i>General practitioner</i>: conclusions.</li> </ul>	✓	✓
Delivery method	<ul style="list-style-type: none"> <li>• One group session per week of 90 minutes (15-20 people at most in each group). The group session was delivered at the participants' Primary Care Center. Patients and Caregivers received the session at the same time in different room.</li> </ul>	✓	✓
Duration		9 weeks	5 weeks

**Table 1.** Comparison of the details from the intervention delivered in the experimental group versus the control group.

PATIENTS	Experimental group	Control group	Student <i>t</i> ( <i>p</i> )
	n = 65	n = 75	
	Mean (SD)	Mean (SD)	
Age	75.4 (8.2)	72.4 (8.2)	2.151 (0.033)
Years of PD diagnosis	5.8 (5.2)	7.8 (6.5)	1.924 (0.056)
	n (%)	n (%)	X <sup>2</sup> ( <i>p</i> )
Gender			
Male	44 (67.7)	53 (70.7)	0.145 (0.704)
Female	21 (32.3)	22 (29.3)	
Marital status			
Married	50 (76.9)	47 (62.7)	10.352 (0.014) <sup>a</sup>
Single	2 (3.1)	13 (17.3)	
Employment status			
Retired	52 (80.0)	58 (76.3)	
Housework	5 (7.7)	5 (6.6)	4.329 (0.525) <sup>a</sup>
Full-time job	1 (1.5)	5 (6.6)	
Education			
Elemental studies	29 (44.6)	29 (38.7)	6.763 (0.228) <sup>a</sup>
University studies	14 (21.5)	12 (16.0)	
Hoehn & Yahr			
Stage I	30 (46.2)	30 (40.0)	
Stage II	17 (26.2)	17 (22.7)	2.974 (0.576) <sup>a</sup>
Stage III	11 (16.9)	20 (26.7)	
Stage IV	6 (9.2)	5 (6.7)	
Stage V	1 (1.5)	3 (4)	
Comorbidity			
Yes	33 (50.8)	32 (42.7)	0.919 (0.338)
CAREGIVERS	Experimental group	Control group	Student <i>t</i> ( <i>p</i> )
	n = 54	n = 73	
	Mean (SD)	Mean (SD)	
Age	66.5 (12.4)	63.9 (14.3)	-1.086 (0.280)
Caregiving time (months)	59.3(63.0)	65.5 (81.5)	0.462 (0.645)
	n (%)	n (%)	X <sup>2</sup> ( <i>p</i> )
Gender			
Male	9 (16.7)	14 (19.2)	0.132 (0.716)
Female	45 (83.3)	59 (80.8)	
Marital status			
Married	47 (87.0)	55 (75.3)	6.370 (0.171) <sup>a</sup>
Single	6 (11.1)	12 (16.4)	
Employment status			
Retired	21 (38.9)	29 (39.7)	
Housework	16 (29.6)	14 (19.2)	3.254 (0.828) <sup>a</sup>
Full-time job	12 (22.2)	18 (24.7)	
Education			
Elemental studies	23 (42.6)	18 (24.7)	6.226 (0.280) <sup>a</sup>
University studies	12 (22.2)	19 (26.0)	
Relation with patient			
Spouse	38 (70.4)	44 (60.3)	2.077 (0.748) <sup>a</sup>
Son/Daughter	8 (14.8)	16 (21.9)	
Long term disease			
Yes	24 (43.6)	26 (36.1)	0.740 (0.390)

<sup>a</sup> Fisher's Exact Test.

**Table 2.** Patients' and caregivers' demographic and disease characteristics by group.

Outcome measure	Pre intervention Mean (SD)	Post, T1 Mean (SD)	Post, T2 Mean (SD)	Time effect, F (p)	Time*Group Interaction, F (p)
<b>PATIENTS</b>					
<b>Quality of life</b>					
PDQ-39 score total					
Experimental, n = 51	21.38 (14.12)	20.42 (14.78)	24.61 (18.54)	8.49 (< 0.001)*	0.59 (0.554)
Control, n = 59	19.44 (12.17)	17.05 (12.87)	23.69 (14.92)		
<b>Psychosocial adjustment</b>					
PAIS-SR score total					
Experimental, n = 51	35.05 (16.90)	32.29 (16.42)	37.80 (18.34)	8.28 (0.001)*	0.14 (0.868)
Control, n = 59	34.12 (19.59)	30.68 (17.72)	37.82 (17.34)		
<b>Coping skills</b>					
BRIEF COPE score total					
Experimental, n = 51	47.36 (9.18)	46.34 (10.28)	46.58 (12.13)	0.76 (0.471)	0.01 (0.988)
Control, n = 58	47.36 (11.21)	46.10 (11.39)	46.28 (11.30)		
<b>CAREGIVERS</b>					
<b>Quality of life</b>					
SQLC score total					
Experimental, n = 37	119.11 (22.55)	120.39 (23.68)	119.64 (21.86)	0.96 (0.386)	1.89 (0.157)
Control, n = 53	117.83 (23.49)	117.02 (23.57)	114.00 (27.33)		
<b>Psychosocial adjustment</b>					
PAIS-SR score total					
Experimental, n = 37	32.41 (16.33)	27.70 (14.51)	30.70 (13.04)	3.88 (0.026)*	0.03 (0.967)
Control, n = 53	28.31 (17.06)	24.36 (14.87)	27.29 (18.91)		
<b>Coping skills</b>					
BRIEF COPE score total					
Experimental, n = 37	46.41 (10.39)	48.14 (9.53)	44.92 (8.18)	5.95 (0.004)*	0.25 (0.781)
Control, n = 53	47.68 (10.21)	49.87 (10.51)	45.13 (10.82)		

**Table 3.** Repeated measures ANOVA on quality of life, psychosocial adjustment and coping skills in patients and informal caregivers at Baseline (Pre-intervention), T1 (Post-intervention) and T2 (6 months Post-intervention).

(\*)  $p < 0.05$