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Family-based psychosocial support and education as part of pulmonary rehabilitation in COPD: a randomized controlled trial

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ABSTRACT

Background: Involving family as part of the patient's rehabilitation plan of care might enhance the management of Chronic Obstructive Pulmonary Disease (COPD). The primary aim of this study was to investigate the impact of a family-based pulmonary rehabilitation (PR) program on patients and family members' coping strategies to manage COPD.

Methods: Family dyads (patient and family member) were randomly assigned to family-based (experimental) or conventional PR (control). Patients from both groups underwent exercise training three times a week and psychosocial support and education once a week, during 12 weeks. Family members of the family-based PR attended the psychosocial support and education sessions together with patients. In the conventional PR, family members did not participate. Family coping and psychosocial adjustment to illness were assessed in patients and family members of both groups. Patients' exercise tolerance, functional balance, muscle strength and health-related quality of life were also measured. All measures were collected pre/post-program.

Results: Forty-two dyads participated (patients: FEV₁ 70.4±22.1% predicted). Patients (p=0.048) and family members (p=0.004) in the family-based PR had significantly greater improvements in family coping than the control group. Family members of the family-based PR had significantly greater changes in sexual relationships (p=0.026) and in psychological distress (p=0.033) compared to the control group. Patients from both groups experienced significant improvements in exercise tolerance, functional balance, knee extensors strength and health-related quality of life after intervention (p<0.001).

Conclusions: This research supports family-based PR programs to enhance coping and psychosocial adjustment to illness of the family system.

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INTRODUCTION

Pulmonary rehabilitation (PR) has been demonstrated to be effective for patients with Chronic Obstructive Pulmonary Disease (COPD) during stable periods or shortly after an exacerbation.¹

This intervention has been also acknowledged as an important component of integrated care to manage COPD.¹ However, successful integrated care interventions demand the involvement of both patients and family members in care planning, implementation and oversight.²⁻⁴

The impact and challenges of living with a patient with COPD at all grades are well described,⁵⁻⁹ including physical and emotional burden and distressing symptoms (e.g., anxiety and depression).^{5,10,11} Moreover, in recent research, families have expressed the need for more information about disease management and for emotional support (e.g., how to handle breathlessness, exacerbations and anxiety symptoms).^{8,10-12} Attending to patients' and family members' needs, preferences and expectations might have potential to promote a more integrated and collaborative approach to care in COPD.^{13,14}

Family interventions have been shown to improve family coping in chronic diseases such as diabetes,¹⁵ cardiovascular¹⁶ and breast cancer¹⁷, but their impact has received limited investigation in COPD. Furthermore, the use of more positive coping and problem solving strategies has been associated with better health outcomes namely less depression and anxiety,¹⁸⁻²⁰ improved exercise tolerance²⁰ and quality of life¹⁹ in patients and better self-rated physical and mental health in family members⁵ living with COPD. However, only one study was identified that tested benefits of including family members in a multidisciplinary PR program.²¹ Therefore, the primary aim of this study was to investigate the impact of a family-based PR program on patients and family members' coping strategies to manage COPD. It was hypothesized that participation in a family-based PR program would improve coping strategies of the family system without interfering with patients' benefit obtained from a conventional PR program. The secondary aims were to explore its impact on family psychosocial adjustment to illness and patients' exercise tolerance and health-related quality of life.

METHODS

Study Design

This was a single-blinded, randomized controlled trial. Family dyads (i.e., patient with COPD and family member) were randomly assigned to family-based PR (experimental) or conventional PR (control) and were unaware of group allocation. Participants were only told that they were entering a PR program which involved the family, and that depending on group allocation, the involvement of the family member would differ.

The outcome measures were collected from patients and family members three days before and after the PR program. The family-based PR was conducted at a different time than the conventional PR. Randomization was performed by a computer-generated schedule in random blocks of three. The allocation sequence was kept in sealed opaque envelopes by a researcher who was not involved in data collection. This researcher drew the envelope and scheduled dyads of both groups. Approval for this study was obtained from the Center Health Regional Administration (2011-02-28) and national data protection committee (8940/2012). Written informed consent was obtained from each participant. This study was reported according to CONSORT (Consolidated Standards of Reporting Trials) recommendations.²²

Participants

Consecutive patients with stable COPD were recruited from three primary care centers. Patients were considered eligible for the study if they were: 1) diagnosed with COPD according to the Global Initiative for Chronic Obstructive Lung Disease criteria; 2) had a family member \geq 18 years old who provided physical and/or supportive care, without receiving any payment and 3) able to provide informed consent to participate in the study. Patients were excluded if they had exacerbations or hospital admissions one month prior to the study; severe neurologic/musculoskeletal conditions and/or unstable cardiovascular disease. Dyads were excluded if one of them presented severe psychiatric conditions or inability to understand and co-operate, or if one of them refused to participate.

Intervention

In both groups, patients underwent 12 weeks of PR composed of exercise training and psychosocial support and education, conducted in primary care centers. Family members assigned to the family-based PR participated in the psychosocial support and education component together with patients. Family members randomized to conventional PR did not attend the sessions with patients, with the exception of sessions used to obtain baseline and post-intervention assessment data.

Exercise training. Training frequency was 3 sessions per week. Sessions lasted 60 minutes and were delivered by the same physiotherapists in both groups, ensuring a consistent and uniform training among all patients. This component is described elsewhere.²³

Psychosocial support and education. Sessions were designed based on a comprehensive literature review on COPD rehabilitation,²⁴⁻²⁶ needs of families living with COPD²⁷⁻²⁹ and interventions for families living with other chronic diseases.^{30,31} Education aimed to provide information about COPD, increase the skills of the family to adjust to and manage the disease, and promote adherence to therapy and healthy lifestyles. Psychosocial support intended to help the family to manage the emotional demands of living with COPD, facilitate the communication within the family and with health/social services, and develop a sense of family identity, enhancing its cohesion.

Weekly sessions, lasting approximately 90 minutes, were conducted by a multidisciplinary team (physiotherapist, gerontologist, psychologist, nurse and clinician). These professionals assumed the role of facilitators by supporting participants in their doubts, encouraging them to share experiences, normalizing emotions and assuming an empathic attitude. Several didactic methods were used during the sessions, such as group discussions, home tasks, role-playing and brainstorming. The topics of each of the 12 sessions are presented in Table 1. On each session, a handout was provided to participants. Content presented to both groups was similar; however in the control group family members did not participate and therefore, the

content relating to psychosocial and educational topics solely focused on the patient's perspective.

(insert table 1)

Outcome measures

Descriptive characteristics. Socio-demographic information (age, gender, educational, marital status and current occupation) was collected from patients and family members. Body mass index, activities limitation resulting from dyspnea, assessed with the Modified British Medical Research Council questionnaire³² and lung function,³³ assessed with a portable spirometer (MicroLab 3500, CareFusion, Kent, UK), were collected from patients. Data on the kin relationship with the patient and the caregiving duration was obtained from family members.

Patients and family members filled in the Family Crisis Oriented Personal Scales (F-COPES) (the main outcome measure)³⁴ and the Psychosocial Adjustment To Illness Scale–Self Report (PAIS-SR).³⁵

The F-COPES identifies family problem-solving and behavioral strategies used by families in crisis situations and has been used to assess the impact of interventions in the family.^{17,36} F-COPES focuses on two levels of interaction: from the individual to the family system (the way in which the family manages crises and problems internally) and from the family to the social environment (the way in which the family manages problems outside its boundaries).^{17,34,36} F-COPES had good internal consistency, with an overall alpha of 0.852 in both patients and family members. This instrument is composed of five sub-scales: acquiring social support (9 items; $\alpha_{\text{patients}}=0.782$ and $\alpha_{\text{family members}}=0.820$), reframing (8 items; $\alpha_p=0.682$ and $\alpha_f=0.654$), seeking spiritual support (4 items; $\alpha_p=0.803$ and $\alpha_f=0.850$), mobilizing family to acquire and seek help (4 items; $\alpha_p=0.567$ and $\alpha_f=0.402$) and passive appraisal (4 items; $\alpha_p=0.430$ and $\alpha_f=0.596$). The acquiring social support subscale measures a family's ability to acquire support from friends, relatives, neighbors, and extended family. The reframing subscale assesses the family's ability to redefine stressful events to help them be manageable by the family. The

seeking spiritual support subscale examines the family's ability to acquire spiritual support. The mobilizing family to acquire and accept help subscale measures the family's ability to seek community resources and accept help from others. The passive appraisal subscale assesses the family's ability to accept difficult issues minimizing reactivity. F-COPES describes a variety of coping behaviors and items are rated using a 5-point Likert scale, ranging from "strongly disagree"(1) to "strongly agree"(5). The total score ranges from 29 to 145, with higher scores indicating more positive coping and problem solving strategies.

The PAIS-SR has been used to assess the impact of rehabilitation programs on psychosocial adjustment to the disease.³⁷⁻³⁹ The PAIS-SR had good internal consistency in patients ($\alpha_p=0.920$) and family members ($\alpha_f=0.912$). The scale has seven domains: health care orientation (8 items; $\alpha_p=0.564$ and $\alpha_f=0.696$), vocational environment (6 items; $\alpha_p=0.658$ and $\alpha_f=0.571$), domestic environment (8 items; $\alpha_p=0.832$ and $\alpha_f=0.590$), sexual relationships (6 items; $\alpha_p=0.865$ and $\alpha_f=0.829$), extended family relationships (5 items; $\alpha_p=0.635$ and $\alpha_f=0.844$), social environment (6 items; $\alpha_p=0.832$ and $\alpha_f=0.678$) and psychological distress (7 items; $\alpha_p=0.808$ and $\alpha_f=0.813$). Each item has four statements determining the levels of adjustment (0-3). The participant selects the statement that best describes his/her personal experience. The total score ranges from 0 to 138 and higher scores indicate poorer adjustment.

The outcome measures described below were collected only from patients.

Exercise tolerance. Exercise tolerance was measured using the 6-minute walk test. The measurement properties of this test are well established in COPD.⁴⁰ Two tests were performed according to standardized guidelines.⁴¹

Functional balance. The Timed Up-and-Go test was used to assess functional balance.⁴² Patients were instructed to walk quickly, but as safely as possible. Two tests were performed and the best performance considered.

Muscle strength. Knee extensors strength of the dominant limb was assessed using the 10-RM with ankle weights.⁴³ In patients with COPD, the completion of 1-RM testing may not be safe,⁴⁴ thus multiple RM, such as 10-RM, were used.

Health-related quality of life. The St. George's Respiratory Questionnaire (SGRQ) is a disease-specific instrument designed to measure quality of life,⁴⁵ and contains three domains: symptoms (8 items), activities (16 items) and impact (26 items). The SGRQ presented high internal consistency with Cronbach's alphas of 0.769 in the symptoms domain, 0.736 in the activities domain, 0.705 in the impact domain and of 0.820 in the overall questionnaire. For each domain and for the total questionnaire, score ranges from 0 (no impairment) to 100 (maximum impairment).

Data Analysis

Using F-COPES data from a previous pilot study (not published), two sample size estimations (for patients and family members) with 95% power at a significant level of 0.05 were performed. These analyzes determined that a statistically significant difference in F-COPES total score would be detected with 42 patients (Partial eta-squared (η^2)=0.078) and with 30 family members (η^2 =0.110). As PR programs have considerable dropouts, varying between 20-40%,^{46,47} 56 family dyads (28 per group) were recruited. These power analyzes were performed using the G*Power 3 software (University Düsseldorf, Germany).

Descriptive statistics were used to describe the sample. For each measure, the normality of data was investigated with Shapiro–Wilk tests. Independent t-tests for normally distributed data and Mann Whitney U-tests for ordinal/non-normally distributed data were used to compare baseline measures between groups. Chi-square tests were used for categorical data. Two-way analysis of variance with repeated measures was used to establish the significant effects for time, group and group x time interaction. The level of significance was set at 0.05. Statistical analysis was completed with the estimation of effect sizes for each outcome measure to evaluate the magnitude of treatment effect.⁴⁸ The effect size was computed via

Partial eta-squared as it is the index more commonly reported for two-way analysis of variance with repeated measures.⁴⁹ Partial eta-squared was interpreted as a small ($\eta^2 \geq 0.01$), medium ($\eta^2 \geq 0.06$) or large ($\eta^2 \geq 0.14$) effect.⁵⁰ Data analyzes were performed using IBM SPSS Statistics version 20.0 (IBM Corporation, Armonk, NY, USA).

RESULTS

Participants' characteristics

Figure 1 shows the CONSORT flow diagram of the trial. Of the 69 dyads screened for this study, 13 were excluded. Eight did not meet inclusion criteria and five declined to participate. Therefore, 56 dyads were allocated to the experimental (n=28) or control (n=28) group. Forty-two dyads completed the intervention and post-test assessments and were included in the analysis. There were no significant differences between completers and dropouts with regard to any of the socio-demographic, clinical or psychological baseline characteristics ($p > 0.05$).

(insert figure 1)

Baseline socio-demographic characteristics of patients and family members of both groups are provided in Table 2. No significant differences between groups were noted in baseline characteristics, with the exception of family members' marital status ($p = 0.037$).

(insert table 2)

Adherence

Patients and family members in the experimental group attended a mean of 11.1 ± 0.9 psychosocial support and education sessions, achieving an overall adherence rate of $92 \pm 8.7\%$. In the control group, patients' adherence to psychosocial support and education component was $90.8 \pm 7.1\%$ (mean of 10.9 ± 0.9 sessions; $p = 0.626$). Attendance to exercise training sessions was similar in both groups, with rates of $82.1 \pm 15.3\%$ and $83.4 \pm 12\%$ ($p = 0.755$).

Family coping

Figure 2 shows the results on family coping in patients and family members of the experimental and control groups. The magnitude of improvement in family coping in patients

($p=0.048$; $\eta^2=0.091$) and family members ($p=0.004$; $\eta^2=0.226$) of the experimental group exceeded the improvement of the control group (Figure 2).

(insert figure 2)

After the intervention, patients ($p=0.017$) and family members ($p=0.047$) of both groups reported the use of more strategies of acquiring social support (Table 3). The coping strategies of reframing, seeking spiritual support and mobilizing to acquire and accept help were more frequent in family members of the experimental group than in those of the control group ($p<0.05$; η^2 from 0.149 to 0.255) (Table 3). The strategy mobilizing to acquire and accept help was also more used by patients of the experimental group than by those of the control group ($p=0.028$; $\eta^2=0.117$) (Table 3).

(insert table 3)

Psychosocial adjustment to illness

The results of the psychosocial adjustment to illness are presented in Table 4. Patients and family members from both the experimental and control groups experienced improvements in psychosocial adjustment to COPD ($p=0.003$ and $p=0.001$), with no differences between groups ($p=0.454$ and $p=0.252$). Family members of the experimental group had significant changes in sexual relationships ($p=0.026$; $\eta^2=0.151$) and in psychological distress ($p=0.033$; $\eta^2=0.123$) compared to family members of the control group.

(insert table 4)

Patients' outcome measures

Both the experimental and control groups experienced significant improvements in exercise tolerance, functional balance, knee extensors strength and health-related quality of life after the intervention ($p<0.001$; η^2 from 0.228 to 0.622), with no differences between groups ($p>0.05$) (Table 5).

(insert table 5)

DISCUSSION

To our knowledge, this is the first randomized controlled trial to investigate the impact of family-based PR on patients and family members' coping strategies. The main findings indicate that integrating the family member in PR contributed to improve the coping strategies of the family to manage the disease, with further improvement in family members' sexual functioning and psychological distress. In addition, patients from both groups experienced significant improvements in exercise tolerance, functional balance, knee extensors strength and health-related quality of life.

Living with COPD has been described as a psychological distressing experience,⁵¹ which involves different coping efforts and affects relational dynamics.^{10,52} This is explained by the incapacitating nature of the disease characterized by stable periods alternated with periods of exacerbations, which leads to family having to deal with the uncertainty of exacerbation occurrence and with specific demands, such as monitoring health status and adherence to treatments. Although these impacts are greater as the disease progresses, families have expressed the need for more information about the disease and strategies for its management.^{5,8,10-12} However, this has been poorly valued by health professionals and researchers. This study has contributed to the current body of knowledge by showing that a family-based PR is effective in enhancing the coping strategies of all of those living with COPD. Specifically, patients and family members of the family-based PR made greater use of community resources to cope with their problems (external coping).³⁶ Moreover, the improvement in family coping was more pronounced in family members than patients, namely in the strategies of reframing (internal coping) and seeking spiritual support (external coping). The ability to manage stressful events by redefining the event in more helpful terms and to obtain spiritual support are frequently endorsed by families living with chronic diseases and have been associated with lower stress levels.⁵³⁻⁵⁵ Therefore, including the broader relational context in which COPD is experienced, is beneficial to the family and seems to be a more integrated care model of delivering PR.

Patients and family members from both groups experienced improvements in their psychosocial adjustment to the disease. Improvements in psychosocial morbidity among patients with COPD after PR have been previously reported.⁵⁶ However, the present study also demonstrated that psychosocial support and education for the family contributed to improved psychological adjustment to the disease and sexual functioning of the family member. These are important results since these family members tend to lose intimacy and caring feelings for their partner, which are replaced by feelings of duty (due to marriage vows and societal expectations),^{8,57} thereby increasing their psychological distress.^{11,51}

Few studies have developed and evaluated interventions involving family members of patients with COPD^{21,58,59} and only one has reported the experience of family members after participating in a multidisciplinary PR program. Positive results on understanding the disease, enhancing the relationship and their coping strategies were reported up to two years after the program.²¹ However, family members were invited to participate in just one session and considered it somewhat insufficient to their needs. Participating in psychosocial support and education interventions has been found to increase the well-being of the family in other populations such as cancer,^{31,60} schizophrenia⁶¹ and psychosis.⁶² This study is innovative as it extends these findings to the COPD population.

Although a greater improvement in patients' functioning of the experimental group compared with those from the control group could be thought to be more compelling, differences between groups were not found. This was not unexpected as similar exercise training was provided to both groups of patients and family members from the experimental group were never directly encouraged to be facilitators of patients' functioning. Future studies should explore whether other levels of family engagement in PR affect patients' functioning, for example, by encouraging patient's physical activities.

Some limitations need to be acknowledged. The main findings of this study were based on self-report instruments and may not represent actual changes in patients' or family members'

behavior. Furthermore, two F-COPES subscales, namely mobilizing family to acquire and seek help ($\alpha_f=0.402$) and passive appraisal ($\alpha_p=0.430$), had slight low internal consistency which may have interfered with the results. Future studies could use other self-reported instruments combined with qualitative methods. This randomized control trial was conducted with a small sample of each COPD grade, therefore it was not possible to determine whether the severity of disease impacted on the outcome. It was also not possible to blind the outcome assessor, which could have influenced the results. Finally, long-term follow-up was not collected which would strengthen these results. Therefore, it is currently unknown if these effects were sustained. Further research with longer follow-ups and with larger samples is necessary to investigate the short- and long-term effects of family-based PR on each COPD grade.

Conclusions

Family-based PR benefits the family by improving the coping strategies and the psychosocial adjustment to illness. In order to contribute for an integrated care towards managing COPD, PR programs should consider to actively involve the family system within the care delivery.

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AUTHOR CONTRIBUTIONS

AM and DF were responsible for the study conception and design. DB was a consultant and provided advice during the conception and design of the project. CJ, JC and RG performed data collection and analysis. AM was responsible for drafting the manuscript. She is the guarantor. All authors critically revised the paper for important intellectual content. AM and DF obtained the funding.

ROLE OF SPONSORS

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Table 1. Topics of the psychosocial support and education component.

Topics	Description
Week 1 Information about COPD/ Impact on family life	Brief overview of COPD (e.g., symptoms, progression and treatments); Period of questions; Identification, exploration and normalization of the impact of COPD on family life.
Week 2 Management of respiratory symptoms	Identification and training of breathing control and airway clearance techniques; Discussion of practical strategies to prevent and manage exacerbations.
Week 3 Family identity and development	Work on family cohesion, exploring the family identity (e.g., participants had to create their "family identity card", which symbolized the specific values of each family).
Week 4 Medication and oxygen therapy	Information about medication and oxygen therapy; Discussion of the importance of treatment compliance; Training of inhalation techniques.
Week 5 Management of stress and anxiety	Discussion of the possible causes of stress and the effects of stress in family life; Ways to manage stress (e.g., relaxation techniques).
Week 6 Healthy lifestyles - Physical activity	Discussion of the benefits of physical activity in the whole family; Work on strategies to increase/maintain physical activity habits.
Week 7 Healthy lifestyles - Nutrition and sleep	Identification of the most common nutritional mistakes; Discussion of ways to address nutritional mistakes, emphasizing the importance of a healthy diet; Description of sleep problems and suggestion of solutions; Discussion of the impact of COPD on sexual relationships.
Week 8 Emotions management/Community Resources	Exploration and normalization of emotions; Training of a practical technique to manage emotions, the " <i>Six thinking hats</i> " from de Bono ¹⁰ ; Identification of available resources for families, as well as the appropriate timing to contact these resources.
Week 9 Fall prevention/ Communication of feelings, needs and concerns	Identification of the most common risk factors for falls and discussion of strategies to reduce/eliminate them; Description of the major communication styles; Training of the DESC (Describe, Explain, Specify, Conclude) technique to communicate assertively ¹¹ .
Week 10 Action plan	Summary of the contents of previous sessions, with emphasis on the key points for an effective disease management.
Week 11 Problem solving techniques/ Unpredictability and future fears	Sharing experiences of personal problems and exploration of ways of solving them. Practice of the problem-solving technique developed by D'Zurilla and Nezu ¹² .
Week 12 Ritualization	Reflection on the importance of social support networks and balance of participation in the group. Celebration, symbolizing the end of the program.

Table 2 – Sample characteristics at baseline.

	Patients		Family members	
	Experimental group (n=22)	Control group (n=20)	Experimental group (n=22)	Control group (n=20)
Age (years)	68.8±7.3	65.9±13.4	62.0±10.5	55.1±12.4
Gender (male), n(%)	18 (81.8%)	10 (50%)	5 (23%)	7 (35%)
Educational level, n(%)				
Primary	12 (54.5%)	7 (35%)	10 (45.4%)	6 (30%)
Secondary	6 (27.3%)	8 (40%)	4 (18.2%)	3 (15%)
High school	3 (13.6%)	2 (10%)	4 (18.2%)	5 (25%)
University	1 (4.5%)	3 (15%)	4 (18.2%)	6 (30%)
Marital status, n(%)				
Married/Living as a couple	20 (90.9%)	12 (60%)	20 (90.9%)	13 (65%)
Widowed	2 (9.1%)	6 (30%)	0	0
Separated/divorced	0 (%)	1 (5%)	1 (4.5%)	2 (10%)
Single	0 (%)	1 (5%)	1 (4.5%)	5 (25%)
Current occupation, n(%)				
Retired	19 (86.4%)	13 (65%)	14 (63.6%)	6 (30%)
Employed	2 (9.1%)	6 (30%)	6 (27.3%)	13 (65%)
Unemployed	1 (4.5%)	1 (5%)	2 (9.1%)	1 (5%)
BMI	27.2±4.6	28.9±5.5		
mMRC, M[IQR]	1[1, 2]	1[1, 2]		
FEV ₁ L	1.74±0.7	1.79±0.7		
FEV ₁ % predicted	67±22.4	74.3±21.7		
FEV ₁ /FVC % predicted	62.8±11.3	61±13.1		
GOLD grade, n(%)				
Mild	8 (36.4%)	8 (40%)		
Moderate	7 (31.8%)	9 (45%)		
Severe to very severe	7 (31.8%)	3 (15%)		
Kin relationship with the patient, n(%)				
Spouse			18 (81.8%)	11 (55%)
Son/Daughter			3 (13.6%)	8 (40%)
Other			1 (4.5%)	1 (5%)

Caregiving period (years), n(%)

< 1	1 (4.5%)	0
1-2	4 (18.2%)	7 (35%)
2-4	17 (77.3%)	13 (65%)

Data are presented as mean±standard deviation, unless otherwise indicated. BMI = body mass index; FEV₁ = forced expiratory volume in one second; FVC = forced vital capacity; GOLD = Global Initiative for Chronic Obstructive Lung Disease; IQR = interquartile range; M = median; mMRC = Modified British Medical Research Council questionnaire.

Table 3 - Family coping in patients and family members of the experimental and control groups.

	Experimental group (n=22)		Control group (n=20)		p-value ^a	p-value ^b	η^2
	Pre	Post	Pre	Post			
Patients: F-COPES							
Global score	91±15.7	102.2±13.9	94.9±19.1	95.7±18.2	0.030	0.048	0.091
Acquiring social support	25.7±7.7	30.1±7.6	26.2±7.6	27.6±8.7	0.017	0.201	0.042
Reframing	31.4±4.1	32±4.6	31.9±5.2	31.5±4.5	0.903	0.533	0.010
Seeking spiritual support	11.5±4.5	12±4.6	11.9±4.8	12.7±3.7	0.237	0.737	0.003
Mobilizing to acquire and accept help	10.5±4.2	13.6±4	11.8±3.9	11.8±4	0.034	0.028	0.117
Passive appraisal	11.9±2.3	13±2.3	13.2±3.2	12.2±3.3	0.845	0.039	0.105
Family members: F-COPES							
Global score	92.5±12.6	109.6±11.3	94.1±19.9	95.2±19.9	0.001	0.004	0.226
Acquiring social support	28.9±6.5	32.3±7.0	28.6±8.9	29.3±7.8	0.047	0.181	0.051
Reframing	29.1±4.6	33.1±3.9	31.7±4.5	10.8±5.4	0.028	0.001	0.255
Seeking spiritual support	11.7±4.3	14.2±3.9	10.7±5.2	11.2±5.8	0.001	0.011	0.160
Mobilizing to acquire and accept help	11.1±3.0	14.2±3.6	12.3±2.2	13.0±3.6	0.001	0.018	0.149
Passive appraisal	12.8±2.2	10.8±2.9	11.3±4.1	10.5±4.1	0.002	0.164	0.054

Data are presented as mean±standard deviation. a=Time; b= interaction time*group; η^2 = Partial eta-squared; F-COPES = Family Crisis Oriented Personal Scales.

Table 4 - Psychosocial adjustment to illness in patients and family members of the experimental and control groups.

	Experimental group (n=22)		Control group (n=20)		p-value ^a	p-value ^b	η^2
	Pre	Post	Pre	Post			
Patients							
PAIS-SR global score ^c	27.2±19.4	23.6±15.3	22.2±11	16.4±8.6	0.003	0.454	0.015
Health care orientation	7.4±3.7	6.8±4.1	7.6±3.4	7.2±3.6	0.396	0.798	0.002
Domestic environment	5.3±5.1	4.8±3.9	3.1±2.8	2.3±1.9	0.236	0.660	0.007
Sexual relationships	4.3±4.3	4.2±4.2	2.6±3.5	2.4±3.7	0.561	0.888	0.001
Extended relationships	1.5±2.6	0.9±1.4	1.3±2.1	1±1.5	0.230	0.607	0.007
Social environment	4.3±4	2.9±2.8	5.1±4.7	2.7±2.9	0.001	0.325	0.025
Psychological distress	4.7±3	3.8±2.6	4.2±3.5	3.1±2.5	0.010	0.729	0.003
Family members							
PAIS-SR global score ^c	22.2±9.7	14.9±5.9	21.4±12.2	16.6±9.2	0.001	0.252	0.040
Health care orientation	7.5±3.1	5.3±2.5	8.9±4.6	6.2±3.9	0.001	0.574	0.009
Domestic environment	2.3±3.1	2.0±2.4	2.1±2.9	1.2±1.6	0.097	0.377	0.034
Sexual relationships	3.4±2.8	1.8±1.9	1.2±2.8	0.8±1.5	0.001	0.026	0.151
Extended relationships	1.3±2.1	0.6±1.1	1.2±1.9	0.5±1.6	0.004	0.963	0.001
Social environment	3.1±2.8	2.3±2.2	2.6±3.5	2.3±3.4	0.099	0.442	0.016
Psychological distress	4.2±2.4	2.7±1.7	4.1±2.8	3.6±3.1	0.001	0.033	0.123

Data are presented as mean±standard deviation. a=Time; b= interaction time*group; c= Samples of the experimental and control groups were unbalanced in the Vocational environment domain and thus results of this domain were not analyzed, nevertheless, they have been accounted for the global score; η^2 = Partial eta-squared; PAIS-SR= Psychosocial Adjustment to Illness Scale – Self Report.

Table 5 – Outcome measures of patients in the experimental and control groups.

	Experimental group (n=22)		Control group (n=20)		p-value ^(a)	p-value ^(b)	η^2
	Pre	Post	Pre	Post			
6MWD (m)	409.6±60.1	445.1±100.4	397.4±121.6	447.7±124.6	<0.001	0.430	0.016
TUG (s)	7.5±1.5	6.5±1.1	8±2.3	7±1.8	<0.001	0.736	0.003
10-RM knee extensors (kg)	4.5±1.8	6.6±1.7	3.8±1.8	6.4±1.9	<0.001	0.438	0.015
SGRQ total score	37.9±18.2	31.4±18.7	38.3±17.9	29.7±18.4	<0.001	0.458	0.015
Symptoms score	51±22.5	40.3±19.4	51.9±17.8	37±22.6	<0.001	0.473	0.014
Activities score	53.2±21.9	43.1±23.8	51.7±23.2	40.8±26.3	<0.001	0.864	0.001
Impact score	23.7±19.5	18.9±16.1	25.1±19.2	20±16.3	<0.001	0.946	<0.001

Data are presented as mean±standard deviation. a = Time; b = interaction time*group; η^2 = Partial eta-squared; 6MWD = 6-minute walking distance; TUG = Timed Up and Go; 10-RM = 10 repetition maximum; SGRQ = St. George's Respiratory Questionnaire.

Figure legends

Figure 1 - Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

Figure 2 - Within-group changes in the F-COPES global score by group in patients and family members. Data are presented as mean change \pm standard error. Significant differences are identified with * ($p<0.05$).