

Benefits of a Home-Based Pulmonary Rehabilitation Program for Patients With Severe Chronic Obstructive Pulmonary Disease

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OBJECTIVE: The benefits of a domiciliary program of pulmonary rehabilitation for patients with severe to very severe chronic obstructive pulmonary disease (COPD) are uncertain. We aimed to assess the short- and medium-term efficacy of such a program in this clinical setting.

PATIENTS AND METHODS: Patients with severe COPD (stages III-IV, classification of the Global Initiative for Chronic Obstructive Lung Disease) and incapacitating dyspnea (scores 3-5, Medical Research Council [MRC] scale) were randomized to a control or domiciliary rehabilitation group. The 9-week supervised pulmonary rehabilitation program included educational sessions, respiratory physiotherapy, and muscle training in weekly sessions in the patient's home. We assessed the following variables at baseline, 9 weeks, and 6 months: lung function, exercise tolerance (3-minute walk test), dyspnea (MRC score), and health-related quality of life with the Chronic Respiratory Questionnaire (CRQ).

RESULTS: Thirty-eight patients with a mean (SD) age of 68 (6) years were enrolled. The mean MRC score was 4 (0.8) and mean forced expiratory volume in 1 second was 29% of reference. Twenty-nine patients completed the study (6 months). Distance covered on the walk test increased significantly in the rehabilitation group ($P=.001$) and the difference was maintained at 6 months. Dyspnea also improved significantly with rehabilitation ($P\leq.05$), but the reduction was not evident at 6 months. Statistically significant improvements in symptoms related to 2 CRQ domains were detected between baseline and 9 weeks: dyspnea (3.1 [0.8] vs 3.6 [0.7]; $P=.02$) and fatigue (3.7 [0.8] vs 4.2 [0.9]; $P=.002$). A clinically relevant but not statistically significant change in mastery over disease was detected (from 4.3 to 4.9). All improvements were maintained at 6 months.

CONCLUSIONS: Home-based pulmonary rehabilitation for patients with severe to very severe COPD and severe functional incapacity leads to improvements in exercise tolerance and health-related quality of life that are maintained at 6 months.

Key words: *Chronic obstructive pulmonary disease (COPD). Pulmonary rehabilitation, domiciliary. Health-related quality of life. Exercise tolerance.*

Beneficios de un programa de rehabilitación respiratoria domiciliaria en pacientes con EPOC grave

OBJETIVO: Los beneficios de la rehabilitación respiratoria domiciliaria (RRD) en pacientes con enfermedad pulmonar obstructiva crónica (EPOC) de grado grave-muy grave son controvertidos. Nuestro objetivo ha sido evaluar la eficacia a corto y medio plazo de un programa de RRD en pacientes con EPOC grave.

PACIENTES Y MÉTODOS: Se trata de un estudio prospectivo y aleatorizado en pacientes con EPOC grave (estadios III y IV de la clasificación GOLD) y disnea invalidante —puntuación de 3 a 5 en la escala del Medical Research Council (MRC)—, distribuidos en grupo control y grupo RRD. El programa de rehabilitación respiratoria fue de 9 semanas y consistía en educación, fisioterapia respiratoria y entrenamiento muscular con supervisión semanal en domicilio. Evaluamos en situación basal, a las 9 semanas y a los 6 meses la función pulmonar, la capacidad de ejercicio (prueba de la marcha de 3 min), la disnea (MRC) y la calidad de vida relacionada con la salud, determinada con el Chronic Respiratory Questionnaire (CRQ). **RESULTADOS:** Participaron en el estudio 38 pacientes, con una edad media \pm desviación estándar de 68 \pm 6 años (puntuación MRC: 4 \pm 0,8; volumen espiratorio forzado en el primer segundo: 29% del valor de referencia), y 29 completaron el seguimiento a los 6 meses. En el grupo RRD se incrementó significativamente la distancia recorrida en la prueba de la marcha de 3 min ($p = 0,001$), resultado que se mantuvo a los 6 meses. La disnea mejoró significativamente tras la RRD ($p \leq 0,05$), pero dicha mejoría desapareció a los 6 meses. Se observó una mejoría clínica y estadísticamente significativa en 2 dominios del CRQ, el de disnea (3,1 \pm 0,8 frente a 3,6 \pm 0,7; $p = 0,02$) y el de fatiga (3,7 \pm 0,8 frente a 4,2 \pm 0,9; $p = 0,002$), y tan sólo clínica (4,3 frente a 4,9) en el control de la enfermedad, mejorías que se mantuvieron a los 6 meses.

CONCLUSIONES: La RRD en pacientes con EPOC grave-muy grave y alta incapacidad funcional aporta beneficios en la calidad de vida relacionada con la salud y la capacidad de ejercicio, que pueden mantenerse hasta los 6 meses.

Palabras clave: *Enfermedad pulmonar obstructiva crónica (EPOC). Rehabilitación respiratoria domiciliaria. Calidad de vida relacionada con la salud. Capacidad del ejercicio.*

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Introduction

Chronic obstructive pulmonary disease (COPD), an important cause of morbidity and mortality worldwide, is characterized by progressive airflow limitation that is partially reversible.¹ As the disease advances, some patients develop systemic manifestations, among them exercise intolerance, peripheral muscle dysfunction, pulmonary hypertension, malnutrition, and exacerbations that often require hospitalization.² Dyspnea, which is the main symptom, causes progressive loss of functional capacity until even the simplest activities of daily living are affected. This leads to loss of autonomy and the development of a considerable degree of disability, with consequent psychosocial changes and loss of quality of life.³

Pulmonary rehabilitation has been shown, with a high level of evidence, to provide benefits in terms of exercise tolerance and health related quality of life (HRQL).⁴ Most pulmonary rehabilitation programs are carried out in hospital or physical therapy settings and are multidisciplinary.^{5,6} Home-based or mixed home-and-hospital-based programs have proven to be similarly effective to hospital programs, and their benefits even seem to be more lasting.⁷⁻¹⁰ However, most studies have been done in patients with moderate COPD with acceptable levels of autonomy and dyspnea that is not incapacitating; very little research has been done on home-based programs in patients with severe airflow limitation.⁹

Our objective was to assess the efficacy of a home pulmonary rehabilitation program in patients with severe to very severe COPD—stages III-IV according to the criteria of the Global Initiative for Chronic Obstructive Lung Disease (GOLD)—and who also have incapacitating dyspnea.

Patients and Methods

Patients

Patients diagnosed with severe or very severe COPD (GOLD stages III-IV) attending an outpatient clinic at either of 2 university hospitals in Spain (Hospital de Cruces in Barakaldo, near Bilbao, and Hospital de la Santa Creu i de Sant Pau in Barcelona) were enrolled prospectively whether or not they were on home oxygen therapy if they met the following criteria: age less than 80 years; dyspnea assessed as 3 or more on the Medical Research Council (MRC) scale; and difficulty coming to the hospital because of serious shortness of breath or problems related to place of residence. Patients were excluded if they had heart disease or any other type of disease that limited exercise tolerance, did not have a positive attitude toward the program, or had some form of mental disability that prevented participation. The study was approved by the ethics committees of both hospitals and written informed consent was obtained from all patients.

Study Design

This was a prospective, controlled trial in which patients were randomized to a control group or a home pulmonary rehabilitation group. Randomization was carried out by assignments placed in sealed, opaque envelopes.

All patients in both groups received the same medical treatment: 50 µg of salmeterol twice a day, 500 µg of fluticasone

twice a day, and 80 µg of ipratropium bromide 3 times a day. Ten days of antibiotic treatment (amoxicillin-clavulanic acid, moxifloxacin, or levofloxacin) and oral corticosteroids (30 mg of prednisone and a regimen of decreasing doses) were prescribed in case of an exacerbation. An exacerbation was defined as the appearance of cough with increased sputum volume or purulence and increased dyspnea, in accordance with the criteria of Anthonisen et al.¹¹

Pulmonary Rehabilitation Program

Intensive phase. The period of intense care (with or without a pulmonary rehabilitation program) was 9 weeks. During the first phase, all patients in both groups attended educational and physical therapy sessions on 3 different days. Each day's session consisted of 1 hour of patient education and 30 minutes of conventional, individualized physical therapy, including the learning of diaphragmatic breathing, pursed lips breathing, and techniques to remove secretions if indicated.

From the second week, patients in the control group were encouraged to carry out the respiratory physiotherapy exercises at home and to walk, but no supervision was given. They were asked to record their activity each week on a special sheet.

Patients in the pulmonary rehabilitation group participated in 3 hospital training sessions in the second week. In these sessions they learned to do the exercises they were to continue doing at home. Each session included *a*) leg exercises on a stationary cycle, performed in intervals consisting of 5 minutes of exercise at a maximum load of 30 W (because the home exercise cycle was a simple one) separated by 2 minutes of rest, and starting with a training period of 5 to 15 minutes which was later lengthened according to tolerance; *b*) exercises to strengthen the arms in sessions of 15 to 30 minutes, initially without weights and with gradual increases in load according to tolerance; and *c*) inspiratory muscle training with the Threshold IMT (Respironics, Cedar Grove, New Jersey, USA) in sessions of 15 minutes at a steady load corresponding to 30% of maximal inspiratory pressure. Between the third and ninth weeks the patients followed the program at home 5 times per week for a period of 1.5 hours, following the exercise protocol learned in the hospital. They filled in a diary during this period and a physical therapist visited them at home on Mondays and telephoned on Fridays to check compliance and resolve doubts or problems related to the program.

Patients on home oxygen therapy adjusted flow to maintain oxygen saturation (SpO₂) above 90%. Patients who were not using home oxygen therapy but who developed desaturation during exercise (SpO₂<90%) were prescribed an oxygen concentrator for use while exercising at home and they also adjusted flow as appropriate for maintaining the same level.

Patients in both groups could reach the physician supervising the program whenever necessary.

Maintenance phase. After the tenth week and until the end of the sixth month, patients in the home pulmonary rehabilitation group were advised to continue exercising according to the same regimen. The physical therapist telephoned each patient once a month and offered to arrange a visit with the supervising physician if there were any signs of possible exacerbation.

Patients in both groups saw the respiratory physician for a check-up every 2 months; that specialist also saw them in case of exacerbation.

Outcome Measures

Lung function tests. Spirometry parameters—forced vital capacity, forced expiratory volume in 1 second (FEV₁), the

ratio of FEV₁ to forced vital capacity—and maximum voluntary ventilation were measured with a Dataspir 91 (SibelMed, Barcelona, Spain). The method and reference values were those recommended by the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR).^{12,13} Maximum expiratory and inspiratory pressures were measured with a manometer (model 163, SibelMed, Barcelona, Spain)¹⁴ and the reference values were those of Morales et al¹⁵ for a Mediterranean population. Arterial blood gas parameters (pH, PaO₂, and PaCO₂) were measured at rest, according to SEPAR recommendations,¹⁶ with an ABL 500 device (Radiometer, Copenhagen, Denmark).

Three-minute walk test. The 3-minute walk test¹⁷ carried out in a corridor 25 m long was used in each hospital to assess exercise tolerance. The patients were asked to walk from one end of the corridor to the other, trying to cover the greatest distance possible in 3 minutes. SpO₂ and heart rate were measured continuously with a pulse oximeter (Pulsox5, Konica-Minolta AVL, Diessenhofen, Switzerland). At the beginning and end of every test the level of dyspnea was recorded on a modified Borg scale of 0 to 10.¹⁸ Patients whose SpO₂ fell below 90% during the walk test were administered oxygen in order to prevent desaturation. For patients who were already on oxygen therapy, the flow rate was adjusted as ordered by the physician to maintain a level of SpO₂ of at least 90%.

Dyspnea and HRQL. Shortness of breath during activities of daily living was quantified from 1 to 5 on the MRC scale.¹⁹ HRQL was assessed with the Chronic Respiratory Questionnaire (CRQ), using a validated Spanish translation.²⁰ The questionnaire contains 20 questions in 4 domains: dyspnea (5 questions), fatigue (4 questions), emotional function (7 questions), and mastery over disease (4 questions). Each domain was scored on a scale of 7 points (the higher the score, the better the HRQL). A clinically significant improvement was defined as an increase of 0.5 points per domain.²¹

Statistical Analysis

Descriptive statistics were compiled during the first part of the study. In the second part comparisons were performed to test hypotheses. Quantitative variables are expressed as the arithmetic mean (SD). Baseline measures were compared with the Student *t* test; qualitative variables were compared with the χ^2 test. Outcomes in the different groups were compared during the study period by 2-factor analysis of variance of a time factor (2 repeated measures: baseline and end point) and a treatment factor (2 independent measures, rehabilitation and control). All analyses were carried out with the SPSS statistical package, version 11.5 for Windows. A 2-tailed significance level of 5% (*P*<.05) was used in all cases.

TABLE 1
Lung Function Variables and Patient Characteristics*

Variables	Control Group (n=19)	Home PR Group (n=19)	<i>P</i>
Sex, men/women	19/0	16/3	.22
Age, y	68.5 (7)	66.9 (5.8)	.14
BMI, kg/m ²	24.7 (4.6)	25.3 (4.7)	.88
FEV ₁ , % reference	29.6 (8)	27.5 (9)	.87
FVC, % reference	62.2 (18)	60.1 (15)	.95
MRC dyspnea rating	3.6 (0.8)	3.4 (0.8)	.14

*Data are expressed as mean (SD). FEV₁ indicates forced expiratory volume in 1 second; FVC, forced vital capacity; BMI, body mass index; MRC, Medical Research Council; PR, pulmonary rehabilitation.

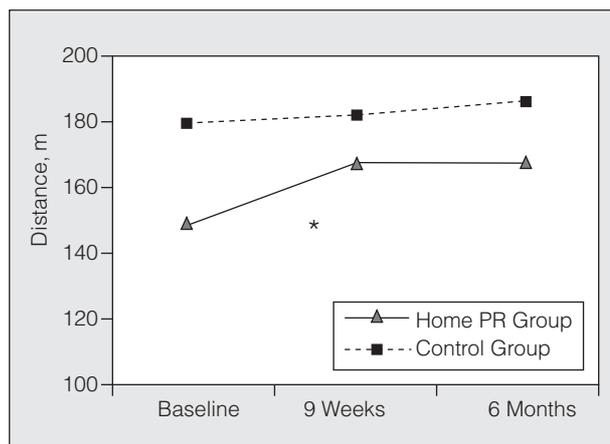


Figure 1. Changes in distance covered in the 3-minute walk test from baseline to 9 weeks and after 6 months. PR indicates pulmonary rehabilitation. *Significant improvement.

Results

Forty-two consecutive patients met the inclusion criteria and 38 were enrolled (35 men, 3 women). The mean (SD) age was 69 (4) years and the mean FEV₁ was 29% of predicted. One of the 4 patients who did not participate was hospitalized for exacerbation when starting the program; the other 3 patients did not cooperate adequately.

Fifty-five percent of the 38 patients were receiving oxygen therapy 24 hours a day. The patients were randomized to the control or home pulmonary rehabilitation group (19 each); the baseline characteristics of patients were similar in each group (Table 1). Of the 38 patients who entered the program, only 29 completed the 6 months (15 in the control group and 14 in the rehabilitation group). Four patients in the control group stopped following recommendations, and in the rehabilitation group 2 patients died and 3 abandoned the program.

No significant changes in lung function or maximal respiratory pressures were observed in either group. Patient performance on the 3-minute walk test improved significantly only in the pulmonary rehabilitation group (from 148 m before the program to 167 m afterwards; *P*=.001) and the difference was still evident at 6 months (Figure 1). No significant differences in dyspnea assessed on the Borg scale, in heart rate, or in SpO₂ at the end of the walk test were observed in either group.

Dyspnea measured on the MRC scale improved significantly: patients in the rehabilitation group had less shortness of breath at 9 weeks than did patients in the control group (3.1 [0.7] vs 3.4 [0.8], respectively; *P*<.05), but the improvement was not maintained at 6 months. Pulmonary rehabilitation patients also experienced statistically significant improvement in 2 CRQ domains: dyspnea (*P*=.02) and fatigue (*P*=.002) after 9 weeks in the intensive program. That improvement was still evident at 6 months. In the domain termed mastery of disease only a clinically significant improvement was evident at 9 weeks (4.21 vs 4.74) and it was maintained at 6 months (Figure 2 and Table 2).

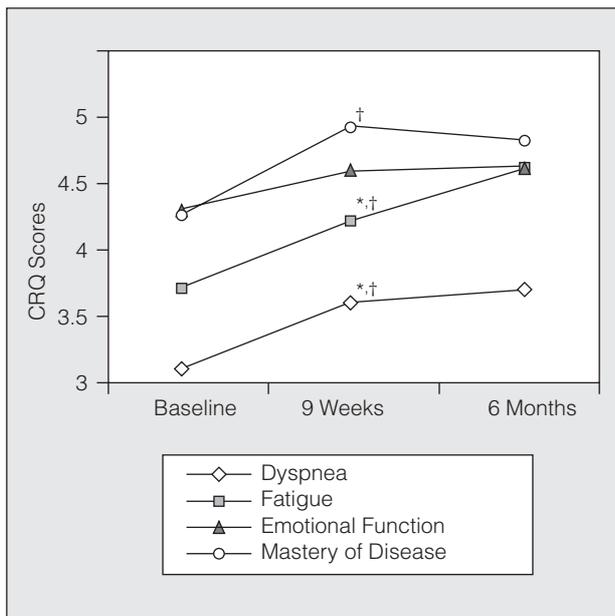


Figure 2. Changes, in the home pulmonary rehabilitation group, on 4 domains of the Chronic Respiratory Questionnaire (CRQ) from baseline to 9 weeks of training and after 6 months.

*Statistically significant difference. †Clinically significant difference.

Discussion

Our findings show that a home pulmonary rehabilitation program for patients with very severe COPD and incapacitating shortness of breath improves exercise tolerance, dyspnea, and certain aspects of HRQL and that the benefits are partially maintained 6 months after the program ends. Previous studies of home pulmonary rehabilitation programs have shown clear improvements in exercise tolerance and HRQL.⁷⁻¹⁰ Few of those studies, however, are comparable to ours for a variety of reasons. First there is the issue of severity of disease. Most studies have enrolled patients with an FEV₁ over 40% of predicted and a lesser degree of dyspnea,¹⁰ whereas our patients had severe obstruction, with an FEV₁ less than 30% of predicted, and incapacitating dyspnea as shown by a mean MRC rating of 4 (0.8). Second, over half the patients in our study had respiratory insufficiency requiring home oxygen

therapy 24 hours a day. Finally, our program was less intense than most of the other programs that have also reported successes and ours did not last as long as those earlier programs. The training workload is usually more than 30 W and programs usually last longer than 9 weeks.^{7,8} When Hernández et al¹⁰ analyzed a longer program that was otherwise comparable to ours, but in patients with a less severe degree of obstruction, their findings indicated there were considerable benefits in HRQL and exercise tolerance.

Very few studies have assessed the possibility of home training in patients with a level of disease severity that was similar to the level in our study. The study most similar to ours was that of Wedzicha et al,⁹ who assessed the effect of peripheral muscle training and aerobic exercise in COPD patients grouped according to baseline dyspnea measured on the MRC scale. Patients with a score of 5 showed no changes in either exercise tolerance or HRQL after the home program, whereas those with scores of 3 to 4 did benefit after a hospital-based program. Our results are not consistent with those, as we did observe a beneficial effect even though our patients had more severe COPD (FEV₁, 29% of predicted or less, vs 37% of predicted in the study of Wedzicha and colleagues); it is true, however, that our patients had a slightly lower mean MRC score for dyspnea, at 4 (0.8). As mentioned by Wedzicha and colleagues, the factors that might have influenced the lack of response to training in those patients with a higher level of dyspnea were a lower intensity of training than the level applied in their group with less dyspnea and the short duration of the program. In our program the duration of treatment was similar but the intensity increased each week, as the amount of time spent on the exercise cycle grew longer and more weight was used during arm exercises. Incidentally, we observed that the 2 patients of the 19 in our rehabilitation group who had a baseline dyspnea score of 5 both increased their distance walked in 3 minutes (by 20 m and 35 m, respectively) after the 9-week program; in contrast, the 2 control group patients who also had baseline dyspnea scores of 5 increased their distances by only 2 m after 9 weeks. Had the sample of patients with MRC ratings of 5 been larger, we might have been able to confirm that trend.

Our patients who received 9 weeks of training significantly increased the distances walked in 3 minutes

TABLE 2
Changes in Measures After 9 Weeks of Exercise and After 6 Months of Follow-Up*

Variables	Control Group			Home PR Group		
	Baseline	9 Weeks	6 Months	Baseline	9 Weeks	6 Months
No. of patients	19	19	15	19	19	14
BMI, kg/m ²	24.7 (4.6)	25.6 (5)	21.5 (9.2)	25.2 (4.5)	25.5 (4)	23 (4)
MRC dyspnea rating	3.6 (0.8)	3.3 (0.6)	3.6 (0.5)	3.4 (0.8)	3.1 (0.7)†	3.4 (0.8)
3-min walk test, m	178.6 (44.5)	181.4 (49.5)	185.7 (53)	148.7 (48)	167.6 (48)†	167.2 (56)†
CRQ dyspnea	3.2 (0.8)	3.3 (0.9)	3.6 (0.9)	3.1 (0.8)	3.6 (0.7)†,‡	3.7 (1)†,‡
CRQ fatigue	4.1 (1.1)	4.5 (1.1)	4.5 (1.2)	3.7 (0.8)	4.2 (0.9)†,‡	4.6 (1.1)†,‡
CRQ emotional function	4.5 (1.3)	4.5 (1.1)	5 (1.1)	4.3 (1)	4.6 (1)	4.6 (1.3)
CRQ mastery of disease	5.1 (1.3)	5.2 (1.3)	5.1 (1.4)	4.3 (1.2)	4.9 (1.3)‡	4.8 (1.8)‡

*Results are expressed as means (SD).

CRQ indicates Chronic Respiratory Questionnaire; BMI, body mass index; MRC, Medical Research Council; PR, pulmonary rehabilitation.

†Statistically significant difference, analysis of variance. ‡Clinically significant difference.

by a mean 18.9 m and the improvement was maintained at 6 months. Redelmeier et al²² demonstrated a clinically significant increase of 54 m in the 6-minute walk test; we might therefore suppose that an increase of nearly 19 m in the 3-minute walk test would have some clinical significance, consistent with the improvement in dyspnea score. We used a shorter walk test in this study for 2 reasons. On the one hand, our patients had very severe dyspnea and were in very poor physical condition; consequently many were unable to complete the 6-minute walk test. On the other hand, short tests have proven valid for patients with COPD.^{8,17} Stribjos et al⁸ observed significant improvement in a 4-minute walk test and in strength during a cycle ergometer test; the duration of that study was longer than ours but our results are consistent with it.

The improvement in our patients' exercise tolerance after muscle training can be attributed to several mechanisms. The first is related to physiological changes on both a muscular and cardiopulmonary level. Change or lack of it appears to be related to the intensity of exercise, but findings have been contradictory: some authors consider it necessary to exercise intensely to obtain benefit,²³ whereas others have demonstrated changes in cardiovascular²⁴ and muscle structure and function²⁵ even with a low level of exercise. Our patients exercised at very low levels. No improvements in physiological parameters (heart rate and SpO₂), lung function parameters, or respiratory pressures were evident. Thus, we cannot attribute the increased exercise tolerance to an improvement in cardiopulmonary response. The second mechanism would be defined by changes in muscle structure and function after training. We cannot know whether our patients' increased exercise tolerance was attributable to such changes, as we did not carry out muscle biopsies or measure blood levels of lactic acid. A third mechanism, as demonstrated by various authors, points to an effect of muscle training on neuromuscular coordination.²⁶ Improvement in this respect would increase an individual's ability to carry out activities of daily living, particularly for the most sedentary patients. Our patients' increased exercise tolerance might be attributable to this factor. The improvements in the dyspnea and fatigue domains of the CRQ might also be indirect indications of peripheral muscle improvement after exercise. A fourth mechanism to which improved exercise tolerance in COPD patients is attributed is that of desensitization to dyspnea during exercise. Belman and Kendregan²³ have shown that familiarity with exercise reduces dyspnea even without specific training. Our patients' dyspnea measures on both the MRC scale and the CRQ decreased significantly with their improved performances on the 3-minute walk test; therefore, we might speak of a certain desensitization to dyspnea during exercise. Finally, the fact that our patients participated in a pulmonary rehabilitation program that included the training of different muscle groups may be an additional factor that explains the good response observed. A combination of specific respiratory muscle training and a general physical exercise program has been shown to provide benefits in terms of HRQL and exercise tolerance in COPD patients.²⁷

An interesting finding of our study is the confirmation that benefits of the pulmonary rehabilitation program were maintained at 6 months even with such a simple intervention as a monthly telephone call. Few studies have been able to demonstrate the long-term maintenance of benefits, beyond 1 or 2 years.^{5,28,29} All such studies have applied more intensive approaches to maintenance than the one used by our group, though it must be remembered that the levels of COPD severity of subjects in those studies were lower than in ours.

A limitation of our study was the fact that the respiratory medicine specialist responsible for the program was not blinded as to group assignment. Another feature that might be considered a limitation was the high rate of abandonment during the 6-month follow-up period. However, that rate is similar to the ones reported for other studies.^{7,8,10} Patients may have stopped exercising because of lack of motivation and/or scarce support from the physical therapist, who only made a monthly telephone call. Outcomes might have been better if there had been greater contact with the supervisor of the program, although given the severity of disease in our subjects, the rate of withdrawal would be expected to be higher than in a group of less seriously ill patients whatever strategy was used.

In summary, our results confirm that a pulmonary rehabilitation program that includes low-intensity training of several muscle groups improves exercise tolerance, dyspnea, and certain HRQL parameters in COPD patients who are severely ill. Furthermore, these benefits are partially maintained at 6 months with a minimal approach to maintenance. Our view is that further studies with a larger number of patients are needed to confirm these findings and that such studies should include other outcome measures, such as the number of exacerbations or the amount of medication used.

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