

## Effects of a comprehensive self-management programme in patients with chronic obstructive pulmonary disease

E. Monninkhof\*, P. van der Valk\*, J. van der Palen\*, C. van Herwaarden<sup>#</sup>, G. Zielhuis<sup>¶</sup>

*Effects of a comprehensive self-management programme in patients with chronic obstructive pulmonary disease. E. Monninkhof, P. van der Valk, J. van der Palen, C. van Herwaarden, G. Zielhuis. ©ERS Journals Ltd 2003.*

**ABSTRACT:** The aim of this study was to assess the effects of a comprehensive self-management intervention on health-related quality of life (HRQoL), symptoms and walking distance in patients with stable moderately severe chronic obstructive pulmonary disease (COPD).

This study was part of the overall COPD study of the Dept of Pulmonary Medicine, Enschede, which consisted of an inhaled corticosteroid (ICS) trial and a self-management trial. After the ICS trial, all patients were randomised again to a self-management and a control group. The self-management intervention consisted of a skill-oriented patient education programme and a near-home fitness programme, on top of usual care. The control group received usual care by the treating chest physician. HRQoL was measured by the St George's Respiratory Questionnaire (SGRQ) and walking distance by the 6-min walking test. Patients recorded their symptoms in diaries and graded their health status from 1–10 in a weekly report.

Altogether, 248 COPD patients were randomly allocated to either an intervention (127) or control (121) group. No differences in the SGRQ scores within and between both groups were observed over 1 yr. Similarly, no differences in symptom scores and 6-min walking distance were found within and between groups. The intervention group reported more exacerbations than the control group. The majority (69%) of the exacerbations in the intervention group were self-treated at home.

This study failed to show positive effects of a self-management programme among moderately severe chronic obstructive pulmonary disease patients.  
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\*Dept of Pulmonary Medicine, Medisch Spectrum Twente, Enschede, <sup>#</sup>Dept of Pulmonary Medicine, and <sup>¶</sup>Dept of Epidemiology and Biostatistics, University Medical Centre, Nijmegen, The Netherlands.

Correspondence: E. Monninkhof, Medisch Spectrum Twente, Dept of Pulmonary Medicine, PO Box 50000, 7500 KA Enschede, The Netherlands.  
Fax: 31 534872638  
E-mail: emonninkhof@intraweb.nl

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Chronic obstructive pulmonary disease (COPD) is a local and systemic inflammatory disease [1]. Airflow limitation, hyperinflation due to loss of elastic recoil, intrinsic airway narrowing, and systemic deficits, such as skeletal and respiratory muscle dysfunction, are prominent features [2–5]. In COPD, therapy is often primarily aimed at improving airflow obstruction by bronchodilator and anti-inflammatory therapy, despite indications that airflow obstruction is not fully reversible and the apparent lack of effect of pharmacological interventions on the progressive decline in lung function. In spite of optimal pharmacological treatment, many COPD patients experience substantial functional impairment [6]. Consequently, there is a growing need for other forms of therapy for COPD patients, not only to control and alleviate symptoms and complications of respiratory dysfunction, but also to teach them skills for adaptational activities of daily living to their physiological impairment [7]. In other chronic diseases (*i.e.* rheumatic arthritis, diabetes mellitus, and asthma) interventions based on self-management principles have been shown to improve disease outcomes [8–11]. Self-management is a term applied to any formalised patient education programme aimed at teaching skills to optimally control the disease, behaviour change, and coping with the disease. The continuum of self-management programmes varies from the provision of written material only, to more intensive patient management, including exercise prescriptions.

In COPD, several studies on the efficacy of self-management

education have been published. A recent Cochrane review [12] of the author's research group, including eight studies of self-management education for patients with COPD, concluded that the available evidence is inconclusive, due to different study designs, methodological limitations and a wide variation of reported outcome measures.

To evaluate the effectiveness of a comprehensive self-management programme for patients with COPD, the authors conducted a large randomised controlled single-centre trial (the COPD study of the Dept of Pulmonary Medicine, Enschede (COPE) self-management study). This self-management programme was offered after a period of lung function optimisation and a smoking cessation programme, and included a near-home fitness programme and instructions for self-treatment of exacerbations.

### Methods

From May 1999 to March 2000, all patients were recruited from the outpatient pulmonary clinic of the Medisch Spectrum Twente, a 1,150 bed teaching hospital in Enschede, The Netherlands. To be eligible for the study the patients had to meet the following criteria: 1) a clinical diagnosis of stable COPD, as defined by American Thoracic Society criteria [13]; 2) no history of asthma; 3) no exacerbation in the month prior to enrolment; 4) current or former smoker; 5) aged 40–75 yrs;

6) baseline prebronchodilator forced expiratory volume in one second (FEV<sub>1</sub>) 25–80% predicted; 7) pre-bronchodilator ratio FEV<sub>1</sub>/inspiratory vital capacity  $\leq$  60%; 8) reversibility of FEV<sub>1</sub> postinhalation of 80  $\mu$ g of ipratropium bromide *via* metered dose inhalator (Boehringer Ingelheim, Ingelheim am Rhein, Germany; four puffs of 20  $\mu$ m) with aerochamber (Nebuchamber; AstraZenica, Sweden)  $\leq$  12% pred [14]; 9) TLC greater than TLC pred - (1.64 $\times$ SD); 10) no maintenance treatment of oral steroids or antibiotics; 11) no medical condition with low survival or serious psychiatric morbidity (*e.g.* cardiac insufficiency, alcoholism); and 12) absence of any other active lung disease (*e.g.* sarcoidosis). Use of medication, such as nasal corticosteroids, theophyllines, chronic use of acetylcysteine and all other bronchodilators, was allowed.

The hospital's medical ethical committee approved the study. All patients provided written informed consent.

### Study design

The overall COPE study was divided into two substudies. During the first substudy (discontinuation of inhaled corticosteroid (ICS) study) [15], the lung function of patients was optimised, including a 4-month regimen of 500  $\mu$ g fluticasone propionate twice daily, bronchodilation, and a smoking cessation programme for current smokers [16]. All patients were instructed in the correct use of their inhaled medication. After these 4 months, patients were randomly assigned to continue fluticasone propionate 500  $\mu$ g twice daily or to receive placebo for 6 months. Results of the first substudy are published elsewhere [15, 16].

Following the first substudy, all patients were randomised again into an intervention group receiving a comprehensive self-management programme and a control group receiving regular care from the chest physician only (the COPE self-management study). Randomisation was performed in blocks of four, stratified by sex and smoking status, using sealed envelopes. Patients attended the hospital every 6 months during the 1-yr follow-up.

### Intervention

The intervention consisted of a self-management education course and a fitness programme. In addition, the patients were supplied with a self-treatment action plan and a specially made booklet with background information on the education course and their disease. The education course took 4 months and the physical training continued for the duration of the study (2 yrs). The self-management education course consisted of five 2 h group sessions of approximately eight patients, given by a respiratory nurse. Four sessions were given with a 1-week interval and the last (feedback) session was given 3 months after the fourth session. The patient's partner or a significant other was also invited to attend the course. Patients who could not attend a planned group session could participate in another course.

The first session addressed coping with breathlessness, *i.e.* reducing the nihilistic idea about the treatment of COPD, obtaining better insight in the nature of the disease, symptom perception, and recognising triggers for breathlessness. During this session, guidelines for self-treatment of exacerbations (action plans), based on symptom perception, were introduced. In order to interpret and use these guidelines properly, they were discussed during each session.

During the second session the importance of exercise and relaxation were emphasised. Patients were motivated to participate in the fitness programme. Furthermore, attention

was paid to ergonomic posture and energy conservation during daily activities or work. The third session concentrated on nutrition and its implications for COPD patients. The risk of involuntary weight loss was emphasised. Patients were instructed to monitor their weight weekly, and they were provided with advice how to gain weight in case of underweight or involuntary weight loss. The themes of the fourth session were communication and social relationships. Changing role patterns and communication with the chest physician and other health care professionals were stressed. Patients were trained how to prepare their scheduled visits to their chest physician. The feedback session was aimed at exchanging experiences and maintaining the acquired knowledge and skills.

The self-treatment action plan was based on symptom perception. If patients experienced an increase of respiratory symptoms and normally would have called their physician, they could start with a short course of prednisolone, and an additional course of antibiotics in case of increase of purulent sputum.

Besides physical goals, the fitness programme was aimed at coping with the disease, recognising their individual capacity, social interactions and behavioural change.

The programme consisted of one or two 1 h small group training sessions per week under guidance of a physiotherapist trained in COPD care. The frequency of the training sessions depended on the initial physical state of the patient. In the first few months, inactive patients were offered two sessions per week to get started. Incorporation of exercise in daily life above the fitness training was the patients' own responsibility. Preferably, patients were referred to a physiotherapist stationed in the neighbourhood of the patient. The programme included strength training, breathing and cardiovascular exercises (stationary bicycling, walking *etc.*). An important factor of the programme was the individual tuning of the training intensity within group training. The physiotherapist, together with the patient, regularly determined the individual goals of the training. Furthermore, each patient had a training log in which their training performances and goals of training were registered.

Patients in the control group received usual care from their chest physician. Pharmacological treatment of exacerbations was standardised as much as possible. In order to obtain valid data about exacerbations, this group of patients was instructed to call the COPE study office if they felt in need of assistance for a worsening of their respiratory symptoms, and they would normally have called their chest physician or general practitioner instead. At the COPE office, the data managers dealt with all telephone calls first. Subsequently, a physician offered treatment advice by telephone or invited the patient to come to the hospital for consultation. Patients in the intervention group were instructed to contact the COPE office in case of doubt, a fast deterioration of their pulmonary condition, or absence of improvement by self-treatment of an exacerbation. Subsequently, the same procedure as in the control group was followed.

Treatment of exacerbations was standardised to a short course of oral corticosteroids of 30 mg prednisolone for 10 days and antibiotics when necessary. First choice of antibiotics was 625 mg amoxicillin/clavulanic acid four times daily for 10 days. Second choice was 100 mg doxycycline daily for 10 days. Patients in the self-management group had prescriptions or medication at home.

### Outcome measurements

At baseline, 6 months and 1 yr follow-up, health related quality of life (HRQoL) was measured by means of the Dutch version of the St George's Respiratory Questionnaire

(SGRQ) [17]. The SGRQ is a disease-specific instrument composed of 76 items that are weighted to produce scores in the domains: "symptoms", "activity" and "impact". A total score is calculated from all items and provides a global view of the patient's respiratory health. The scores range from 0–100, a score of 100 indicating maximum disability. A difference of four units or more indicates a clinically relevant effect [18, 19]. Exacerbations were defined as worsening of respiratory symptoms that required treatment with a short course of oral corticosteroids or antibiotics, as judged by the patient in the self-treatment group or by the study physician in the intervention and control groups. Walking distance was measured at randomisation and after 1-yr follow-up by the standardised 6-min walking test [20]. The performance of the test was standardised [21]; patients performed a practice walk, were instructed pre-test, and no encouragement was used during the test. A change of 54 m or more in walking distance is considered clinically important [22].

Patients were asked to complete a 2-week diary for symptoms of COPD prior to each follow-up visit [23]. These COPD symptoms were measured by a breathlessness score, cough, sputum volume and sputum colour. Every week patients graded their general well-being score (1–10) in a report. Mean scores for each of four periods of 3 months were used for analysis.

After 1 yr of follow-up, self-confidence regarding COPD was measured by one item, to which patients could respond on a five-point Likert scale (1=large reduction in self confidence, 5=large improvement in self confidence).

Demographical data were also collected. This included the level of education achieved. Low education was defined as ≤10 yrs, moderate 10–12 yrs and high was >12 yrs of formal education.

*Statistical analysis*

The authors calculated that a total of 125 patients (per treatment group) were required to detect a clinically relevant difference of four units on the SGRQ total score between both groups, with 80% power and a two-sided 0.05 α-level test. All analyses were performed according to the intent-to-treat principle.

Within and between-group differences in continuous variables over time (HRQoL scores, distance walked in 6 min, symptom scores, well-being weekly report scores) were assessed by analysis of repeated measurements using Proc Mixed (mixed models approach) and 95% confidence intervals (95% CI) were calculated. Difference between groups in self-confidence at the end of the study period was analysed with a Chi-squared test.

**Results**

Of the 509 eligible patients, a total of 269 were enrolled in the overall COPE study (fig. 1). All patients who finished the first substudy (n=242) plus six patients who were excluded from this substudy because of intolerance of the inhaled steroid Fluticasone Propionate, entered the self-management study. Altogether, 248 COPD patients were randomly allocated to either the self-management (127) or control (121) group. Table 1 shows the baseline characteristics of both treatment groups. These were similar with respect to all known prognostic variables.

The mean age of the participants was 65±7 yrs, and the mean FEV1 % pred was 57±15%. Three patients in the self-management group and one in the control group have received pulmonary rehabilitation in the past. Only 65% of the patients used ICS at randomisation, due to the procedure

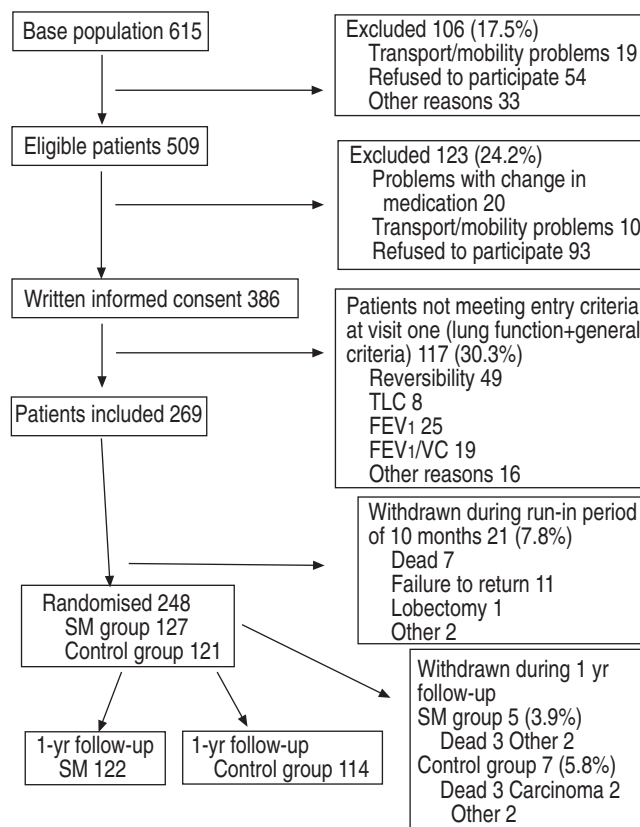


Fig. 1.—Flow diagram of subject progress through the chronic obstructive pulmonary disease study of the Dept of Pulmonary Medicine, Enschede self-management study.

Table 1.—Baseline characteristics of the two treatment groups

	Self-management group	Control group
Patients n	127	121
Age yrs	65±7	65±7
Male	85	84
BMI kg·m <sup>-2</sup>	27±4	27±4
Number of exacerbations in year preceding study	1.4±1.5	1.3±1.6
Smoking status		
Ex-smokers	72	74
Current smokers	28	26
Lung function post bronchodilation		
FEV1 L	1.71±0.56	1.76±0.54
FEV1 % pred of normal	56.1±15.4	58.4±14.5
VC L	3.89±0.85	3.77±0.84
Inhaled corticosteroid use	65	64
Long-acting β-agonists use	46	45
Total score SGRQ	37±18	38±17
6-min walking test m <sup>#</sup>	428±91	442±83
Education level		
Low	68	59
Moderate	21	23
High	11	18

Data are presented as mean±SD or % unless otherwise stated. All variables were measured at baseline unless otherwise stated. BMI: body mass index; FEV1: forced expiratory volume in one second; % pred: % predicted; VC: vital capacity; SGRQ: St George's Respiratory Questionnaire. #: mean values were based on 122 and 118 patients in the intervention and control group, respectively.

of the former ICS trial. Placebo patients who did not experience rapid recurrent exacerbations and did not have a 20% or 300 mL decrease in FEV<sub>1</sub> after 6 months follow-up, did not receive ICS again at the start of the self-management trial [15].

In the intervention group five patients (three deaths, two other) dropped out, as did seven patients (three deaths, two carcinoma, two other) in the control group. Thus, 122 patients in the intervention and 114 in the control group completed the 1-yr follow-up (fig. 1).

Altogether, five of the patients randomised to the intervention group refused to attend the self-management education course. These patients were younger and had a better health status compared with the other patients in the intervention group. Ninety-eight (77%) patients participated in the fitness programme, and the mean attendance frequency per week was  $0.77 \pm 0.22$  (n=68).

During 1-yr follow-up, the median number of exacerbations was two (range 0–12) and one (range 0–9) per patient in the intervention and control group, respectively. The majority (69%) of the exacerbations in the intervention group were self-treated at home.

### Health-related quality of life

Results of the repeated measurements analysis of the SGRQ scores are presented in table 2. No significant differences were detected between the groups over 1 yr. The proportion of patients for whom HRQoL has improved, been maintained or deteriorated, based on the minimal important difference of four points on the SGRQ total score was not significantly different between both groups. In the intervention group, 37% (45/122) of the patients had an improvement of HRQoL, compared with 33% (37/113) in the control group. HRQoL deteriorated in 36% (44/122) of the patients in the intervention group, compared with 32% (36/113) in the control group.

### Six-minute walk

During the 1-yr follow-up, the mean distance walked  $\pm$ SD in 6 min was reduced by  $13 \pm 7$  m in the intervention group and  $2 \pm 5$  m in the control group. These differences are not statistically or clinically relevant.

### Symptoms and well-being score

No between-group differences were seen in breathlessness (-0.04 95% CI -0.2–0.12) and sputum production (-0.03 95% CI -0.2–0.1) score, extracted from diaries. Small differences in cough (-0.1 95% CI -0.3–0.01) and sputum colour (-0.1 95% CI -0.3–0.02) scores were seen in favour of the intervention

group. Although these differences reached borderline significance, these are probably not clinically relevant.

The mean ( $\pm$ SD) well-being weekly report scores were not different between groups. The proportion of patients for whom the well-being score improved or deteriorated did not significantly differ between groups; 41.7% (30/72) improved in the intervention group and 36.4% (28/77) in the control group.

### Self-confidence

No statistically significant difference in the proportion of patients reporting improved, maintained or deteriorated self-confidence was observed between groups ( $p=0.289$ ), although a positive trend in favour of the self-management group was observed. The proportion of patients reporting improved self-confidence was greater in the intervention group (21.2% versus 13.6%). Additionally, a smaller proportion of patients reported deteriorated self-confidence in the intervention group (15% versus 19%).

## Discussion

This randomised controlled trial did not find a positive effect of a comprehensive self-management programme on HRQoL, walking distance, symptoms and exacerbation frequency in COPD patients. Subgroup analysis did not reveal specific categories for which this negative result did not hold.

Before drawing conclusions, several aspects of the intervention, the study design and study population should be reviewed in the context of literature.

Two comparable self-management studies also failed to show positive effects on HRQoL measured by SGRQ [24, 25]. A third study found a clinically significant improvement on HRQoL measured by the SGRQ in the self-management group after 1-yr follow-up [26]. However, this study differed on two important aspects from the current study. First, the population recruited from general practice was more severely impaired. Secondly, the intervention in this study was far less intensive than in the current study. It consisted of a patient brochure and action plan only, and no exercise component was included.

The patients in this study were fairly well stabilised and had moderate-to-severe COPD (mean FEV<sub>1</sub> 57% pred). During an optimisation phase before the self-management trial, all patients received inhalation instruction in small group sessions, COPD medication was optimised, and current smokers were offered a smoking cessation programme. As a result, unlike other studies reporting effects of self-management, the authors were able to measure the net effect of a self-management programme without influence of, for example, smoking cessation and optimisation of medication (*i.e.* optimisation

Table 2. – St George's Respiratory Questionnaire (SGRQ) scores at each study time point and mean difference between both treatment groups

SGRQ	Self-management group			Control group			Treatment effect <sup>#</sup>	
	Baseline	6 month	12 month	Baseline	6 month	12 month	$\Delta$	95% CI
Patients n	127	124	122	121	117	113		
Total	37.2 $\pm$ 1.6	37.3 $\pm$ 1.6	37.4 $\pm$ 1.7	38.1 $\pm$ 1.5	38.6 $\pm$ 1.5	37.7 $\pm$ 1.6	-0.6	-2.8–1.7
Symptoms	47.8 $\pm$ 2.0	48.6 $\pm$ 1.9	46.1 $\pm$ 2.1	48.5 $\pm$ 2.0	47.3 $\pm$ 2.1	47.3 $\pm$ 2.0	1.1	-2.5–4.8
Activity	50.7 $\pm$ 2.3	50.8 $\pm$ 2.2	51.4 $\pm$ 2.3	52.9 $\pm$ 1.9	52.1 $\pm$ 2.0	52.3 $\pm$ 2.0	-0.2	-3.2–2.8
Impact	26.2 $\pm$ 1.6	25.7 $\pm$ 1.6	26.4 $\pm$ 1.7	26.5 $\pm$ 1.6	28.1 $\pm$ 1.5	25.8 $\pm$ 1.6	-1.4	-3.9–1.1

Data are presented as mean  $\pm$ SE unless otherwise stated. 95% CI: 95% confidence interval. <sup>#</sup>: self-management-control.

bias). At the same time, the study population was probably preselected on motivation, as is the case in all randomised trials. Patients gave consent to participate in an investigation that was going to last for 3 yrs, and at time of randomisation for the self-management trial, they were already participants for 10 months. It should be noted that the participation rate (63%) is high. Although this type of preselection might raise concerns about generalisability, the validity of the study is not compromised (no selection bias) because randomisation ensured comparability of intervention and control group.

Although the inclusion criteria selected almost exclusively moderately severe patients in stage II of the GOLD classification [3], the mean HRQoL of these patients was relatively high. Consequently, the room for improvement in this group of patients was limited. The authors observed the same phenomenon in a previous asthma study [27], and have no explanation for this except that in this area of the Netherlands people do not usually complain about their health.

The authors expected deterioration in HRQoL over time in the control group, considering the results of the ISOLDE study [28]. This study showed that health status as measured by the SGRQ declines  $\sim 3.2$  units $\cdot$ yr $^{-1}$  in patients with moderate-to-severe COPD. This expected deterioration in HRQoL was not found in the control group. This lack of decline may be due to the fact that the patients in the current study had less severe COPD than the ISOLDE patients, and that participating in a trial may improve performance not because of any specific condition being tested, but simply because of the increased attention they receive (the so-called Hawthorne effect). It should be noted that this trial could not be blinded. Although some patients in the control group might have changed their behaviour after notification of allocation, it is unlikely that this phenomenon have masked a real effect in the intervention group.

In general, exacerbations deteriorate HRQoL in patients with COPD [29]. However, in the current study HRQoL did not differ between the intervention and control group, despite an almost double exacerbation frequency. Probably, self-treated exacerbations have another impact on HRQoL than physician-treated exacerbations. This might be due to the fact that early self-treatment of exacerbations by the patient might prevent further deterioration of the condition and self-treatment might increase disease-specific self-confidence and self-determination of the patient. Furthermore, the apparent paradox of increased use of courses of oral steroids or antibiotics for respiratory symptoms in self-management trials [26, 30, 31], does not mean that self-management education leads to a worsening of respiratory symptoms, but more likely to an enhanced ability to recognise symptoms earlier.

In general, insufficient compliance with a self-management programme diminishes possible effects. However, in the current study the high attendance rates during the course, the follow-up visits and the fitness programme indicate a rather high compliance.

The intensity of the programme can be discussed. Weekly visits to a physiotherapist and 10-h self-management education is rather intensive. However, to reach improvement in exercise performance, higher exercise intensity is probably needed [32]. To induce physiological changes CASABURI *et al.* [32] recommended exercise above anaerobic threshold 30–45 min  $>3$  times a week. Conversely, this is not a realistic option for outpatients with moderate COPD, and increasing exercise capacity needs not to be the only goal of training programmes. Important patient specific goals, such as increased functionality, increased walking capacity, dyspnoea sensation and socialisation, might be gained by less intensive programmes.

Although the SGRQ and the 6-min walking test are

frequently used as outcome measures in COPD research, these might be insensitive to pick up (small) relevant self-management specific changes. For example, the SGRQ does not reflect the management and control aspect of quality of life. In future studies cognitive and psychological outcomes, such as coping strategies, anxiety and depression, should be included besides HRQoL measures.

With these reservations in mind, it might be concluded that for this category of stable moderately severe chronic obstructive pulmonary disease patients, who are receiving close to optimal treatment, this type of intervention does not lead to measurable effects on health-related quality of life, symptoms and walking distance. Future research should focus on other types of interventions, other (more severe) chronic obstructive pulmonary disease patients, and other types of outcomes, such as anxiety, depression or coping strategies, and more sensitive scales to measure these outcomes.

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