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# Cost-saving effect of supervised exercise associated to COPD self-management education program

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## KEYWORDS

Randomized controlled trial;  
Pulmonary disease, chronic obstructive;  
Self-management program;  
Exercise;  
Health-related quality of life

## Summary

**Background:** Although the benefits of comprehensive pulmonary rehabilitation have been demonstrated in patients with COPD, the effects of exercise sessions within self-management programs remain unclear. We hypothesized that 8 supervised exercise sessions incorporated in a 1-month self-management education program in COPD patients would be effective to improve health outcomes and to reduce direct medical costs after one year, compared to usual care.

**Methods:** In this randomized controlled trial, 38 moderate-to-severe COPD patients were assigned either to an intervention group or to a usual care group. The hospital-based intervention program provided a combination of 8 sessions of supervised exercise with 8 self-management education sessions over a 1-month period. The primary end-point was the 6-min walking distance (6MWD), with secondary outcomes being health-related quality of life (HRQoL) – using the St. George's Respiratory Questionnaire (SGRQ) and Nottingham Health Profile (NHP), maximal exercise capacity and healthcare utilization. Data were collected before and one year after the program.

**Results:** After 12 months, we found statistically significant between-group differences in favor of the intervention group in 6MWD (+50.5 m (95%CI, 2 to 99)), in two domains of NHP (*energy*, –19.8 (–38 to –1); *emotional reaction*, –10.4 (–20 to 0)); in SGRQ-*symptoms* (–14.0 (–23 to –5)), and in cost of COPD medication (–480.7 € (CI, –891 to –70) per patient per year).

**Conclusion:** The present hospital-based intervention combining supervised exercise with self-management education provides significant improvements in patient's exercise tolerance and HRQoL, and significant decrease of COPD medication costs, compared to usual care.

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## Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a serious public health problem. According to the World Health Organization, COPD is currently the fourth leading cause of mortality worldwide, with approximately 2,75 million deaths yearly and a further increase in mortality predicted for the coming years.<sup>1</sup> Since many patients with COPD exhibit progressive disability rather than immediate death, mortality data do not present a complete picture of the disease's burden.<sup>1</sup> In addition to the economic burden imposed on healthcare systems, a loss in health-related quality of life is seen in many patients. Therefore, appropriate therapies are necessary to deal with this disease.

Self-management is a term applied to any formalized patient education program aimed at teaching skills needed to carry out disease-specific medical regimens, guide health behavior change, and provide emotional support to enable patients to control their disease and live functional lives. The influence of self-management education in patients with COPD is not clear since previous studies that have addressed the issue have used a variety of programs.<sup>2</sup> Some investigations, for example, added action plans and/or exercise interventions to the self-management education program. The type and intensity of the education component also varies across studies from group education to individual education to written education only. The effectiveness of pulmonary rehabilitation and, more specifically, of exercise training, has been extensively documented using both inpatient<sup>3</sup> and outpatient approaches.<sup>4</sup> However, the effects of exercise interventions administered within self-management programs remain unclear and have been the focus of only four studies.<sup>5–8</sup> The exercise programs included in these investigations did not systematically meet rehabilitation standards (e.g., frequency and intensity of supervised training sessions) and non-participation was not a criterion for study withdrawal, thus affecting the uniformity of interventions offered. Moreover, only two studies<sup>9,10</sup> have evaluated the cost-effectiveness of such self-management program, i.e. comprising education and exercise components, with only the Quebec study of Bourbeau et al.<sup>10</sup> which showed significant benefits. Given the current context of financial uncertainty, there is a need for more randomized controlled trial to achieve more evidence about the cost-saving effect of exercise interventions incorporated within self-management education programs, compared to usual care.

Therefore, the objective of the present study was to determine the 1-year beneficial effect of a self-management education program which included supervised exercise sessions. The primary outcome measure was the 6-min walking distance (6MWD). Secondary outcome measures were health-related quality of life (HRQoL), maximal exercise capacity and direct medical costs.

## Methods

### Design

This study followed a prospective, randomized, parallel-group design. It was part of a wider study investigating the effects of a self-management education program on

healthcare costs for various chronic diseases, including chronic heart failure, type-2 diabetes<sup>11</sup> and COPD. Patients were recruited from pulmonary clinics in a university-based hospital between January 2002 and November 2003. This center had extensive prior experience in providing pulmonary rehabilitation. Participants were randomly assigned either to usual care without any practical intervention (control group) or to a 4-week standardized, comprehensive, self-management program comprising education and exercise sessions. After the 4-week intervention, participants were encouraged to continue exercising at home, and were followed-up for 48 weeks to complete the 1-year study. During the maintenance phase (1–12 months), contacts with study personnel were limited (for both groups) to telephone interviews to reinforce the importance of exercise and to ask about adverse events. Participants from both groups were assessed at inclusion and at 1 year. The institutional research ethic board approved the study, and each patient provided informed consent.

### Participants

Participants were recruited from the university-based center by flyers advertizing the study. Patients were eligible for participation if they had stable COPD, that is, no change in medication and symptoms (i.e. dyspnea, volume, or color of sputum) for at least 4 weeks before screening; were 40 years of age or older and had a forced expiratory volume in 1 s (FEV<sub>1</sub>)/forced vital capacity (FVC) ratio of less than 0.70. No participant had previously been involved in pulmonary rehabilitation or had lived in a long-term care facility. Everyone understood, read, and wrote French. Exclusion criteria included a previous diagnosis of asthma, oxygen dependence, unstable and/or uncontrolled cardiac disease, musculoskeletal problems precluding exercise training, a terminal disease, dementia, or an uncontrolled psychiatric illness.

### Intervention

#### Self-management program

The self-management program was provided in the hospital on an outpatient basis. A health professional gave 8 lectures to small groups of 4–8 participants at a rate of 2 sessions (i.e. 2 h per session) per week for 4 weeks. The program emphasized on the acquisition of self-management skills: to promote smoking cessation, encourage prompt management of acute exacerbation (e.g., advice about when to initiate antibiotics or steroid regimens), ensure correct inhaler techniques, ensure right secretion removal techniques, optimize nutrition and promote active lifestyle (particularly exercise). After each educational session within the same group, participants performed the usual exercise program used in our laboratory<sup>12</sup> (i.e. cycling at the level of the ventilatory threshold for 30–45 min under the supervision of a qualified exercise trainer). The provider was insisted on the use of correct breathing techniques during exercise.

We defined adherence to the self-management program as completing at least seven of the eight sessions – combining exercise and education components.

### Usual care intervention (UC)

Patients assigned in UC group were discharged from hospital by the attending physician who decided on the outpatient control regime. Patients in the UC group were visited by their own physician without additional support. Specifically, the controls did not benefit from the self-management program (neither the education nor the exercise components).

### Follow-up strategy

The maintenance program was identical in both groups; it did include neither supervised training sessions nor education sessions. There was only a telephone support (i.e. 3 times during the follow-up period) which consisted of standardized contact of patients – encouragement to follow personalized endurance-training (i.e. home exercise, moderate intensity, 2 times per week) – and relied on reporting of symptoms.

### Randomization

Participants were randomly assigned either to the self-management program or usual care group. The trial statistician, MCP, generated the random allocation sequence using the random procedure in SAS (SAS v.9.1 – SAS Institute, Cary NC), with a 1:1 allocation using block size of 4. The enrollment of patients in the study proceeded as follows: (i) patients were contacted via flyers advertising the study in the corridors of the hospital; (ii) they met the investigator (i.e. physician) who informed them about the objective of the study; and he verified their eligibility; (iii) eligible patients were invited to participate in the study. After the physician had obtained the patient's consent, he sent by fax the randomization form to the Clinical Research Unit (AJ) for allocation consignment re-addressed by fax. He subsequently informed patients of their group allocation. Due to the nature of the intervention conditions, it is not possible to blind research participants or assessors. Several stratagems were adopted in an effort to ensure that objectivity was maintained as rigorously as possible. Participants were unaware of their group allocation until they had completed all of their pre-intervention assessment. The individuals carrying out the assessments were not part of the intervention team. Research participants were asked not to divulge information regarding their group allocation in conversation during assessments at 12 month.

### Measurements and outcomes

Evaluation visits were scheduled at the study center at enrollment (initial visit) and at 12 months (end of study). Patients from both groups kept a diary to help collect information on medical events and physical activity.

### Primary outcome variable

The pre-specified primary outcome was the change in 6MWD at 12 months to measure the impact of self-management program including exercise training.

### Secondary outcome variables

Secondary outcomes included domains of the St. George's Respiratory Questionnaire (SGRQ) and the Nottingham Health

Profile (NHP), maximal exercise capacity (measured as peak work rate), daily physical activity and healthcare utilization at 12 months.

### Six-minute walking test

The 6MW test was performed twice with more than 30 min between tests to allow heart rate and dyspnea to return to their initial resting values. Subjects were asked to walk, during 6 min, at their own maximal pace along a perimeter of 30 m. No encouragement was given, and subjects were informed each minute of the time remaining. A dyspnea score was measured on a visual analog scale (VAS, 0–10 cm) before and at the end of the test. The minimum, clinically important difference (MCID) was set at 35 m for the 6MWD.<sup>13</sup>

### COPD-specific health status questionnaire

Patient completed the French version of the SGRQ. This validated 50-item questionnaire<sup>14,15</sup> has been widely used in patients with COPD. The SGRQ is composed of three domains: *symptoms*, *activity* and *impacts*. Scores range between 0 (no impairment) and 100 (worst possible health). A difference  $\geq 4.0$  units is considered as the MCID.<sup>16</sup>

### Generic health status questionnaire

Perceived health status was measured according to the first part of the NHP, developed in the UK in the 1970s for use in population surveys.<sup>17</sup> This self-administered instrument, validated in a French version,<sup>18</sup> consists of 38 items pertaining to how people feel or operate in their daily life. The items cover the following six dimensions: physical mobility, pain, sleep, energy, social isolation and emotional reactions. Patients were asked whether or not each item applied to them. Positive answers were given the appropriate weight, resulting in score range from 0 to 100 for each dimension. Dimension scores were only calculated if no data were missing on the dimension concerned. Higher scores correspond to a lower perceived health status.

### Maximal exercise test

At the time of enrollment and at 12 month, each patient completed a symptom-limited, incremental cycle exercise test to determine peak work capacity. The test was performed on an electromagnetically-braked cycle ergometer following the individualized protocol usually used in our laboratory and recommended by the American Thoracic Society.<sup>19</sup>

### Daily physical activity

Physical activity level was measured using the Voorrips questionnaire<sup>20</sup> at the time of enrollment and at 12 month. This questionnaire provides a reliable and valid method for classifying the activity level of older subjects as high, medium or low with a score of 9.4 or less indicating a low physical level, thus classifying the subject as being sedentary.<sup>21</sup> Moreover, to ensure "realistic" conditions of training at home, during the follow-up, the actual practice of the physical activity were recorded: everyday, patients had to keep track of all their activity in a diary.

### Healthcare utilization

Assessment of the use of healthcare resources by individual interviews was carried out after 12 months in both arms of

the study. Also, data concerning the number and length of hospital admissions were retrieved from patients' medical chart.

### Pulmonary function tests

Flow rates, lung volumes, and diffusion capacity were measured using standard techniques<sup>21,22</sup> at the time of enrollment. Spirometry was repeated at 12 months.

### Safety monitoring

Patients were asked to complete a weekly diary card during the study period to record medical events, such as COPD exacerbations, hospitalizations, cardiovascular events, or any other relevant event. Serious adverse events were defined as death or hospitalizations for any cause and were tracked throughout the study during the standardized telephone interviews. The investigators and the study steering committee reviewed all serious adverse events to determine whether they were related to the study intervention.

### Sample size calculation

We calculated that we would need a study of 23 patients to have an 80% chance of detecting a difference of 50 m between-group means in 6MWD – derived from the overall effect size of a rehabilitation program calculated in the review of Lacasse et al.<sup>23</sup> – with an SD of 65 m and an alpha error of 0.05 (one-sided).

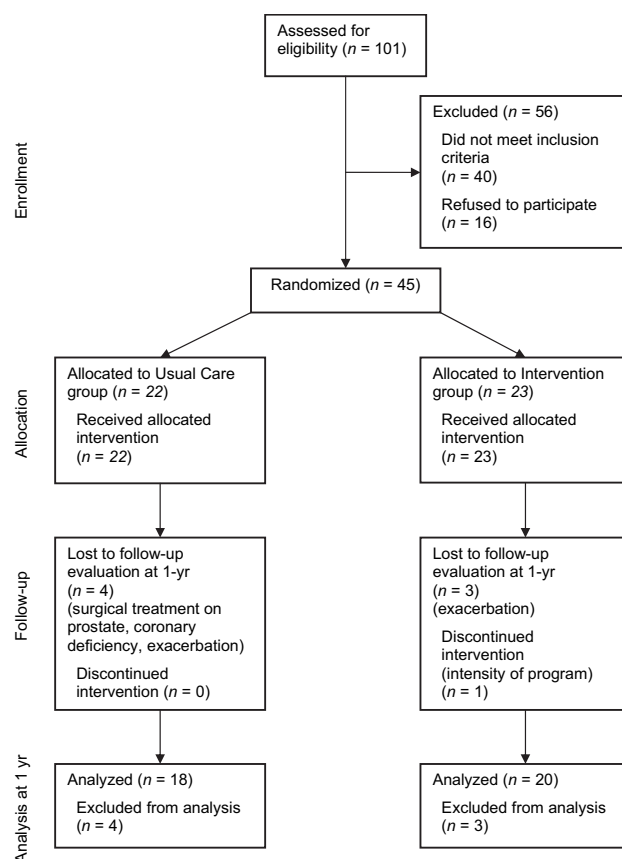
### Statistical analysis

Measures of central tendency and dispersion were computed for quantitative baseline measures, while proportions were obtained for categorical measures. Differences are reported as outpatient intervention minus usual care intervention. Only the patients with complete final outcome data were included in the main analyses. For the primary outcome – 6MWD – the within-group differences were calculated from baseline, and 95% CIs were obtained (with a fixed effects regression model), adjusting for baseline 6MWD and using treatment group as a predictor. Separate regression analyses were used to predict treatment differences at 12 month. A series of General Linear Model (SAS v.9.1 – SAS Institute, Cary NC) were conducted to estimate adjusted treatment differences and within-group differences. Secondary outcomes were analyzed using the same analyses. All tests of statistical significance were 2-sided.

## Results

### Study patients

Fig. 1 displays the patients' flow throughout the study. Between 2002 and 2003, we assessed 101 patients for eligibility and randomly assigned 45 patients. Fifty-six patients did not meet all inclusion criteria and 16 refused to participate without financial compensation. One patient from the intervention group did not fulfill our adherence criteria to the 4-week program, and also did not complete the 1-year evaluation. Six more patients were not available for follow-up evaluation: four in the usual care group, and



**Figure 1** Study Flow Diagram (as recommended by CONSORT guideline).

two in the intervention group. The withdrawals were due to miscellaneous medical conditions ( $n = 3$ ), and COPD exacerbation ( $n = 3$ ). Due to the missing data, we did not retain these patients in our 1-year analyses.

### Sample characteristics

Table 1 summarizes selected descriptive characteristics in all 38 eligible COPD patients. As indicated, at entry, patients from both groups showed similar characteristics except for total lung capacity, which was significantly higher in usual care group ( $p = 0.02$ ). Baseline characteristics of the patients who withdrew from the study were similar to those of patients who completed the trial: Patients who withdrew were aged 67 ys (SD  $\pm$  11 yrs) and had a predicted FEV<sub>1</sub> value of 47% (SD  $\pm$  17%) and a 6MWD of 388 m (SD  $\pm$  79 m).

### Primary outcome

Table 2 shows changes (difference between 12 months and baseline) in clinical, functional and quality of life variables, by treatment group, as well as the difference of this change in the intervention group compared to the usual care group, which is equal to the coefficient of the linear regression model.

**Table 1** Baseline Characteristics of Patients.

	Usual Care Group (n = 18)		Intervention group (n = 20)	
<b>Sociodemographics</b>				
Age, y	61	(56–65)	65	(59–74)
Men/women, n/n		14/4		18/2
Employed, n (%)	3	(17)	1	(5)
Distance from hospital, km	15	(5–30)	8	(5–28)
<b>Clinical and functional profile</b>				
Current smoker, n (%)	5	(28)	5	(25)
Ever smoked, n (%)	17	(94)	19	(95)
Body-mass index, kg/m <sup>2</sup>	26	(22–27)	25	(23–28)
Mood disorder, n (%)	4	(22)	3	(16)
FEV <sub>1</sub> , L	1.52	(1.06–1.85)	1.69	(1.17–2.01)
FEV <sub>1</sub> , % predicted	54	(42–57)	56	(42–67)
FVC, L	3.10	(2.44–3.53)	2.85	(2.50–3.59)
FVC, % predicted	77	(72–84)	75	(65–92)
FEV <sub>1</sub> – FVC ratio, %	49	(41–58)	56	(53–59)
Total Lung Capacity, % predicted	110	(103–127)	101	(88–114)
Six-minute walking distance, m	397	(360–470)	450	(385–505)
Baseline dyspnea VAS score (end of 6MWD)	5.5	(4–6)	6.2	(5–8)
Peak work rate, W	80	(50–100)	76	(62–105)
Peak VO <sub>2</sub> , mL <sup>-1</sup> kg <sup>-1</sup> min <sup>-1</sup>	26	(23–28)	24	(22–28)
Baseline Voorrips score	2	(1–4)	3	(2–4)
<b>Baseline SGRQ score</b>				
Symptoms	46	(34–61)	47	(22–70)
Activity	51	(41–79)	54	(45–67)
Impacts	28	(17–45)	36	(16–47)
Total	41	(27–51)	44	(26–56)
<b>Baseline NHP score</b>				
Energy	44	(26–100)	27	(0–63)
Pain	5	(0–18)	11	(0–22)
Emotional reaction	19	(8–40)	9	(0–29)
Sleep	26	(0–57)	32	(0–52)
Isolation	10	(0–25)	0	(0–0)
Mobility	12	(0–23)	16	(0–33)

Data are expressed as median (25th to 75th percentile), n or n/n; SGRQ = St. George's Respiratory Questionnaire; NHP = Nottingham Health Profile.

The within-group comparisons for the primary outcome showed that only the intervention group was associated with statistically significant improvements in 6MWD at 12 month (Table 2). Moreover, after adjustment for the baseline value, results showed that the intervention group walked 50.5 m (95%CI: 2–99 m) farther than the usual care group (Table 2). In the same period, the results indicate no significant between- or within-group difference in dyspnea (post 6MWD) scores.

### Secondary outcomes

A clinically significant between-group difference was observed for *symptoms* of SGRQ 12 months after the beginning of the study. In addition, the score in the intervention group improved for all four domains of the SGRQ and the *energy* and *emotional reaction* domains of the NHP. The usual care group was also associated with statistically and clinically significant improvement in the *activity* dimension of the SGRQ. No effect was found for other domains of the NHP.

Both groups showed significant increases in the *total Voorrips* scores, with higher values at 1-year than at admission (intervention group: +4.1,  $p < 0.001$ ; usual care group +1.4,  $p < 0.001$ ). Also, subgroup comparisons revealed a significant difference after one year with higher scores for the intervention group (2.7 (95% CI: 1.1–4.3 units)). Given that a large majority of patients forgot to keep track of their daily physical activity in their diary, we did not analyze this data.

Results indicate no significant between-group difference in maximal exercise capacity (peak work rate or  $\dot{V}O_2$ max values). Nevertheless, the intervention group shows a significant increase of peak work rate values after 12 months.

Regarding healthcare utilization, the number of days spent in the hospital for respiratory problems and for all causes, as well as the associated cost per patient and per year did not differ between groups after 12 months (Table 2). Nevertheless, a decrease in COPD medication cost was noted in the follow-up period for the intervention group (–481 € (95% CI: –891 to –70) per patient and per year).

**Table 2** 6MWD, Dyspnea, Peak Work Rate, Peak VO<sub>2</sub>, Voorrips Score, NHP Score, SGRQ Score and HealthCare Use Differences from Baseline to 12 month.

Variable	Within-Group Differences from Baseline (Median, 25th to 75th percentile)				Between-group Difference (Intervention Minus Usual Care group)			
	Usual Care group (n = 18)		Intervention group (n = 20)		Univariate analysis		Linear regression	
	1 yr	P	1 yr	P	P	β (95%CI)	P	
6-min walking distance, m	12.5 (-15 to 48)	0.52	<b>30.0 (5 to 80)</b>	<b>&lt;0.01</b>	0.15	50.5 (2-99)	<b>0.04</b>	
Dyspnea VAS score (end of 6MWD)	0.0 (-1 to 1.50)	0.90	-1.0 (-3.25 to 0.75)	0.06	0.18	-0.5 (-2 to 1)	0.52	
Peak work rate, W	<b>8.0 (0 to 20)</b>	<b>&lt;0.01</b>	0.0 (-4 to 11)	0.45	0.14	-6.3 (-15 to 3)	0.17	
Peak VO <sub>2</sub> , mL <sup>-1</sup> kg <sup>-1</sup> min <sup>-1</sup>	0.1 (-0.1 to 0.1)	0.90	-0.1 (-0.2 to 0.1)	0.50	0.40	-0.03 (-0.2 to 0.1)	0.76	
Voorrips total	<b>1.4 (0.6 to 2.3)</b>	<b>&lt;0.001</b>	<b>4.1 (2.5 to 6.7)</b>	<b>&lt;0.001</b>	<b>&lt;0.001</b>	<b>2.7 (1.1-4.3)</b>	<b>&lt;0.01</b>	
NHP score								
Energy	0.0 (-39 to 0)	0.18	-13.3 (-63 to 0)	0.03	0.47	-19.8 (-38 to -1)	<b>0.04</b>	
Pain	0.0 (-10 to 6)	0.97	-5.7 (-12 to 5)	0.11	0.21	-4.7 (-14 to 5)	0.32	
Emotional reaction	0.0 (-8 to 0)	0.66	-8.2 (-18 to 0)	<b>0.03</b>	0.11	-10.4 (-20 to 0)	<b>0.04</b>	
Sleep	0.0 (0-20)	0.17	0.0 (-1 to 0)	0.68	0.16	-12.2 (-26 to 1)	0.07	
Isolation	0.0 (-17 to 0)	0.68	0.0 (0-25)	0.84	0.49	-8.5 (-20 to 3)	0.15	
Mobility	0.0 (-3 to 1)	0.99	0.0 (-13 to 5)	0.23	0.53	-2.2 (-10 to 6)	0.58	
SGRQ score								
Symptoms	3.7 (-8 to 18)	0.31	-7.0 (-19 to 1)	0.02	0.02	-14.0 (-23 to -5)	<b>&lt;0.01</b>	
Activity	-6.7 (-13 to 0)	<b>0.03</b>	-6.7 (-16 to -5)	<b>&lt;0.01</b>	0.61	-2.8 (-13 to 7)	0.58	
Impacts	-5.6 (-9 to 9)	0.52	-6.3 (-24 to 0)	0.04	0.18	-8.9 (-19 to 1)	0.08	
Total	-4.7 (-11 to 4)	0.33	-7.6 (-18 to -1)	<b>&lt;0.01</b>	0.15	-8.0 (-16 to 0)	0.06	
COPD-related hospital LOS <sup>#</sup> , day	0.0 (-1 to 0)	0.50	0.0 (-3 to 0)	0.64	1.00	1.7 (-1 to 4)	0.18	
All cause hospital LOS <sup>#</sup> , day	0.0 (0-2)	0.94	0.0 (-3 to 0.5)	0.71	0.61	1.2 (-1 to 4)	0.34	
Cost of COPD medication <sup>#</sup> , €	-9.6 (-17 to 157)	0.76	-6.5 (-179 to 0)	<b>0.025</b>	0.30	-480.7 (-891 to -70)	<b>0.02</b>	
Cost of COPD-related hospitalizations <sup>#</sup> , €	0.0 (-1017 to 0)	0.44	0.0 (-2879 to 49)	0.67	0.89	1690.8 (-812 to 4194)	0.18	
Cost of all cause hospitalizations <sup>#</sup> , €	0.0 (0-2035)	0.94	0.0 (-2905 to 509)	0.62	0.56	1110.0 (-1551 to 3771)	0.40	

Results presented as: † = mean (95% confidence interval) or ‡ = median (25th to 75th percentile); # = per patient and per year; LOS = length of stay. Regression coefficient β (95% confidence interval) of variable 'group', adjusted for the baseline value of the outcome measure concerned.

## Discussion

### Main results

The objective of this randomized controlled study was to determine the beneficial effect of a 1-year self-management program which provided supervised exercise and education sessions. After one year, the program was associated with a statistically significant difference in 6MWD, daily physical activity level, HRQoL (NHP – *energy* and *emotional reaction*, SGRQ – *symptoms*) and costs of COPD medication compared to usual care. Administering a simple intervention that combined supervised exercise with standard self-management education yield small but significant benefits compared to usual care.

### Exercise tolerance

Given that the inferior limit of the confidence interval around our effect size (2–99 m) lies below the limit of the confidence interval around the estimate of the MCID for the 6-min walking test (CI: 30–42 m),<sup>13</sup> the clinical significance of our result is low. This finding parallels those of Boxall et al. (CI: 8–92 m) who also included the 6MWD as an outcome measure of a self-management education program with supervised exercise. Their shorter follow-up period (i.e. 3 months) renders comparisons with our trial difficult. With a comparable 12-month follow-up, our results on exercise tolerance and dyspnea do contrast those of two larger randomized study from Bourbeau et al. (CI: –44 to 26 m) and Monninkhof et al. (CI: –47 to 1 m), where the exercise program was not an obligatory component of the intervention. It is not clear in these prior studies how many patients really participated in the exercise program. The standardized supervision of exercise in our intervention (i.e. 8 sessions) may be an explanation for our better result. Furthermore, the fact that our patients showed a similar COPD severity ( $FEV_1 \sim 1.5$  L) and baseline exercise tolerance (6MWD  $\sim 420$  m) to those of Monninkhof et al.,<sup>7</sup> makes the confounding effect of these two known factors on the 6MWD's change unlikely.

Despite the large confidence interval of our effect size, our results are positive and suggest that peer interactions and exercise in the self-management education program may be necessary for letting patients acquire and practice skills, and for achieving more active behavioural change and better dyspnea control. Patients learn with experts to cope with their spontaneous anxiety provoked by dyspnea during exercise.<sup>24</sup>

### Healthcare utilization

Over the 1-year follow-up period, no significant differences were found between the two study groups in terms of cost per patient for COPD-related or all-cause hospitalizations. Our results are consistent with a recent systematic review from Adams and colleagues<sup>25</sup> which showed that the relative risk for hospitalization was not significantly different between the intervention and control groups in studies that provided only one chronic care model (CCM) component (self-management alone). In contrast, the pooled results from

randomized controlled studies<sup>5,8,26,27</sup> that implemented multiple CCM components (interventions on delivery system design, decision support, or clinical information systems) demonstrated significant reductions in hospitalizations in the intervention groups (relative risk (95%CI), 0.78 (0.66–0.94)). So far, only the study published by Bourbeau et al.<sup>5</sup> demonstrated the cost-effectiveness of a self-management education program (reduction in respiratory-related hospital admission and emergency department visits per person and per year). They combined self-management program with interventions on delivery system design and decision support. A recent Dutch paper<sup>28</sup> highlights the mechanisms, nested in the social learning theory, that may explain the added value of such programs, called disease-management or integrated programs, which combined patient-related and professional-directed interventions. The patient-professional partnership implies that while professionals are experts about diseases, patients are experts about their own lives. For patients, the provision of knowledge should lead to enhanced self-efficacy, which in turn influences health behavior and eventually health status. For professionals, access to decision support should affect professional behavioral intention, which in turn influences professional behavior and eventually leads to improved health outcomes. When informed, patients take an active role in managing their health, and professionals feel prepared and supported with time and resources, thus likely rendering their interaction to be much more productive. The effects of a self-management program on healthcare utilization are hypothesized to result from behavioral change, which in turn is caused by enhanced self-efficacy, knowledge and skills.<sup>29</sup> Although our program provided exercise sessions combined with education, patient-related intervention is definitely insufficient, in particular without active sustained follow-up, for leading to strong behavioral change and reduction in utilization of healthcare services.<sup>30</sup> Moreover, as provided in the respiratory rehabilitation programs, the psychological support is a key core-component of the patient-related intervention to optimize the adoption and maintenance of healthy behaviours.<sup>31</sup>

### Health-related quality of life and cost

Regarding HRQoL scores, after adjustment for baseline values, significant between-group differences were found only for the *energy* and *emotional reaction* dimensions of the NHP and the SGRQ-*symptom* score. These two dimensions of the NHP have been shown in prior studies to vary more in response to pulmonary rehabilitation<sup>32</sup> or other professional-related interventions<sup>33</sup> in COPD patients. The *emotional reaction* dimension that is close to the concept of subjective *tension*, and the *energy* dimension, are widely described in literature as two important factors in the mechanisms explaining the benefits of moderate exercise on mood.<sup>34</sup> Therefore, the significant improvement of scores on these dimensions is very interesting. It suggests changes in the behavior of patients with an increased daily physical activity (supported by change of Voorrips total scores, +4.1 points), which in turn leads to an increased subjective energy and tension reduction, two basic elements of a good mood.



Although insufficient to lead to significant or clinically relevant between-group differences on the SGRQ-domain *physical activity* (−2.8; 95% CI (−13 to 7 units)), the benefits seen at 12 month in the *energy* and *tension* dimensions are associated with lower perceived symptoms measured by the SGRQ (−14.0; 95% CI (−23 to −5 units)). These results concerning SGRQ-*symptom* scores are original, compared to the pooled summary estimate for mean change calculated in the review of Effing et al. (−1.4; 95% CI (−4 to 1 units)).<sup>2</sup> However, they are consistent with the results reported by Boxal et al., who also provided supervised exercise sessions within the self-management education program.<sup>6</sup> This emphasizes the importance of exercise to act on the determinants of mood, such as energy and tension; mood that may bias symptom reporting.<sup>35</sup> This change in perception of respiratory symptoms may explain the reduction observed in mean cost of COPD medication in favor of the intervention group (−481; 95% CI (−891 to −70 €) per patient and per year). Mood is strongly associated with investment beliefs,<sup>36</sup> which have been shown as the primary predictor of physically active behavior<sup>37</sup>; thus the encouraging changes in two important elements of mood that we observed one year after a short self-management education intervention should be verified with a longer follow-up period.

### Limitations of study

Factors that need to be considered in the interpretation of our findings include insufficient power and potential biases. The actual power to detect a clinically important change (i.e. four points or greater) in the SGRQ was low (13%). Our failure to detect statistically significant between-group differences in the SGRQ-domain *impact* and *activity* was thus likely limited by sample sizes, since the direction and magnitude of treatment effects consistently approached values that are considered to be clinically important. Moreover, because of the low occurrence of emergency department utilization and hospitalizations, the power to detect differences between the groups for these outcomes was even lower. Although this was a randomized trial, a few baseline characteristics were not equally distributed among the experimental groups. For this reason, we used multivariate analysis to adjust for these baseline differences. In addition, our study did not report measures on determinants of behavioral change. As such, more attention should be paid to the patterns of physical activity with process indicators (i.e. knowledge, psychosocial beliefs and self-efficacy) — since they determine behavioral change, which in turn determines clinical and quality of life outcomes.<sup>29, 37</sup> Moreover, these indicators may be more sensitive in capturing relevant changes specific to self-management, and reduce the risk of false-negative results.<sup>29</sup> Finally, we cannot exclude the presence of an attrition bias since seven patients allocated in each group were not available for the evaluation at 1 year. However, this potential bias is minimized given their comparable baseline characteristics with patients who completed the follow-up. Moreover, the frequency and the causes of dropping out were comparable between the intervention groups.

### Conclusion

The results of our investigation show that a sensitizing intervention that combined 8 exercise sessions with a self-management education program is suitable for improving patient skills over a 1-year period. It provides clinically significant improvements in patient's exercise tolerance and HRQoL, and reductions in cost of COPD medications, compared to usual care. The education component within a self-management program should not be considered as an isolated intervention. Clinicians should consider adding supervised exercise to change patients' habits and enable them to learn ways to get desensitized to the sensation of dyspnea and to the fear of physical exertion (also called kinesiophobia).<sup>24</sup>

The absence of relevant results concerning hospital admissions suggest that a self-management program has to be part of an integrated care system which consists of multiple interventions at different levels (i.e. the patient, professionals and/or the organizational level).<sup>25,29,38</sup> Achieving behavioral changes in patients as well as professionals appears essential for substantially changing the partnership dynamic between patients and care providers, and patient self-management behaviour. To this end, organizational structure should also be modified to include case management, follow-up systems and/or multidisciplinary care provision.

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### Conflict of interest

None of the authors have conflicts of interest to disclose.

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