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Effects of an integrated care intervention on risk factors of COPD readmission

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KEYWORDS Chronic obstructive pulmonary disease; Healthcare delivery; Information technol- ogy; Integrated care; Planned care	Summary An integrated care intervention including education, coordination among levels of care, and improved accessibility, reduced hospital readmissions in chronic obstructive pulmonary disease (COPD) after 1 year. This study analyses the effectiveness of this intervention in terms of clinical and functional status, quality of life, lifestyle, and self- management, under the hypothesis that changes in these factors could explain the observed reduction in readmissions. A total of 113 exacerbated COPD patients (14% female, mean (SD) age 73(8) years, FEV ₁ 1.2(0.5)l) were recruited after hospital discharge in Barcelona, Spain, and randomly assigned (1:2) to integrated care (IC) ($n = 44$) or usual care (UC) ($n = 69$). The intervention consisted of an individually tailored care plan at discharge shared with the primary care team and access to a specialized case manager nurse through a web-based call centre.
	by 1.34 kg/m ² . Additionally, they scored better in self-management items: COPD knowledge 81% vs. 44%, exacerbation identification 85% vs. 22%, exacerbation early treatment 90% vs. 66%, inhaler adherence 71 vs. 37%, and inhaler correctness 86 vs. 24%. There were no differences in the evolution of dyspnea, lung function, quality of life scores, lifestyle factors, or medical treatment. <i>Conclusions:</i> This IC trial improved disease knowledge, and treatment adherence, after 1 year of intervention, suggesting that these factors may play a role in the prevention of severe COPD exacerbations triggering hospital admissions. © 2007 Elsevier Ltd. All rights reserved.

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Introduction

The burden of chronic obstructive pulmonary disease (COPD) is very high in terms of prevalence, morbidity, mortality and economic costs.¹ The need to reduce this burden, in the context of a general concern about chronic diseases management,² has prompted the development of new management strategies for COPD. These strategies focus particularly on the active role of the individual³ (selfmanagement programmes), with the aim of avoiding the rigidity and fragmentation of traditional healthcare systems.^{4,5} The intervention relies on care arrangements being shared between professionals working in different levels of the healthcare system and promotes accessibility of target patients to healthcare professionals following well-standardized procedures.⁶ Knowledge about effectiveness and cost of these new approaches in COPD is still scarce

Self-management education programmes try to teach patients how to carry out the activities of daily living optimally, and to prevent or decrease the severity of exacerbations by early recognition and treatment of the episodes.⁷ A self-management programme in COPD patients in Quebec reduced hospital admissions and emergency-room visits during the 1 year study period.⁸ Patients maintained a significant reduction in hospitalization risk after a 2-year period.⁹ However, most of the educational programmes have found negative or inconclusive results with regard to health services use, lung function, respiratory symptoms or health-related quality of life.⁷ An innovative management strategy is hospital at home or supported discharge, which are proposed as an alternative to hospital admission when a COPD exacerbation appears, to increase patients' satisfaction and reduce costs, without adverse health effects for the patients.¹⁰ Compared to inpatient treatment, hospital at home or supported discharge programmes reduce costs, free up hospital inpatient beds, and are safe for the patients, but do not change risk of hospital readmission or mortality.¹⁰ Recently, systematic reviews of educational and home hospitalization programmes have revealed that differences in populations under study, in content of the programmes, and in outcome measures, make the generalization of their results difficult, implying that more research is needed in this area before recommending these treatments.7,10

In a recent paper, we reported that an integrated care intervention including education, coordination among levels of care, and improved accessibility, reduced hospital readmissions in COPD after 1 year of follow-up by 50%, in a randomized controlled trial in 155 COPD patients from Barcelona, Spain, and Leuven, Belgium, both in the pooled and by-site analysis.⁶ The present analysis in the subgroup of patients from Barcelona, aims to assess the effectiveness of this intervention in terms of enhancing clinical status (dyspnea, body mass index (BMI)), health-related quality of life, lifestyle (smoking, physical activity), self-management (COPD knowledge, alarm knowledge and treatment, treatment adherence), medical treatment, and patients' satisfaction, after a 1-year follow-up period, under the hypothesis that changes in these factors could explain the reduction in readmissions. Functional status (lung function and arterial blood gases) was also measured.

Methods

Design

Randomized controlled trial, subjects were assessed at baseline. The follow-up period was prolonged for one full year with patient's assessment performed at 6 and 12 months.

Subjects

A total of 113 COPD patients were consecutively recruited during 1 year in one tertiary hospital (Hospital Clínic) in Barcelona, Spain, immediately after hospital discharge, and were blindly assigned (1:2 ratio) using computer generated random numbers either to integrated care (IC) or to usual care (UC). All of them had been admitted because of an episode of exacerbation requiring hospitalization for more than 48 h. Exclusion criteria for the study were: (1) not living in the healthcare area or living in a nursing home; (2) lung cancer or other advanced malignancies; (3) logistic limitations due to extremely poor social conditions, illiteracy, or no phone access at home; and (4) extremely severe neurological or cardiovascular co-morbidities. All participants were informed in detail of the characteristics of the study, and written informed consent was obtained in accordance with the Committee on Investigations Involving Human Subjects at the hospital.

Integrated care (IC) intervention

The IC intervention has been described in detail elsewhere⁶ and includes 4 key features. First, a comprehensive assessment of the patient at discharge including severity of the respiratory disease, evaluation of co-morbid conditions, treatment adherence, and analysis of requirements in terms of social support, was done by a specialized nurse. Secondly, an educational session of approximately 2 h duration on self-management of the disease was administered at discharge, also by the specialized respiratory nurse specifically trained for the study intervention. This session covered several items, including knowledge of the disease, smoking cessation, promotion of physical activity, nutrition recommendations and other instructions on non-pharmacological treatment, assessment of correctness of administration techniques for pharmacological therapy and teaching of self-management strategies to cope with future exacerbations.^{11,12} Written information was provided to all patients.¹³ Education on skills to identify clinical deterioration was an important aspect of the programme. Patients were taught to generate a phone call to the call centre if symptoms or signs indicating clinical deterioration occurred. The call was transferred to a specialized nurse (case manager) that either solved the problem by phone or triggered a home visit. Thirdly, an individually tailored care plan, following international guidelines, ^{12, 14} was elaborated through the interaction between the specialized nurse case manager and the primary care team. Reinforcement of the logistics for treatment of co-morbidities and social support was done accordingly. One joint visit of the specialized nurse and the primary care team (physician, nurse and social

worker) to the patient's home was made within 72 h after discharge. Weekly phone calls during the first month after discharge and one phone call at months 3 and 9 were carried out to reinforce self-management strategies. Lastly, access to the specialized nurse at the hospital was guaranteed to patients, caregivers and primary care professionals during the follow-up period through an Information and Communication Technologies (ICT) platform including a web-based call centre.¹⁵ It is important to note that the IC intervention did not include further scheduled visits during the follow-up period. Non-scheduled visits could be triggered by the patients through the call centre.

Usual care (UC) group

Patients included in the UC group were discharged from the hospital by the attending physician who decided on the outpatient control regime. Pharmacological prescriptions at discharge and in-hospital treatment followed the standard protocols of the centre and were similar in the two groups (IC and UC).^{12,14} However, patients did not receive the support of a specialized nurse which included the educational session, joint visit with the primary care team, nor was access to the call-centre provided.

Variables and instruments

Early assessment of patients at their admission to the study was identical for both groups. It included a blind administration of a questionnaire, described in detail elsewhere^{11,16} concerning: sociodemographic factors (sex, age, educational level, economic status and caregiver support); clinical factors (co-morbidities, dyspnea (Medical Research Council scale), body mass index (BMI), and previous hospital and emergency room admissions due to COPD); health-related quality of life (Saint-George's Respiratory Questionnaire (SGRQ) and Eurogol (EQ-5D)); lifestyle (smoking, alcohol, and physical activity); self-management (knowledge about symptoms and treatment of COPD, identification and early treatment of a COPD exacerbation, treatment adherence-using the Medication Adherence Scale (MAS) and Inhaler Adherence Scale (IAS),¹⁷ and observed skills for administration of inhaled drugs¹⁸); drug (short and long-acting β_2 -agonists, anticholinergics, methilxanthines, inhaled and oral corticosteroids) and non-drug treatment (vaccines, oxygen therapy); and satisfaction with health services. Vital signs, chest X-ray films, and pulmonary function tests, including arterial blood gases, were obtained in all patients on admission.

At 6 and 12 months of follow-up, the same questionnaires and lung function tests were administered to the two arms of the study together with a detailed list of questions on the utilization of healthcare resources during each period.

Statistical analysis

Results are expressed as mean (SD), median ($P_{25}-P_{75}$), or as number (percentage) in the corresponding categories. To assess the possibility of selection bias, comparisons of baseline characteristics between UC and IC, both for the followed-up and for the lost subjects were performed using independent *t*-tests, Kruskal–Wallis test or the Chi-square test, depending on the distribution of each variable. Since data about outcome variables was not available in the lost subjects (whether due to exclusion, loss to follow-up or death), an intention-to-treat principle was not possible. Thus, all analyses about the impact of intervention were restricted to subjects with complete data during the followup. No values were imputed to subjects lost to follow-up. Four approaches were used. First, for continuous variables, the difference between 12 months values and baseline values was modelled using linear regression. Second, for categorical variables, the difference between 12 months and baseline values was turned into three categories (no change, improvement, or impairment), which were modelled using politomic logistic regression. Since many of the variables had a very small number of subjects in some categories, the politomic logistic regression led to large confidence intervals. Therefore, and considering that there were no baseline differences in these categorical variables between the UC and IC groups, final (12 months) values were directly compared between groups using chi-square test, and these are the results which are actually shown. Finally, variance analysis with repeated events, which allowed to include 6 months values and a better modelling of changes over time, was also used for all outcome variables. This analysis provided both differences among groups (p-group effect) and differences among periods (p-time effect). No adjustment for baseline variables was done in any of the approaches, since there were no baseline differences between groups.

Results

Fig. 1 displays patient's flow throughout the study. One hundred and thirteen subjects were identified and randomly assigned to the intervention or control group. Five subjects refused to participate. During follow-up, *a priori* defined exclusion criteria, such as lung cancer, appeared in 9 subjects. Twenty-one subjects died, and 16 were lost to follow-up. Only 57% of subjects finished the study at 12 months.

Subjects were mostly male, over 70 years old, and suffered from severe COPD. Table 1 shows baseline characteristics of the subjects, comparing the UC and IC groups, according to whether subjects were lost or completed the follow-up. No differences were found at baseline between the UC and IC groups, except for the SGRQ score, which was lower in the IC group than the UC group among those that completed the follow-up, this difference being clinically important although not statistically significant. No differences in adherence, drug and non-drug treatments were found (not shown). Subjects who were lost for the present analysis had a higher number of COPD admissions in the previous year and in the follow-up year, and they were using long-term oxygen therapy in a higher proportion than those subjects who participated in the 12 months assessment.

Table 2 shows changes (difference between 12 months and baseline) in clinical, functional and quality of life variables, by groups of treatment, as well as the difference of this change in the IC group compared to the UC group, which is equal to the coefficient of the linear regression model. Dyspnea worsened slightly in both groups during the follow-up period. Body mass index did not change in the UC

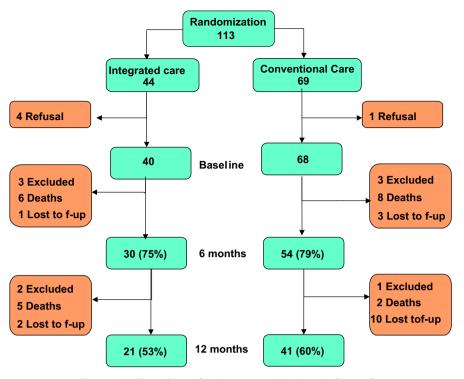


Figure 1 Flow chart of patients participation in the study.

group while it increased in the IC group, this difference being statistically significant. Lung function did not change in any group. Arterial oxygenation improved in both groups, without statistically significant differences between groups. Quality of life scores (according to the SGRQ and the Euroqol visual analogue scale) slightly improved in the follow-up year, without differences between groups, with the exception of the symptoms score, which improved more in the IC group, this difference not being statistically significant.

There were no differences in smoking habits or physical activity practice at 12 months between the UC and IC groups (Table 3). All variables related to self-management (COPD knowledge, identification and treatment of a COPD exacerbation, and adherence to treatment), were better in the IC group than in the UC group, most of these differences being statistically significant. There were no differences in pharmacological or non-pharmacological treatments, or degree of satisfaction of the patients between groups.

Variance analysis with repeated events, which allowed inclusion of 6 months values, was performed for all variables. With the exception of PaO_2 , no additional information was obtained from this analysis, since most variables followed the same pattern in the various intervals (baseline—6 months, 6–12 months, baseline—12 m). However, PaO_2 improved between baseline and 6 months in both groups, and afterwards improved further in the IC group while it worsened in the UC group (Fig. 2).

Discussion

This is one of the few studies that have examined and showed that IC, including self-management education,

coordination among levels of care, and increased accessibility in COPD patients, is associated with an improvement in disease knowledge, treatment adherence and nutritional status. The study was not able to show changes in lifestyle variables, medical treatment, lung function or quality of life. A complete interpretation of these results needs to consider that this intervention was effective to reduce COPD admission risk.⁶

The intervention improved disease knowledge, consistently with previous trials of self-management,19 home based care,²⁰ or respiratory rehabilitation²¹), which included education as a component. The importance of the present findings lies in three key issues: (i) the present programme was not intensive in education, including only a session of 2 h at baseline supported by the practice team; (ii) effects persisted after 12 months, while previous studies, with more intensive interventions, reported effects after shorter periods of follow-up^{19,20}; (iii) we also assessed the effect of intervention on hospital admissions, which allows us to hypothesize that the increase in knowledge could be partially responsible for the previously reported reduction in admissions.⁶ It is likely that, even without changes in the frequency or severity of COPD exacerbations, subjects with better knowledge and skills may not need hospital admission because of an early treatment of the exacerbation. This is supported by a previous study in a panel of COPD patients which found that early treatment of COPD exacerbation improved exacerbation recovery and reduced risk of hospitalization²²).

Self-reported adherence to inhaled medication and performance of the inhaler manoeuvre improved in the IC group, according to a previous educational programme which found an improvement in the inhalation technique

	Lost to follow-up (death, lost or excluded)			Followed-up			P (lost vs. — followed)
	Usual care (UC) n = 28	Integrated care (IC) n = 23	Ρ	Usual care (UC) n = 41	Integrated care (IC) n = 21	Ρ	, , , , , , , , , , , , , , , , , , , ,
Sex: female n (%)	1 (4)	7 (30)	0.009	4 (10)	4 (20)	0.302	0.673
Age (years) m (SD)	74 (8)	73 (6)	0.717	73 (9)	72 (10)	0.829	0.675
Less than primary education n (%)	5 (19)	8 (36)	0.159	13 (33)	5 (24)	0.480	0.730
Smoking							
Current n (%)	3 (11)	4 (17)	0.571	6 (15)	5 (24)	0.571	0.819
Former n (%)	23 (82)	16 (70)		31 (76)	15 (71)		
Never n (%)	2 (7)	3 (13)		4 (10)	1 (5)		
Dyspnea (MRC scale) Median (P ₂₅ -P ₇₅)	4 (3–5)	5 (3–5)	0.197	4 (3–5)	3 (3–4)	0.601	0.390
BMI $(kg/m^2) m$ (SD)	25.6 (5.9)	26.3 (5.9)	0.700	27.4 (5.7)	28.1 (4.3)	0.632	0.117
FEV ₁ (l) Median (P ₂₅ -P ₇₅)	1.1 (0.8–1.5)	1.0 (0.8–1.5)	0.550	1.0 (0.8–1.5)	1.2 (0.8–1.4)	0.512	0.929
FEV ₁ /FVC (%) m (SD)	54 (18)	57 (18)	0.524	51 (18)	48 (17)	0.613	0.126
PaO_2 (mmHg) m (SD)	65 (14)	62 (14)	0.399	61 (9)	64 (10)	0.323	0.446
$PaCO_2$ (mmHg) m (SD)	43.3 (9.1)	44.1 (8.4)	0.750	43.8 (6.5)	43.1 (6.6)	0.715	0.916
Any comorbidity n (%)	27 (96)	19 (83)	0.099	39 (93)	17 (81)	0.167	0.799
COPD admissions in the last year Median	0 (0–1)	1 (1-2)	0.004	0 (0–1)	0 (0–1)	0.929	0.003
$(P_{25}-P_{75})$							
COPD admissions during follow-up Median	1 (0–2)	1 (0–2)	0.813	1 (0–1)	0 (0–1)	0.083	0.077
(P ₂₅ -P ₇₅)		,					
Long-term oxygen therapy n (%)	11 (39)	9 (39)	0.991	8 (20)	6 (29)	0.419	0.055
Health-related quality of life $(SGRQ)^* m (SD)$	53.4 (19.3)	61.8 (17.6)	0.131	60.5 (20.2)	51.2 (16.9)	0.077	0.951

 Table 1
 Subjects' characteristics in usual care (UC) and integrated care (IC) groups, according to follow-up status.

*Saint-George's Respiratory Questionnaire (SGRQ) score goes from 0 (better health status) to100 (worse health status).

	Change, m (SD) (months—baseline		Linear regression	
	Usual care (UC) n = 41	Integrated care (IC) n = 21	coefficient (95% CI)*	Ρ
Dyspnea score (MRC)	-0.15 (1.44)	-0.52 (1.12)	-0.38 (-1.1 to 0.34)	0.299
BMI (kg/m ²)	-0.01 (1.63)	1.33 (1.73)	1.34 (0.31 to 2.37)	0.012
FEV ₁ (l)	0.06 (0.35)	0.01 (0.14)	-0.05 (-0.24 to 0.14)	0.569
FEV ₁ /FVC (%)	-1.66 (17.94)	-0.82 (8.18)	0.84 (-8.27 to 10.66)	0.863
PaO_2 (mmHg)	3.12 (8.5)	5.36 (8.54)	2.24 (-2.57 to 7.06)	0.355
PaCO ₂ (mmHg)	-1.1 (5.57)	-0.26 (5.24)	0.84 (-2.25 to 3.93)	0.588
Specific health-related quality of life (SGRQ †)				
Symptoms	-17.11 (24.44)	-24.4 (19.68)	-7.29 (-19.66 to 5.07)	0.243
Activity	-8.36 (19.95)	-5.08 (16.61)	3.27 (-6.91 to 13.46)	0.523
Impact	-11.29 (16.34)	-13.7 (15.62)	-2.41 (-11.24 to 6.42)	0.587
Total	-11.02 (15.57)	-13.41 (13.43)	-2.39 (-10.56 to 5.78)	0.560
Generic health-related quality of life (Euroqol [‡])	0.93 (2.11)	1.56 (1.77)	0.62 (-0.51 to 1.75)	0.273

Table 2Changes in clinical status, functional status, and quality of life between baseline and 12 months, in UC and IC groups
(linear regression).

*Relative change in IC group compared to UC group.

[†]SRGQ score goes from 0 (better health status) to100 (worse health status). Negative change means improvement.

[‡]Euroqol score goes from 0 (worse health status) to 10 (better health status). Positive change means improvement.

Table 3Lifestyle factors, self-management, medical treatment, and health care satisfaction, at 12 months, in UC and IC
groups.

	Usual care (UC) n = 41	Integrated care (IC) $n = 21$	Р
No current smokers <i>n</i> (%)	36 (88)	20 (95)	0.349
Any physical activity <i>n</i> (%)	34 (83)	18 (86)	0.778
Regular walking or exercising n (%)	32 (78)	18 (86)	0.470
Knowledge about			
Name of the disease (COPD) n (%)	18 (44)	17 (81)	0.005
Identification of a COPD exacerbation n (%)	9 (22)	17 (85)	< 0.001
Early treatment of a COPD exacerbation n (%)	27 (66)	19 (90)	0.036
Adherence to oral treatment (MAS scale)* n (%)	35 (85)	19 (90)	0.570
Adherence to inhaled treatment (IAS scale)* n (%)	15 (37)	15 (71)	0.009
Correct inhaler manoeuvre n (%)	9 (24)	18 (86)	< 0.001
Long-term oxygen therapy \geq 16 h <i>n</i> (%) <i>n</i> = 23	15 (94)	7 (100)	0.499
Influenza vaccination n (%)	32 (78)	19 (90)	0.442
Pneumococcal vaccination n (%)	25 (61)	16 (76)	0.348
Long-term oxygen therapy n (%) n (%)	16 (39)	7 (33)	0.661
Short-acting β_2 -agonists <i>n</i> (%)	36 (88)	21 (100)	0.095
Long-acting β_2 -agonists <i>n</i> (%)	31 (76)	11 (52)	0.064
Anticholinergics n (%)	32 (78)	15 (71)	0.565
Methilxanthines n (%)	1 (2)	0 (0)	0.471
Inhaled corticosteroids n (%)	30 (73)	19 (90)	0.113
Oral corticosteroids n (%)	1 (2)	2 (10)	0.219
Satisfaction with health care n (%)	34 (92)	21 (100)	0.180

*MAS and IAS continuous scores were recoded as compliant (all correct answers in the scale), and non-compliant (one or more mistakes).

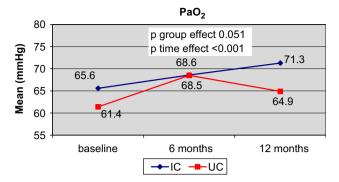


Figure 2 Changes in mean PaO_2 values (mmHg) along time, in UC (n = 41) and IC (n = 21) groups.

in the treated group.²³ The effects of poor adherence to treatment in COPD are not known, and it has been said that studies using adherence as an outcome should also measure clinical benefits.²⁴ Although we cannot attribute the reduction of the admissions risk⁶ to any specific component or effect of the intervention, our data suggest that treatment adherence may have positive effects in COPD patients.

Nutritional status (as measured with body mass index) did not change in the UC group while it increased steadily in the IC group. We are not aware of any educational trial that measured nutritional status in COPD patients. Since there were no undernourished patients (only 1 patient had BMI \leq 20), nutritional advice of our intervention was directed to avoid overweight. The difference at 12 months, although small in absolute numbers (1.34 kg/m²), could be due to the higher rate of admissions during the follow-up period in the UC group, which would have had a negative effect on nutritional status. One limitation of the study was the lack of measurement of fat free mass index.

The lack of change in lung function after 1 year of intervention is consistent with previous findings of educational^{7,8} or home based care^{25-27'} programmes, and plausible given the natural history of COPD.²⁸ However, we found that pulmonary gas exchange improved in both groups until 6 months, something probably due to recovery after the exacerbation, and, from 6 to 12 months, worsened in the UC group while it improved in the IC group. One likely explanation is that the intervention leads to a better control of hypoxemia. However, the lack of differences in oxygen prescription and oxygen compliance between groups of treatment may rule out this possibility. Another explanation could be that changes in the course of the disease during the 12 months of treatment (such as exacerbations and admissions) are responsible for final values of pulmonary gases exchange. Existing literature does not help in understanding these findings, since none of the previous studies measured arterial blood gases, and only one study involving supported discharge intervention²⁶ found that oxygen saturation improved at 8 weeks in the treated group without changes in the control group.

We did not find differences in general (Euroqol) or specific (SGRQ) health-related quality of life (HRQL) measures, although both improved in both groups as a result of recovery after the exacerbation.²⁹ A meta-analysis of educational programmes in COPD did not find effects in

the general HRQL, and only small effects in the specific HRQL measures.⁷ Most of the home care or supported discharge programmes assessed their effect in specific HRQL, and only one found improvements after a short period of time,¹¹ while the remainder did not find effects after short,²⁶ medium,²⁷ or long periods.²⁵ Since trials of respiratory rehabilitation, which share some of the components with educational or home care based interventions, found an effect in quality of life,²¹ it could be hypothesized that this effect is not attributable to "education" but to other components, among which "exercise" would be a key candidate, given the strong association between quality of life and physical activity in COPD patients.³⁰ In fact, a study which included self-management and exercise training without supervision in $COPD^8$ found improvements in the impact subscale of the SGRQ at 4 months but not at 12 months, their difference between groups being lower than what we found in symptoms.

The lack of differences in pharmacological prescriptions between UC and IC groups suggests that adherence to international guidelines in severe COPD after a hospital admission, is acceptable in our area. In addition, treatment of co-morbidities at 12 months was scored as correct in 100% of patients both in the UC and IC group. We did not find changes in smoking or physical activity habits related to the intervention, probably because of a ceiling effect.

Main limitations of the present study are the small sample size and the high proportion of patients lost to follow-up. The study sample size was computed to answer the primary objective of reduction in admissions in all subjects included in the trial, but unfortunately only part of the patients (those from Barcelona) had information about changes in risk factors. Even then, sample size was very similar to previous educational or home care intervention studies. We tested the degree of selection bias by comparing characteristics of subjects lost to follow-up between the IC and UC groups. There was no relationship between variables that were different in these groups and outcome variables, reducing the possibility of selection bias as an explanation for the present results (data available from the authors). The extent to which our intervention can be exported to other subgroups of the COPD population or other health care systems is debatable and has been discussed elsewhere.⁶ We conclude that, compared to UC, an IC programme including education, coordination among levels of care and increased accessibility, helped COPD patients to enhance knowledge and to influence health behaviour such as treatment adherence after 1 year of intervention. The interpretation of these findings together with the previously reported reduction in admission risk, suggest that these factors play an important role in the treatment of COPD exacerbations at an early stage, being able to reduce the need of hospital admission.

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