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Feasibility, acceptability and effectiveness of integrated care for COPD patients: a mixed methods evaluation of a pilot community-based programme

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Summary

QUESTION UNDER STUDY: The aim of this study was to assess the feasibility, acceptability and effectiveness of a pilot COPD integrated care programme implemented in Valais, Switzerland.

METHODS: The programme was adapted from the self-management programme Living Well with COPD, and included the following elements: self-management patient-education group sessions, telephone and medical follow-ups, multidisciplinary teams, training of healthcare professionals, and evidence-based COPD care. A process and outcome evaluation of the pilot phase of the programme was conducted by means of qualitative and quantitative methods. Reach (coverage, participation rates), dosage (interventions carried out), fidelity (delivered as intended) and stakeholders' acceptance of the programme were evaluated through data monitoring and conduct of focus groups with patients and healthcare professionals. Effectiveness was assessed with pre-post analyses (before and after the intervention). The primary outcome measures were; (1) generic and disease-specific quality of life (36-Item Short Form Health Survey, Chronic Respiratory Questionnaire); and (2) hospitalisations (all-cause and for acute exacerbations) in the past 12 months. Secondary outcomes included self-efficacy, number of exacerbations and exercise capacity. Finally, controlled pre-post comparisons were also made with patients from the Swiss COPD Cohort for three common outcome measures (dyspnoea [mMRC score], number of exacerbations and smoking status).

RESULTS: During the first 2 years of the programme, eight series of group-based education sessions were delivered to 57 patients with COPD in three different locations of the canton of Valais. Coverage objectives were achieved and attendance rate at the education sessions was high (83.6%). Patients' and healthcare professionals' reported a high degree of satisfaction, except for multidisciplinarity and transfer of information. Exploration of the effectiveness of this pilot programme suggested positive pre-post results at 12 months, with improvements in terms of health-related quality of life, self-efficacy, exercise capacity, immunisation coverage and Patient Assessment of Chronic Illness Care score. No other outcome, including the number of hospital admissions, differed significantly after 12 months. We observed no differences from the control group.

CONCLUSIONS: The evaluation demonstrated the feasibility and acceptability of the programme and confirmed the relevance of mixed method process evaluation to ad-

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just and improve programme implementation. The introduction of multidisciplinary teams in a context characterised by fragmentation of care was identified as the main challenge in the programme implementation and could not be achieved as expected. Despite this area for improvement, patients' feedback and early effectiveness results confirmed the benefits of COPD integrated care programmes emphasising self-management education.

Trial registration number: ClinicalTrials.gov, identifier NCT02001922.

Key words: *COPD, integrated care, education and self-management, mixed methods, programme evaluation, community*

Introduction

Chronic obstructive pulmonary disease (COPD), which presents as a progressive airflow obstruction associated with systemic comorbidities such as sarcopenia, and ischaemic heart and metabolic diseases, is now the third cause of mortality worldwide [1]. COPD is characterised by acute exacerbations, which are responsible for frequent emergency visits and hospitalisations, as well as deaths. These acute exacerbations also durably reduce quality of life and put a high burden on the healthcare system, not only in terms of health but also in terms of healthcare costs [2].

Current care for COPD is usually based on inhaled pharmacotherapy for symptom relief and prevention of exacerbations, but often neglects the systemic impact of COPD and patients' perspectives on care. In addition, the quality of COPD care is suboptimal and does not always reflect current guidelines. For example, Swiss and Canadian studies have shown that pulmonary rehabilitation is largely underprescribed and inhaled corticosteroids are prescribed to patients despite disease severity not requiring them [3–5]. A study conducted in the United States reported that COPD patients received only 58% of recommended care [6]. Studies have suggested several explanations, at the healthcare professional and patient levels, for inappropriate care and poor outcomes. At the healthcare professional level, primary care physicians may lack familiarity with clinical evidence, they may lack confidence in diagnosing and staging COPD, and they may face time constraints [7]. At the patient level, patients may lack information and skills to perform self-care, as well as confidence and motivation, especially when it comes to engaging in regular physical activity and perform recommended self-care activities. In addition, depression and anxiety, which are associated with low self-efficacy, have been shown to predict low levels of physical activity in COPD [8].

In this context, integrated care programmes, based on the Chronic Care Model [9, 10], can contribute to overcoming patient and healthcare professional barriers to appropriate care, and, hopefully, to closing the observed quality care gap. Integrated care is a polymorphous concept that was developed within the context of an ageing population and the rise in long-term conditions, and which promotes patient-centeredness and care coordination [11]. Integrated care programmes, which focus on long term behavioural change and self-management support, foster formal contacts between healthcare providers and multidisciplinary care, promote evidence-based care such as early detection and management of acute exacerbations, and encourage physical activity, healthy diet, smoking cessation and adherence to medication. These programmes have been shown to improve health-related quality of life, exercise capacity and hospital admissions in COPD patients [12–14]. In addition, and despite their heterogeneity, integrated care programmes for COPD were found to be cost-effective [15].

Whereas European countries such as the Netherlands, the UK, Germany and Spain started implementing integrated programmes almost two decades ago, developments in Switzerland are more recent and programmes often lack resources for appropriate implementation and evaluation [16]. However, an ongoing study, aimed at identifying and describing integrated care initiatives in Switzerland, identified 162 integrated care initiatives, two of which specifically targeted COPD (Schusselé-Fillietaz, personnal communication, October 2016). Based on the Chronic Care Model and Bourbeau's "Living Well with COPD" programme [17, 18], two integrated care programmes were implemented in two different Swiss regions, the cantons of Zurich [19] and Valais.

The canton of Valais is a rural and alpine region characterised by a homogeneous but geographically dispersed population, a low population density, and lower density of general practitioners and specialised healthcare providers compared with the rest of Switzerland. Solo practices remain the norm, and medical homes and care networks did not exist at the time of the programme implementation. Implementing a multidisciplinary integrated care programme in such a setting was an innovative challenge. Hence, the aims of the present evaluation were: first, to assess the feasibility and acceptability of the implementation of a pilot COPD evidence-based integrated care programme in an alpine and rural Swiss canton, and second, to explore its effectiveness.

Methods

Study design

For this process and outcome evaluation, we used a mixed-methods approach. The qualitative part consisted of focus groups of COPD patients and healthcare professionals to assess the feasibility and acceptability of the programme. The quantitative part consisted in the data collection of both clinical and self-reported survey measures to assess the effectiveness of the programme. We conducted pre-post analyses on these latter measures, with a matched control group for three comparisons.

The study protocol was reviewed and approved by the Cantonal Ethics Committee of the Canton of Valais (December 2012; No. CCVEM 046/12).

Participants and recruitment (health professionals and patients with COPD)

Healthcare professionals residing in the French-speaking part of the canton of Valais, Switzerland, were recruited through individual visits to their practice or group information sessions, during which information on programme participation, programme implementation, and guidelines for treatment and management of COPD were provided. General practitioners and pulmonologists were in charge

of recruiting patients, meeting them regularly and encouraging them to follow the medical recommendations. The pulmonologists were also invited to collaborate in the development of the patient action plan and could intervene during education sessions, along with physiotherapists and pharmacists. Pharmacists were also prompted to distribute flyers at their pharmacies, strengthen the smoking cessation message and offer polypharmacy consultations. Finally, all healthcare professionals were encouraged to take part in the multidisciplinary seminars and training sessions organised within the context of the programme.

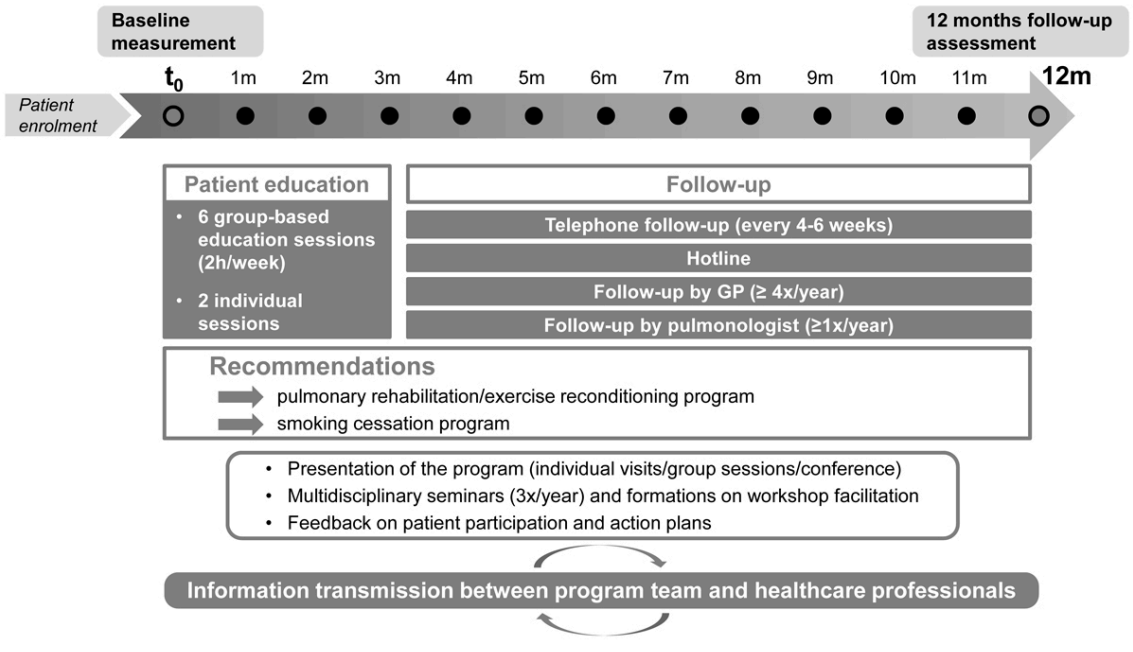
Patients recruited by healthcare professionals were contacted by the programme coordinator, who gave them information about the programme, verified eligibility criteria and asked for written consent. Patients with a diagnosis of COPD (GOLD stage I–IV or B-C-D), aged 35 years and over, not institutionalised and residing in the French-speaking part of the canton of Valais in Switzerland were eligible to participate in the pilot programme. Patients were excluded if they had cognitive problems, their level of French was insufficient, or their life expectancy was less than 12 months. Patients in the control group were sampled from the Swiss COPD Cohort [3, 4] and matched with the programme participants on age, gender and COPD Assessment Test (CAT) scores.

Intervention

The pilot programme, called "Soins intégrés BPCO Valais – Mieux vivre avec une BPCO", was based on the Chronic Care Model (CCM) and the Canadian programme "Living Well with COPD: A Plan of Action for Life" [18, 20, 21]. Before the implementation of the programme, we conducted focus groups with healthcare professionals to discuss the appropriateness and feasibility of the key components of the programme [9, 10, 22].The programme, as implemented in 2013 and 2014, included the following elements (fig. 1):

1. *Patient education and self-management*, the key component of the programme consisted of six weekly group-based self-management education sessions (90–120 minutes per session), led by a respiratory physiotherapist and/or a nurse specialised in self-management support, accompanied by a pulmonologist and a pharmacist during two specific sessions, as well as two individual sessions that took place once before and once after the six group sessions. Topics covered by the group-based sessions included disease education, medication, breathlessness and stress management, prevention and management of exacerbations, and lifestyle behaviours (physical activity, smoking cessation, healthy diet, good sleep habits, satisfying sexual life, leisure activities). Educational materials of the Canadian programme, including the action plan, were adapted to the local context, in collaboration with the team led by Professor Bourbeau from McGill University.
2. *Scheduled follow-up*. Proactive telephone-call follow-ups (every 4–6 weeks) were continued for up to 12 months after inclusion in the programme; patients were invited to regularly consult their general practitioner (three to four times per year) and pulmonologist (twice per year).
3. *Multidisciplinarity* was encouraged by regular formal meetings, to enhance the collaboration between healthcare professionals involved in the management of COPD and, ultimately, to improve care coordination. To this end, tasks and responsibilities of each healthcare professional were defined before the implementation. The programme coordinators (specialised physiotherapist and nurse), assisted by participating pulmonologists, were in charge of the recruitment, organisation and conduct of the self-management education sessions, the follow-up and hotline telephone calls, the transfer of information between professionals and the data collection process. General practitioners and

Figure 1: Life cycle of the programme.



pulmonologists participated in patient recruitment and collected medical data; they also continued the regular evidence-based care follow-up of their patients and encouraged them to change behaviours. Pulmonologists were also in charge of discussing and writing action plans. Physiotherapists and pharmacists were invited to reinforce COPD care messages. Finally, professionals of all care groups could co-facilitate group sessions and offer specific additional support to patients (e.g., pulmonary rehabilitation, medication therapy management).

4. *Information to and training of healthcare professionals*. We held several seminars on COPD management and training sessions on the content of group-based self-management sessions, and notified the patient's primary healthcare provider of their patient's participation in the programme and sent the action plan.
5. *Evidence-based COPD care* was encouraged through the distribution of GOLD pocket guidelines to healthcare providers [23].

Data collection

Qualitative data were collected via focus groups conducted with patients and healthcare professionals during and at the end of the programme, and quantitative data were collected at baseline (during the first visit of the programme) and after 12 months of participation. Baseline data included various self-reported health-related and personal variables and medical data reported by the patient's physician. At 12 months, self-reported data and data on physical activity were collected during an individual session.

For the control group, we extracted data from the Swiss COPD Cohort database.

Measurements

Process evaluation: feasibility and acceptability measures

Based on the literature [24–27], we decided to measure four process indicators: reach, dosage, fidelity to assess the programme's feasibility (defined as the extent to which an intervention can be carried out in a particular setting) and acceptability.

- *Reach* refers to the degree to which the population that is eligible to benefit from an intervention actually receives it. In our study, we focused on patient and healthcare professional participation rates.
- *Dosage* relates to the "amount" of the programme's content that was actually delivered to participants. We operationalised it by counting the number of learning materials printed and distributed, the number and location of group-based education sessions delivered, the mean number of telephone follow-up contacts, the number of seminars/symposiums organised for healthcare professionals, etc.
- *Fidelity* refers to the degree to which an intervention was implemented according to the original protocol. It was evaluated by comparing the protocol written in December 2011 to what had indeed been done in the field (dosage), as described in the 2012 and 2013 annual reports
- *Acceptability* refers to the stakeholders' perceptions that an intervention is agreeable, satisfactory. It was assessed using data from the focus groups organised to discuss participating patients and healthcare professionals' opinions on, and experiences with, the programme. We organised two focus groups with patients (n = 11) and three focus groups with healthcare professionals (n = 22: six general practitioners, four pulmonologists, eight pharmacists, three physiotherapists and one tobaccologist) in 2013 and 2014. We also used data from a patient satisfaction questionnaire sent at the end of the programme (12 months) to assess its acceptability.

Outcome evaluation: effectiveness measures

In contrast to "efficacy" trials, which are conducted in settings that maximise the management of and the control over the research process, "effectiveness" evaluations aim "to measure the impact of an intervention when it is tested within a population that is representative of the intended target audience." [28]. An effective programme is thus defined as "a programme [that] does more good than harm when delivered under real-world conditions" [29]. We assessed effectiveness by conducting pre-post analyses (before and after the intervention) on several primary and secondary outcomes, and comparing three of these outcomes with those in a matched control group.

Our two primary outcomes were health-related quality of life and hospital admissions in the past 12 months, two key indicators in the field of integrated care programme generally [30] and COPD management more specifically [13, 14].

Health-related quality of life (HRQoL) was measured using two self-administered questionnaires: (1) the Chronic Respiratory Questionnaire (CRQ), a disease-specific instrument comprising 20 questions on a seven point Likert-type scale, producing four domain scores for dyspnoea, mastery, fatigue and emotion (scores ranged from 0 to 7, a higher score indicating better quality of life) [31, 32]; (2) the 36-Item Short Form Health Survey (SF-36), a generic instrument measuring eight dimensions of health: physical functioning, role limitations due to physical problems, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, mental health (scores ranged from 0 to 100, with 100 indicating better quality of life) [33–35].

We used two indicators for hospital admissions: the proportion of patients with one or more hospitalisations (all-causes) in the past 12 months and the proportion of patients with one or more hospitalisations for acute exacerbations in the past 12 months.

We also measured the following secondary outcomes:

- self-efficacy, measured with the Self-Efficacy for Managing Chronic Disease 6-Item Scale [36] which was adapted to the management of COPD (scores ranged from 1 = not at all confident to 10 = totally confident);
- a global measure of the impact of COPD on daily life, the COPD Assessment Test (CAT) score (total score ranges from 0 to 40; <10 indicates low impact, 10–20 medium impact, 21–30 high impact, >30 very high impact on life) [37];
- dyspnoea, measured with the modified Medical Research Council scale" (mMRC) (grade 0 "I only get

breathless with strenuous exercise" to grade 4 "I am too breathless to leave the house or I am breathless when dressing") [38, 39];
- number of COPD exacerbations, as the patient-reported average number of exacerbations during the past 12 months, and the proportion of patients reporting ≥1 exacerbations during that same period;
- physical capacity, using the Six-Minute Walk Test [40] and the Sit-to-Stand Test [41, 42];
- healthcare services utilisation, with the average number of visits to physicians (family physician and pulmonologist) during the past 12 months, and emergency department visits / unscheduled physician visits during the same period;
- smoking status, seasonal influenza vaccination and pneumococcal vaccination status;
- respiratory drugs prescribed, and
- care congruence with the Chronic Care Model (CCM), using the Patient Assessment of Chronic Illness Care" questionnaire (PACIC) (20 questions on a five point Likert-type scale, 1 = never to 5 = always; mean scores ranged from 1 to 5, with 5 representing the greatest congruence with the CCM) [43, 44].

We also collected sociodemographic data (age, gender, relationship status, living situation, education, employment status, type of residence, insurance status, nationality) and health status data (body mass index, lung function).

Data analysis

Qualitative data analysis

The focus groups, conducted with a pre-established interview guide, were recorded and fully transcribed; content analysis [45, 46] was used to extract the arguments associated with each topic under discussion.

Quantitative data analysis

Descriptive analyses were carried out first, with data reported as means or percentages for continuous or categorical variables, respectively. We then used bivariate analyses to compare before and after measures of all primary and secondary outcomes; paired t-tests and McNemar tests were considered for continuous and categorical variables, respectively. Only data from patients who participated in the evaluation at 12 months were included in the analyses. In order to compare the results between the patients participating in the programme and the patients from the Swiss COPD Cohort, we first selected a control group (two controls per case), performing a propensity score matching for age, gender and CAT score [47]. We then analysed overtime differences within groups for three commonly available outcome variables: dyspnoea (mMRC score), the proportion of patients reporting ≥1 exacerbations during the last 6/12 months, and smoking status. The confidence intervals (CIs) for mean paired differences were computed with the Student distribution for continuous variables and a method developed by Newcombe [48] for dichotomous variables. We then computed the between group differences of within group differences. For continuous variables, we used a Student confidence interval for the mean difference of two independent samples and for the dichotomous variables we used a method developed by Newcombe [49] to compare differences of paired differences of proportions. Statistical significance was set at $p < 0.05$, and all analyses were performed using Stata 14.

Results

Process evaluation: feasibility and acceptability

Reach

For this pilot phase of the programme, we aimed to include between 30 and 50 patients over 2 years (2013–2014), with a follow-up of 12 months. Between 2013 and 2014, 83 patients were identified during the recruitment process. Of these, 57 patients were eligible and consented to participate in the study; 3 did not meet the inclusion criteria and 23 declined to participate at a first telephone contact or after a first meeting with a programme coordinator (specialised physiotherapist or nurse). The target of 30 to 50 participants for the pilot phase of the programme was therefore achieved. The average participation rate in the education sessions was 83.6%; patients participated in five sessions out of six on average. Three participants were not present at the individual session that followed the six group sessions, and 46 out of 57 agreed to be assessed at the 12-month follow-up. The 11 non-adherent patients at the 12-month evaluation did not differ significantly from the participating patients on key demographics, but were less likely to live alone and presented lower forced expiratory volume in 1 second (FEV_1) and Tiffeneau index.

Baseline characteristics of the participants are presented in table 1. On average, patients were 66 years old and 56% were male. Most patients lived with a partner and half were retired. Two thirds of patients had at least one exacerbation in the previous year and most had moderate COPD. Demographics of the participants were similar to the population of Swiss patients living with COPD and were typical of the population targeted by comparable interventions [50].

Healthcare professionals participated in patient enrolment to various degrees: pulmonologists, general practitioners (GPs) and, pharmacists enrolled 34, 14, 1 patients, respectively. The GP participation rate was weaker than expected: during the first year of the programme, of the 11 general practitioners who agreed to meet the programme coordinator, only three finally recruited patients. Furthermore, the response rate to the GP questionnaire was so low that we stopped sending it to GPs in 2014. On the other hand, the six half-day seminars on COPD management were successful, with a mean of 60 participants each time coming from a wide range of professional backgrounds.

Dosage

During the first 2 years of the programme, eight series of group-based education sessions took place in three different locations in the canton of Valais (Sion, Martigny, Monthey). During each series, all six group-based education sessions were delivered. The teaching material was printed and handed out to all participants prior to education sessions (469 workbooks and action plans in total for 57 patients and 10 healthcare professionals). Two thirds of patients received an action plan for acute COPD exacerbations, whereas all patients were offered an individual session at home or at the hospital before and after the group sessions. Patients received telephone calls from the phys-

Table 1: Baseline characteristics of participants (n = 57 patients with COPD).

Sociodemographic and general health characteristics		
Age	(n = 57)	66.0 ± 8.3
Female	(n = 57)	(43.9)
Marital status	(n = 57)	
Single		1(1.8)
Married or living with partner		37 (64.9)
Separated, divorced, widowed		19 (33.3)
Education	(n = 56)	
Primary		18 (32.1)
Secondary		25 (44.7)
Tertiary		13 (23.2)
Employment status	(n = 56)	
Employed		8 (14.2)
Reduced working time because of health problem		14 (25.0)
Unemployed, house wife		6 (10.8)
Retired		28 (50.0)
Living alone	(n = 57)	15 (26.3)
Habitation	(n = 56)	
Rural		37 (66.1)
Urban		19 (33.9)
Current smoker	(n = 51)	22 (43.1)
Body mass index	(n = 57)	
Overweight (25–29.9 kg/m^2)		17 (29.8)
Obese (≥30 kg/m^2)		14 (24.6)
COPD		
Lung function	(n = 45)	
FEV_1, % predicted		57.5 ± 18.9
FEV_1/FVC		49.9 ± 13.4
GOLD stage*	(n = 54)	
1: mild (FEV_1 ≥ 80% predicted)		5 (9.3)
2: moderate (50% ≤ FEV_1 < 80% predicted)		30 (55.5)
3: severe (30% ≤ FEV_1 < 50% predicted)		13 (24.1)
4: very severe (FEV_1 < 30% predicted)		6 (11.1)
GOLD stage, ABCD classification†	(n = 54)	
A: low risk, less symptoms		2 (3.7)
B: low risk, more symptoms		21 (38.9)
C: high risk, less symptoms		3 (5.6)
D: high risk, more symptoms		28 (51.9)
mMRC score ‡	(n = 57)	
0		3 (5.3)
1		13 (22.8)
2		23 (40.3)
3		14 (24.6)
4		4 (7.0)
CAT score	(n = 57)	17.3 ± 7.5
≥1 exacerbations in previous year	(n = 46)	31 (67.4)
≥1 hospitalizations in previous year	(n = 56)	24 (42.9)
Respiratory treatments	(n = 50)	
Short-acting β_2 agonist		22(44)
Short-acting anticholinergic		4(8)
Long-acting β_2 agonist		15(30)
Long-acting anticholinergic		38(76)
Combined long-acting β_2 agonist and inhaled corticosteroids		26(52)
Inhaled corticosteroids		3(6)

CAT = COPD Assessment Test; FEV = forced expiratory volume; FEV_1 = forced expiratory volume in 1 second; FVC = forced vital capacity; mMRC=modified Medical Research Council. Data are presented as mean ± SD or n (%). * From lung function tests. † From lung function tests, number of exacerbations (past 12 months), CAT score and mMRC score. ‡ mMRC scale is divided into five categories: 0 = breathless with strenuous exercise, 1 = short of breath when hurrying on level ground or walking up a slight hill, 2 = walks slower than people of the same age because of breathlessness, or has to stop for breath when walking at own pace, 3 = has to stop for breath after walking about 100 yards or after a few minutes, 4 = too breathless to leave the house or breathless while dressing.

iotherapist / specialised nurse every 4 to 6 weeks according to their needs, and the hotline was active five days a week and was used 42 times by the patients during the 2 years of the pilot phase. Furthermore, an information campaign was implemented in order to communicate on the programme and inform on the COPD management guidelines. Flyers were distributed in pharmacies and medical offices, articles were published in the local newspaper, and several conferences and workshops were held.

Fidelity

Intervention reports and monitoring data showed good adherence to the programme protocol. However, the programme required several adaptations in order to respond to local constraints. First, we revised the recruiting method to be more efficient, by extending the range of healthcare professionals authorised to recruit patients and replacing individual visits to GPs and pulmonologists by group information sessions. Second, the multidisciplinarity component was underdeveloped in the first 2 years of the pilot phase of the programme, mainly because considerable effort had been dedicated to the preparation of the material and the group-based education sessions instead. Although the protocol aimed to foster collaboration between the different healthcare professionals involved in the management of patients with COPD, in practice, information transfer was not optimal and GPs' involvement not sufficient. Third, we had to stop conducting education sessions in one of the regions because it was difficult to access and it registered low attendance rates in the first year of the programme. The group sessions took place in three different towns in Valais, instead of four as originally planned.

Acceptability

Patient and healthcare professionals perceptions collected via focus groups at the end of the intervention are summarised in table 2. Overall, patients and professionals were satisfied with the programme. Both mentioned better knowledge and know-how about COPD, and peer contact was unanimously regarded as helpful and a potential source of motivation for patients. Some areas required improvement nevertheless. The major criticism made by patients and healthcare professionals related to communication. The information provided to stakeholders and the community was deemed insufficient. Patients were faced with practitioners outside the programme who were not aware of it or were critical of it. They were also confused about the evaluation and monitoring aspect intrinsically linked to the pilot programme. Healthcare professionals said they wanted more information about their patients' follow-up. A general lack of coordination between healthcare professionals was also mentioned. Finally, GPs expressed difficulties in motivating patients to follow medical recommendations and change life habits. Despite these criticisms, qualitative data revealed that the intervention

was well received by patients and healthcare professionals, confirming the acceptability of the programme. The results from the patient satisfaction questionnaire at the end of the programme were consistent with this conclusion, with 96% of patients giving a positive evaluation to the programme, and 85% stating they would recommend the programme to another person living with COPD (n = 46).

Outcome evaluation: effectiveness

Primary and secondary outcomes before (baseline) and after (12 months) the intervention are presented in detail in table 3. Only patients with complete data were included in these analyses (n = 46).

Primary outcomes

The mastery domain of the disease-specific quality-of-life score (CRQ) increased significantly at 12 months (+0.5; p = 0.01). A significant improvement on two generic HRQoL dimensions was also observed: social functioning (+10.3; p <0.01) and role limitations due to emotional problems (+14.8; p = 0.02). Whereas these three dimensions presented changes that can be considered clinically significant, the other dimensions or domains of (health-related) quality of life remained stable.

The proportion of patients with one or more hospitalisations (all causes) and the proportion of patients with one or more hospitalisations for acute exacerbations were not statistically different between baseline and follow-up, even though the proportion of patients with one or more hospitalisations (all-causes) decreased from 40% to 27%.

Secondary outcomes

Both the mean self-efficacy score – corresponding to the patients' beliefs in their capabilities to manage COPD – and the results of the sit-to-stand test increased significantly between baseline and 12 months (+0.6, p<0.01 and +2.5, p<0.01, respectively). Severity of symptoms, measured as the CAT and mMRC scores, as well as the frequency of exacerbations, remained stable at 12 months. No change was observed in the number of emergency department visits / unscheduled physician visits. Regarding risk factors, results showed that influenza vaccination coverage improved significantly at 12 months (70% at baseline vs 87% at 12 months), whereas there was no significant change in the proportion of current smokers between baseline and 12-month follow-up (43 vs 38%).

Comparison with the control group (patients from the Swiss COPD Cohort)

The demographic and medical characteristics of both groups were similar except for lung function and number of exacerbations, which were lower in the intervention group, and for inhaled corticosteroid use which was much higher in the intervention group. Evolution differences of dyspnoea measures (mMRC), number of exacerbations and smoking status are shown in table 4. These results suggest that (1) the proportion of patients reporting at least one exacerbation in the previous year or in the previous six months increased less strongly in the intervention group (not statistically significant); (2) the proportion of current smokers decreased more sharply in the intervention group (not statistically significant).

Discussion

The results of this mixed methods evaluation showed that the implementation of a pilot COPD integrated care programme emphasising self-management was feasible in an alpine canton of Switzerland. The investigation of the implementation process showed a suitable reach, considering that the programme was in its pilot phase, and a good dosage with regard to the self-management sessions, a core component of the programme; multidisciplinarity was in contrast less successful. In addition, whereas the evaluation of fidelity showed that the intervention was delivered according to the protocol, notwithstanding a few adjustments linked to the results of the focus groups and field constraints; acceptability among stakeholders was moderately high whereas participants were highly satisfied with the programme. Finally, exploration of the effectiveness of this evidence-based pilot programme showed that health-related quality of life, self-efficacy, exercise capacity, immunisation coverage and PACIC score improved after 12 months of participation in the programme, and comparisons with a matched control group suggested trends towards improvements despite the absence of statistically significant differences.

The qualitative part of the evaluation truly added value to the quantitative evaluation. Feedback from participating patients and healthcare professionals helped improve and adapt the programme to the needs of those concerned. For

Table 2: Patients' and healthcare professionals' feedback on the programme.

Positive feedback	Negative feedback
Patients	
Improved knowledge on COPD mechanism and medications	Objectives of the programme unclear / research side of the project confusing
Raised awareness of the presence of COPD (if denial) and the need to change lifestyles	External healthcare professionals poorly informed about the programme
Acquired breathing techniques and stress management skills	Lack of communication and coordination between healthcare professionals
Peer support	Lack of impact on motivation to change lifestyles
Clarity of the education material	Organisational problems (during the first year)
Healthcare professionals	
Focus on healthy lifestyles (physical activity and smoking cessation)	Lack of information about the programme
Peer support	Difficulty in recruiting patients
Improved self-efficacy	Poor transmission of information between healthcare professionals
Duration of the programme	Absence of feedback on patients monitoring
Action plan for acute COPD exacerbations	Measures to help patients with tobacco cessation could be improved

example, once we realised that healthcare professionals outside the programme were poorly informed about it and sometimes even reluctant to show interest and accompany their participating patients, and that healthcare professionals involved in the programme reported insufficient feedback from the programme coordinator regarding their own patients, we decided to send formal letters containing patient data to patients, pharmacists, referring GPs and pulmonologists. Sent at entry into the programme, after the self-management education sessions and at 12 months, these letters included a summary table containing results of pulmonary function tests, quality of life, physical activity level, exacerbation rate, CAT score, smoking status and quality of inhaled medication techniques. Healthcare professionals seemed to appreciate this easy-to-read and valuable information.

Another example of programme improvement following the process evaluation relates to the use of action plans in cases of COPD acute exacerbations. Upon finding that only two thirds of patients had received an individualised action plan during the pilot phase, which is a key element for reducing healthcare utilisation [18, 51], we decided to change the procedure. At first, action plan drafting and distribution were left to the referring practitioner. Now, they are prepared by the programme's team involved in self-management education sessions, who have a good understanding of patients' self-efficacy. This approach, similar to that of Benzo et al. in other settings [52], reduced practi-

Table 3: Primary and secondary outcomes.

Primary outcomes		**Baseline**	**12 months**	**p-value**
Disease specific quality of life (CRQ)	(n = 46)			
Dyspnoea		4.8 ± 1.5	5.1 ± 1.5	0.12
Fatigue		4.0 ± 1.5	3.9 ± 1.4	0.70
Emotion		4.3 ± 1.5	4.4 ± 1.5	0.39
Mastery		4.7 ± 1.6	5.2 ± 1.4	**0.01**
Generic health-related quality of life (SF-36)				
Physical functioning	(n = 44)	55.5 ± 26.1	54.7 ± 25.5	0.76
Role physical	(n = 44)	50.0 ± 39.3	50.6 ± 40.5	0.93
Bodily pain	(n = 46)	54.8 ± 26.5	57.1 ± 24.8	0.56
General health	(n = 44)	42.9 ± 21.9	45.5 ± 19.0	0.23
Vitality	(n = 46)	47.4 ± 21.9	45.4 ± 20.6	0.47
Social functioning	(n = 45)	59.7 ± 30.3	70.0 ± 26.4	**<0.01**
Role emotional	(n = 45)	48.0 ± 44.1	62.8 ± 41.6	**0.02**
Mental health	(n = 46)	56.3 ± 23.8	60.5 ± 22.8	0.09
Hospitalisations				
≥1 hospitalisations (all-causes) in previous year	(n = 45)	18 (40.0)	12 (26.7)	0.21
≥1 hospitalisations for acute exacerbations in previous year	(n = 38)	8 (21.1)	7 (18.4)	1.00
Secondary outcomes				
Self-efficacy	(n = 45)	7.9 ± 1.4	8.5 ± 1.2	**<0.01**
Symptoms and acute exacerbations				
CAT score	(n = 46)	17.3 ± 7.4	17.6 ± 8.3	0.73
mMRC score	(n = 46)	2.0 ± 1.1	1.8 ± 1.1	0.20
Number of exacerbations in previous year	(n = 38)	1.53 ± 1.6	1.58 ± 1.7	0.87
≥1 exacerbations in previous year	(n = 38)	24 (63.2)	25 (65.8)	1.00
Exercise capacity				
6 min walking test, m	(n = 31)	429.6 ± 115.1	449.6 ± 102.2	0.15
Sit-to-stand test	(n = 37)	20.6 ± 6.4	23.1 ± 6.7	**<0.01**
Preventative measures				
Current smoker*	(n = 42)	18 (42.9)	16 (38.1)	0.69
Influenza vaccination in previous year	(n = 46)	32 (69.6)	40 (87.0)	**<0.01**
Pneumococcal vaccination in the last 5 years*	(n = 37)	22 (59.5)	26 (70.3)	0.22
Healthcare utilisation				
≥1 ER visits / unscheduled physician visits in previous year	(n = 45)	19 (42.2)	17 (37.8)	0.82
Family physician visits in the previous year	(n = 45)	6.5 ± 4.9	6.5 ± 4.7	1.00
≥1 pulmonologist visits in the previous year	(n = 46)	34 (73.9)	38 (82.6)	0.34
Congruence with CCM (PACIC score)	(n = 46)	2.2 ± 0.9	3.4 ± 1.0	**<0.01**

CAT = COPD Assessment Test; CCM = Chronic Care Model; CRQ = Chronic Respiratory Questionnaire; ER = emergency room; mMRC = modified Medical Research Council; PACIC = Patient Assessment of Chronic Illness Care; SF-36 = Short Form 36. Data are presented as mean ± SD or n (%). Bold values are marking statistically significant difference (p <0.05). * Data reported by GPs at baseline and by patients at 12 months follow-up.

Table 4: mMRC score, number of exacerbations and proportion of current smoker: within and between group differences at 12 months.

		Intervention group			**Control group**			**Difference in differences**
		Baseline	**12 months**	**Difference**	**Baseline**	**12 months**	**Difference**	
mMRC score	n = 46	2.0 ± 1.1	1.8 ± 1.1	−0.2 (−0.5–0.1)	1.8 ± 0.9	1.9 ± 0.9	0.1 (0.0–0.3)	−0.3 (−0.7–0.0)
≥1 exacerbations in last 6/12 months	n = 38	63.2 ± 7.8%	65.8 ± 7.7%	2.6% (−19.1–24.0%)	21.1 ± 4.7%	28.9 ± 5.2%	7.9% (−4.9–20.4%)	−5.3% (−30.4–19.7%)
Current smoker	n = 42	42.9 ± 7.6%	38.1 ± 7.5%	−4.8% (−16.5–7.2%)	38.1 ± 5.3%	35.7 ± 5.2%	−2.4% (−7.6–2.8%)	−2.4% (−15.2–10.7%)

tioners' workload and increased the number of action plans delivered to patients.

Negative feedback allowed us to improve the intervention, but positive aspects highlighted during the evaluation are promising. Patients' reports of improved COPD knowledge, improved breathing techniques skills to manage dyspnoea, usefulness of peer support and recognition of the clarity of the "Living Well with COPD" course material, confirmed the appropriateness and utility of the self-management education group sessions. Our pilot programme also appears effective in term of quality of life and exercise capacity, which is consistent with results of recent meta-analyses on self-management COPD programmes [13, 14]. Furthermore, participants increased their self-efficacy score, showing better confidence in their capabilities to manage their disease, thus confirming the effectiveness of self-management education as reported by patients and demonstrated before by Stellefson et al. [53]. Our pilot study did not allow us to confirm a reduction of hospitalisations, unlike other studies on implementation of the "Living Well with COPD" programme [18, 20]. This might be due to the low prevalence of severe exacerbations before entry into the programme. For safety reasons, we choose in the first year of our programme to include only patients in a stable condition, excluding those recently admitted for COPD exacerbations.

Effectiveness of integrated care programmes might be improved by good training of the programme staff and fidelity to the intervention. Regular evaluations, involvement of the programme leaders, formal feedbacks about strengths and weaknesses, individualised multidisciplinary assessment of patients and a centralised database with patients' electronic reports to insure easy quality control represent some necessary elements. Future developments of the programme will target multidisciplinarity, a component that did not receive enough attention in the pilot phase; this is particularly important since the development of mutual trust and clarity around each actor's role is a complex process that requires time. Up to now, the promotion of the programme during multidisciplinary seminars, physician-specific meetings and via traditional media and regional newspapers led to its better acceptability, and also improved interprofessional collaboration between healthcare professionals involved in COPD care; in addition, it increased the coverage of the programme.

The main strengths of this project were that it was conducted under real-world conditions, that it combined both a process (feasibility and acceptability) and an outcome (effectiveness) evaluation, and that it took advantage of both qualitative and quantitative methods. This choice enabled the continual adaptation and improvement of the programme, and confirmed that COPD patients participating in the programme benefited from it. Our results need nevertheless to be interpreted with caution on account of the following main limitations. First, the control group was not randomly selected. However, we used propensity score matching to compare the intervention group to the control group (the Swiss COPD Cohort), which allowed us to adjust for patient age, gender and CAT score, but not for other variables that could be associated with outcomes. Therefore, our results related to the effectiveness of the programme need to be interpreted with caution. Second, the sample size for the effectiveness analyses (46 observations) was small, conferring low power to detect differences and make robust conclusions about effectiveness. However, this is not problematic, since the primary target of the evaluation was not to assess its effectiveness, because the programme was in its pilot phase and only included a small number of patients. In addition, the effectiveness of integrated care programmes for COPD patients has been reported in other studies [13, 14]. Third, clinical measures were collected as part of routine clinical assessment of COPD patients to monitor their evolution; they were not collected to prove the effectiveness of COPD integrated care programmes per se. In that context, the positive trends towards effectiveness, which are in line with previous results, are encouraging, even if they need to be interpreted carefully. Fourth, besides limitations associated with pre-post study design, selection bias cannot be excluded, since patients participating in this programme were volunteers and patients lost to follow-up were on average less symptomatic. Finally, the implementation of complex interventions makes the identification of causal effects very difficult, as we cannot associate an outcome to a specific component. However, systematic reviews have shown that the implementation of one single or two components of the Chronic Care Model are associated with significantly improved clinical and process outcomes [54, 55].

Conclusions

This evaluation demonstrated that a community-based COPD integrated care programme emphasising self-management education is both feasible and acceptable in an alpine and rural canton of Switzerland. Improvement in social and emotional dimensions of health-related quality of life, self-efficacy, exercise capacity, COPD knowledge and breathing technique skills tend to confirm the known benefits of integrated care with self-management education for COPD patients. Considering the specificities of the canton of Valais in term of geographical spread, fragmentation of care and lack of familiarity of primary care physicians with similar programmes for other chronic diseases, the implementation of the programme can be considered as successful overall even if some components, such as multidisciplinarity and information transfer, need to be further developed. An extension of the programme to the German-speaking part of the canton is planned, and a nation-wide programme, led by the Swiss Lung League and involving a variety of healthcare stakeholders, is currently being developed. To achieve successful implementation in other settings, rigorous organisation is required, and fidelity to the designed intervention should be secured and regularly verified, while leaving some leeway to adapt if necessary. It is also important to allow integrated care programmes to run their course, since the lack of familiarity with nonpharmacological interventions among healthcare professionals means that changes in care take time.

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Competing interests
MK has received consultancy fees from Roche, Novartis, AstraZeneca, Boehringer Ingelheim and CSL Boheim in the previous 24 months.

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