Respiratory Medicine (2014) 108, 453–462

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/rmed

A home telehealth program for patients with severe COPD: The PROMETE study

G. Segrelles Calvo [a,*], C. Gómez-Suárez [b], J.B. Soriano [c], E. Zamora [a], A. Gónzalez-Gamarra [d], M. González-Béjar [e], A. Jordán [b], E. Tadeo [b], A. Sebastián [f], G. Fernández [g], J. Ancochea [a]

[a] Pneumology Service, La Princesa Institute for Health Research (IP), Hospital Universitario de la Princesa, Madrid, Spain
[b] Linde Healthcare, The Linde Group, Spain
[c] Epidemiology and Clinical Research Program, CIMERA, Bunyola, Illes Balears, Spain
[d] Goya Primary Care Center, Spain
[e] Montesa Primary Care Center, Spain
[f] Hospital Universitario de la Princesa, Madrid, Spain
[g] Department of Medical Research and Documentation, Hospital Universitario de la Princesa, Madrid, Spain

Received 21 May 2013; accepted 8 December 2013
Available online 16 December 2013

KEYWORDS
Telehealth;
Telemedicine;
COPD;
Comorbidities;
Elderly;
Hospitalizations

Summary
Background: Acute exacerbations of chronic obstructive pulmonary disease (AECOP) are key events in the natural history of the disease. Patients with more AECOPD have worse prognosis. There is a need of innovative models of care for patients with severe COPD and frequent AECOPD, and Telehealth (TH) is part of these programs.
Methods: In a cluster assignment, controlled trial study design, we recruited 60 patients, 30 in home telehealth (HT) and 30 in conventional care (CC). All participants had a prior diagnosis of COPD with a post-bronchodilator forced expiratory volume (FEV_1)% predicted $<50\%$, age ≥ 50 years, were on long-term home oxygen therapy, and non-smokers. Patients in the HT group measured their vital signs on a daily bases, and data were transmitted automatically to a Clinical Monitoring Center for followed-up, and who escalated clinical alerts to a Pneumologist.
Results: After 7-month of monitoring and follow-up, there was a significant reduction in ER visits (20 in HT vs. 57 in CC), hospitalizations (12 vs. 33), length of hospital stay in (105 vs. 276 days), and even need for non-invasive mechanical ventilation (0 vs. 8), all $p < 0.05$. Time to the first severe AECOPD increased from 77 days in CC to 141 days in HT (K-M $p < 0.05$).

* Corresponding author. Servicio de Neumología, Hospital Universitario La Princesa, c/Diego de León 62, 6° planta, 28006 Madrid, Spain.
E-mail address: gsegrelles@hotmail.com (G. Segrelles Calvo).

http://dx.doi.org/10.1016/j.rmed.2013.12.003

There was no study withdrawals associated with technology. All patients showed a high level of satisfaction with the HT program.
Conclusions: We conclude that HT in elderly, severe COPD patients with multiple comorbidities is safe and efficacious in reducing healthcare resources utilization.

Abbreviations list

AECOPD	acute exacerbations of chronic obstructive pulmonary disease
CAT	COPD Assessment Test
COPD	chronic obstructive pulmonary disease
CC	conventional care
ER	emergency room
FEV_1	forced expiratory volume in the first second
HT	home telehealth
HULP	Hospital Universitario La Princesa
ICS	inhaled cortico-steroids
IPC	informal primary carer
LABA	long-acting beta-adrenergic agonists
LAMA	long-acting muscarinic antagonist
NIV	non-invasive ventilation
PEF	Peak expiratory flow
PDE4i	phosphodiesterase 4 inhibitor
PCC	primary care center
PROMETE	Madrilian Telehealth PROject for COPD
SD	standard deviation
SGRQ	Saint George Respiratory Questionnaire
TH	Telehealth
CMC	Clinical Monitoring Center

Introduction

Chronic obstructive pulmonary disease (COPD) is a leading but under-recognized cause of morbidity and mortality worldwide. No other disease that is responsible for comparable burden worldwide is neglected by healthcare providers as much as COPD [1,2]. COPD is projected to move from the currently fourth to third position in terms of morbidity by 2020 [3,4]. A key aspect in the natural history of the disease are episodes of acute exacerbations (AECOPD). AECOPD are more frequent in patients with larger airflow obstruction and a history of more episodes in the previous year [5]. Moreover patients who suffer the highest numbers of AECOPD are considered to have a faster disease progression, presence of comorbidities, and worse functional prognosis [6].

Research is therefore needed on innovative models of care for patients with severe COPD and frequent AECOPD, in order to detect and manage the occurrence of exacerbations of AECOPD at an early stage, and hence reduce their negative effect on the disease progression. The importance of these programs has been highlighted in the National Strategy for COPD of the Spanish National Health System [7]. Telehealth (TH) is part of these programs, as it allows patients to be monitored in their home, gathering useful information that can be used for an early intervention should an AECOPD occur [8].

Current evidence shows that Home Telehealth (HT) programs can reduce the number and length of stay in hospital admissions and emergency visits [9]. And Sicotte et al. demonstrated that TH increases empowerment and patient's satisfaction, specially in the older and more severe patients [10].

Although TH programs have been developed for COPD patients, none has been specifically geared to people who experience severe airflow obstruction, multiple comorbidities, and limitations in daily life. We hypothesized that HT can be a useful strategy for monitoring these patients at the home in a follow-up program that coordinates Primary and Secondary Care services.

The purpose of our study (the PROMETE study, "Madrilian Telehealth PROject for COPD) was to assess the efficacy and effectiveness of a home telehealth program for COPD patients with severe airflow obstruction by measuring the number of emergency room visits, hospitalizations, length of hospital stay, and mortality.

Material and methods

Study population

We conducted an open-label, controlled, non-blind clinical trial, coordinarted at the Pneumology Service of the Hospital Universitario La Princesa (HULP) with the Primary Care Centres (PCC) in its area of influence.

Initially we randomized the PCC customers that belonged to HULP into two groups: HT or Conventional Care (CC). Patients were randomized following a two-color code. All PCC customers were assigned to one or another color using an envelope system dividing into two groups by chance. According to PCC membership patients were

Table 1 Sociodemographic and clinical characteristics of participants, by randomization to conventional care (CC) or telemedicine (TM).

Parameters		CC (n = 30)	TM (n = 29)	p-Value
Male, n (%)		22 (73.3)	22 (75.9)	1.00
Age (years), mean ± SD		72.7 ± 9.3	75.0 ± 9.7	0.357
Education level. n (%)	Illiterate	1 (3.3)	1 (3.4)	0.998
	Primary	10 (33.3)	10 (34.5)	
	Secondary	10 (33.3)	10 (34.5)	
	University	9 (30.0)	8 (27.6)	
Employment status, n (%)	Active	2 (6.7)	1 (3.4)	0.443
	Retired	25 (83.3)	23 (79.3)	
	Disabled/unable	3 (10.0)	5 (17.2)	
With caretaker, n (%)		19 (63.3%)	18 (62.1%)	1.00
Dyspnea mMRC, n (%)	II	8 (26.7)	3 (10.3)	0.183
	III	17 (56.7)	17 (58.6)	
	IV	5 (16.7)	9 (31.0)	
COPD hospitalizations in the last year, mean ± SD		1.9 ± 1.4	1.7 ± 1.0	0.663
COPD hospitalizations in the last year, n (%)	1 or none	16 (55.2)	16 (53.3)	0.548
	2 or more	13 (44.8)	14 (46.7)	
Mobility, n (%)	Bed-armchair	3 (10)	0 (0.0)	0.201
	Within home	8 (26.7)	10 (4.5)	
	Leaves home	19 (63.3)	19 (65.5)	
Home status, n (%)	Alone	5 (16.7)	4 (13.8)	0.836
	With partner	18 (60.0)	19 (65.5)	
	With other relatives	6 (20.0)	4 (13.8)	
	With caretaker	1 (3.3)	2 (6.9)	
Barthel, mean ± SD		84.5 ± 15.1	89.3 ± 13.7	0.239
Charlson, mean ± SD		3.4 ± 2.1	3.7 ± 1.4	0.555
Drugs per day, mean ± SD		8.3 ± 2.8	8.3 ± 3.7	0.980
Respiratory medications, n	LAMA + LABA + ICCI	23	26	0.95
	PDE4 inhibitors	6	2	0.103
	Mucolythics	12	11	1.000
	Theophyllines	3	2	1.000
	Oral steroids	4	1	0.353
Lung function, mean ± SD	FEV_1 post-BD	37.1 ± 10.8	38.3 ± 11.9	0.525
	BODEX	5.7 ± 1.2	5.2 ± 1.0	0.125
	Home oxygen, hours/day	20.2 ± 4.7	18.6 ± 3.8	0.198
	Home oxygen flow in L/minute	2.06 ± 0.5	2.04 ± 0.4	0.851
Quality of life and other assessments	CAT	21.2 ± 6.6	18.2 ± 7.3	0.771
	euroQOl	4.50 ± 1.8	5.10 ± 2.2	0.396
	Goldberg anxiety	3.0 ± 2.4	3.70 ± 2.9	0.203
	Goldberg depression	3.5 ± 2.7	3.80 ± 2.9	0.468
Parameters measured by home[a] telehealth, mean ± SD	Blood pressure (systolic/ diastolic; mmHg)	123 ± 14.1/ 69 ± 12.4	130 ± 13/ 80 ± 12.1	0.52
	Pulsioximetry (%)	92 ± 3.1	94 ± 1.6	0.17
	Heart rate (beat per minute, bpm)	80 ± 14.8	76 ± 15.2	0.71
	Peak-flow (litre/second)		132 ± 57.5	

LAMA: Long action muscarinic antagonist; LABA: long action beta-adrenergics agonist; ICCI: inhaled cortico-steroids; PDE4 inhibitor: phosphodiesterasa 4 inhibitor.

[a] These parameters were collected in the first clinical visit at home in the CC group and by telemonitoring (first day) in the TM group.

assigned to each study group (group allocation). Patients referred from the Goya, Montesa, Lagasca and Castello PCC were assigned to HT, and the rest were cluster assignment to the CC group. We performed group treatment allocation by center, one case to one control. All PCC customers shared the same geographic localization (District of Salamanca in Madrid), population characteristic, cultural and economic levels (Table 1), and hence it is fair to state that all determinants were equally balanced by study group.

In addition, all patients were followed up at the pneumology clinic in our hospital, which also unifies the criteria for monitoring and treatment of respiratory disease. Whenever patients from either group came to the emergency room (ER), they were evaluated by the Pneumologist in charge,

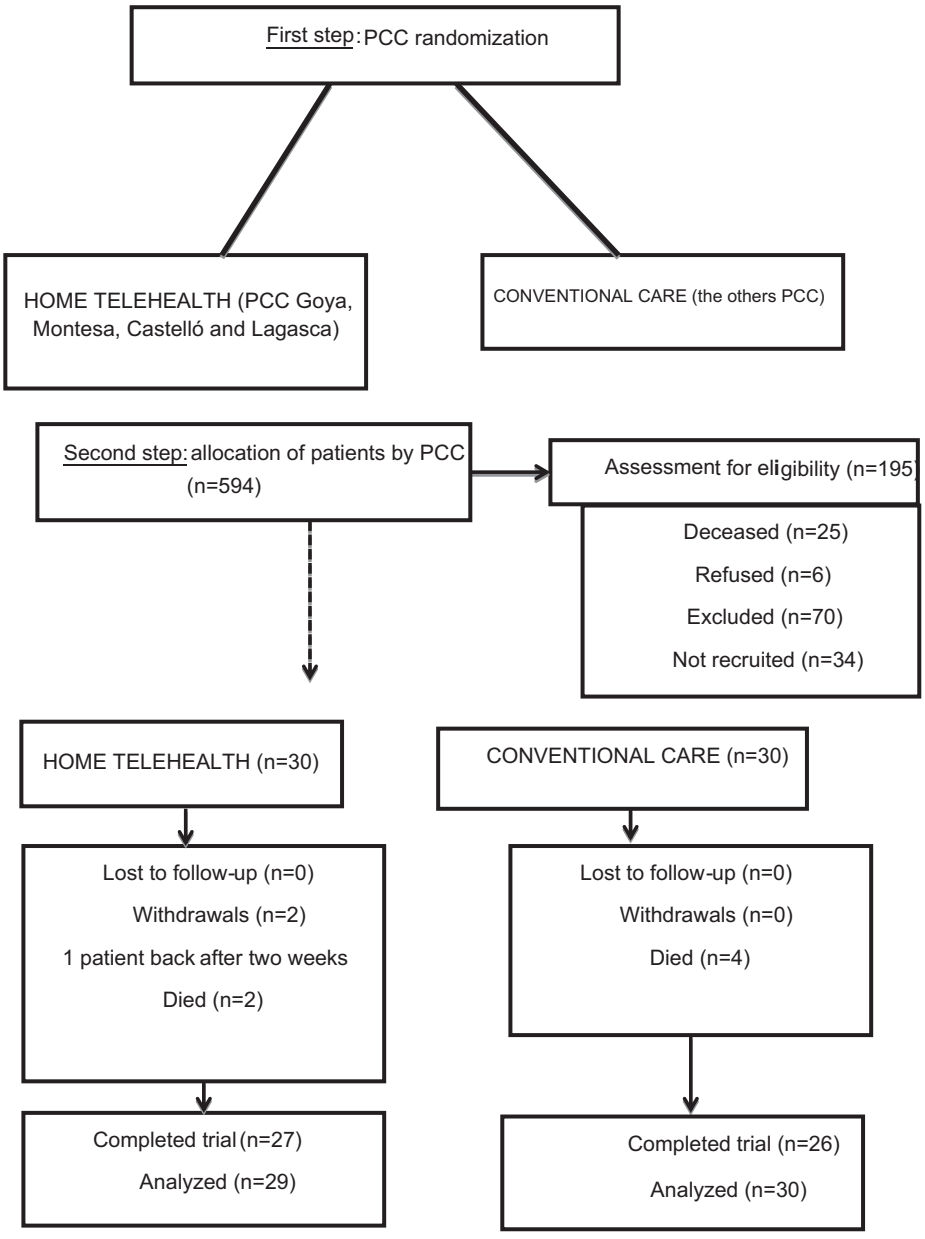

Figure 1 CONSORT flow chart of trial participation.

ergo maintaining a similar approach in the assessment of ERs and deciding whether the patient should be admitted or discharged, independently of their group assignment.

Eligible patients were identified if they had been admitted to any of the following units in our hospital: Pneumology, Internal Medicine and Infectious Diseases services, with a clinical diagnosis of "COPD exacerbation" during the period from January 1, 2010 to July 31, 2011. We identified a total of 594 patients in the HULP database system (Fig. 1).

Consecutively we selected patients who met the following inclusion criteria: 1) prior diagnosis of COPD according to GOLD criteria [11]; 2) severe or very severe obstruction to airflow (post-bronchodilator forced expiratory volume (FEV_1)/forced vital capacity (FVC) < 0.70 and FEV_1 %predicted $<50\%$); 3) age older than or equal to 50 years; 4) on long-term home oxygen therapy; 5) no current smoker, at least for the past 6 months, determined by measuring carboxyhemoglobin levels in arterial blood gas $\leq 2\%$. Patients were excluded if: 1) did not meet at least one of the above criteria; 2) were enrolled in a palliative care program for lung or another disease; 3) were institutionalized or at risk of social exclusion; 4) were deemed unable to understand all procedures.

Both study groups continued with their scheduled medical visits during the entire study period within the standard universal, free healthcare for all of the Spanish public system, and therefore we did not change the regular office visits and home calls either by the Pneumologist or the Primary Care doctors.

Patients in the control group had no intervention apart from this standard, conventional care, and no other pro-

active interventions during the entire study. All information during the study was collected by visit at the patient's home except for the satisfaction questionnaire that was obtained through telephone calls in a blinded fashion in both groups.

The study was approved by the Ethics Committee of the HULP, and the study number was 1819. All patients signed an informed consent form prior to inclusion.

Study procedures

The PROMETE telehealth program was based on the daily follow-up of patients with severe COPD at the home by monitoring the following parameters: blood pressure, oxygen saturation and heart rate on a daily basis, and peak expiratory flow (PEF) three times a week.

Other TH programs have used similar parameters to monitor the patients as: pulsioximetry, blood pressure, temperature, PEF and spirometry [12—14].

We chose to use PEF according to Jódar-Sánchez et al. as PEF as it showed more acceptable to being carried out by the patient [15], and since van de Berge et al. [16] have linked the fall of percentage of peak-flow with the risk of COPD exacerbations.

Measurements were made once a day in the morning, and given the following set of conditions: 20 min after medication had been taken, at rest and while on oxygen therapy. The patients took their measurements on a daily bases (Monday through Sunday). Monday through Friday the data were monitored and assessed by the Clinical Monitoring Center (CMC) from 9:00 to 17:00. And during weekends, the data were directly analyzed by a Pneumologist.

During the recruitment period all patients who were presumed to satisfy the inclusion criteria were consecutively contacted by telephone, until there were 30 patients in each group. The purpose of the study was explained to them, and if they agreed to participate an appointment was made for a home visit with the Pneumologist.

At the first clinical visit the informed consent form was signed, and data were collected including: gender, age, level of education, household composition, limitations of activities of daily living, presence or absence of carer, medication, relevant medical history (Charlson index) [17], basic physical examination, quality of life questionnaires (generic like SF-12, and EuroQol, and disease-specific like SGRQ, and COPD Assessment Test, CAT) [18—20], the Barthel Index [21], and finally the Goldberg questionnaire for anxiety and depression [22].

Throughout the duration of the study we collected the number of ER visits, hospitalizations, length of hospital stay, need for non-invasive ventilation (NIV), and need for admission to ICU for both groups.

Patient monitoring and follow-up

On the first day of the HT programme, monitoring devices were delivered and installed at the patient's home by nursing staff. Patients were trained in their operation and it was verified that they were able to take all measurements properly. Written information was as well given on how to handle/use the monitoring devices, and how to correctly transmit the measurements. A contact phone number from the CMC was left to the patients for any technical problems.

The parameters were collected using the following devices: a spirometer, a pulse-oximeter and heart rate monitor (Spirotel®, MIR), and blood pressure monitor (A&D, model UA-767 BT). Each day after taking these measurements, data were sent automatically via a modem (TeleModem™, Aerotel Medical Systems) over the patients' telephone lines. Further details can be found in the online supplement.

Patients entered the study in a stable situation, being exacerbation-free for at least 15 days. Entry into the study of patients in the exacerbation phase was postponed until it was over.

The information was received, monitored, assessed and followed-up by the CMC through an application that acted as a traffic light system:

- Green: meant that measurements had been taken and were within the predefined limits, and no further action was required.
- Yellow: "technical alert". This means that the measurements had not been taken or had not been received. This alert could lead to a "clinical alert" due to a lack of adherence or discouragement. When the parameters were not received the nurse at the CMC called the patient to find the reason behind the alert, and either ruled out medical causes or, if one, notified the Pneumologist leading the study.
- Red: "clinical alert". Meant that a measurement exceeded the limits that were previously preestablished for each patient (further details can be found in the online supplement).

After verification of a Red Flag -Clinical Alert by the CMC, a protocolized escalation and clinical response procedure commenced.

Clinical support

Clinical support occurs as a result of the coordination between the CMC, the Pneumology specialist and the Primary Care physician.

Whenever a Red Flag (clinical alert) was triggered the nurse at the CMC contacted the patient to verify the alert (further details can be found in the online supplement). When a Red Flag was confirmed, the nurse escalated the clinical alert to the Pneumologist who then classified the exacerbation as moderate, severe or very severe. For moderate exacerbations, advice to start medical treatment was given over the telephone; in severe cases, visits were made to the patient's home, and in the very severe cases the patient was advised to come to the emergency room department (Figs. 2 and 3).

As we worked in coordination with each Primary Care Center, the head of the PCC was alerted when a Red Flag was detected and, in accordance with our protocol, patients with moderate exacerbations who did not improve with the prescribed treatment were referred to their corresponding PCC for further follow-up.

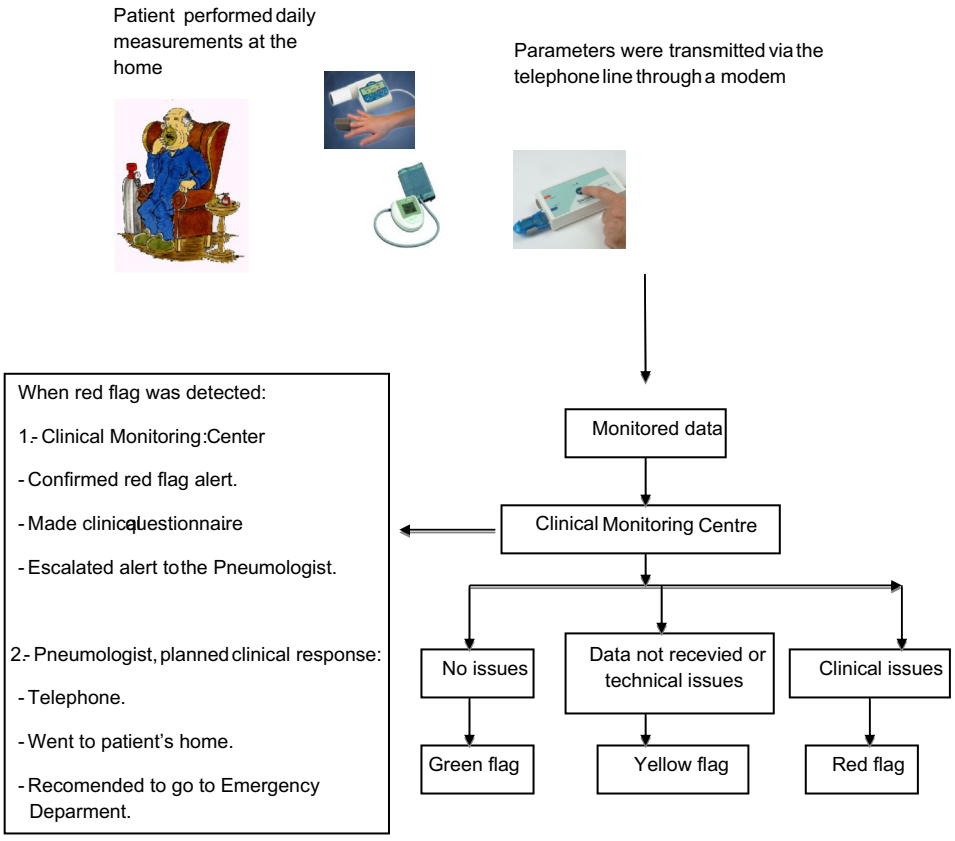

Figure 2 Telemonitoring protocol and Clinical Monitoring Center follow-up.

Exacerbation

In our study COPD exacerbation was defined as: "an acute event" characterized by a worsening of patient's respiratory symptoms (increased dyspnea, expectoration, purulent sputum, or any combination of these three symptoms) that is beyond normal day-to-day variations and leads to change in medication [11].

Control group

The control group received Conventional Care. There was a first clinical visit at the home during which baseline data were collected for the study and quality of life questionnaires were completed, and also a visit at the end. Data relating to clinical activity were obtained from the HULP information system and through monthly telephone calls to the patients.

For these patients we collected data related to blood pressure, pulsioximetry and heart rate in the first clinical visit at home. The baseline of these parameters at the beginning of the study compared with the HT group is show in Table 1.

Statistical analysis

For the descriptive analysis we used mean, range, and standard deviation for quantitative variables, while qualitative variables were expressed in terms of frequencies and percentages. To measure the relationship between independent quantitative variables Student's *t*-test was used, and for qualitative variables the Chi^2 test was used. The relationship between two qualitative variables and relative risk was obtained through use of contingency tables. Clinical follow-up and monitoring of both groups was measured using Kaplan—Meier curves to indicate the time to the first contact with the hospital (emergency room visit or hospitalization) analysis. Statistical significance was considered at $p < 0.05$.

Given the nature of this pilot study, no formal sample size was estimated a priori. For convenience and availability, we piloted 30 patients per group, which is reasonable number of patients with severe COPD and multiple comorbidities considered to be a representative sample. The study duration was based upon covering the peak months of maximum stability and number of exacerbations (December to February) followed by another period of stability until May. A posteriori, given the differences obtained in all primary and secondary outcomes, they should be considered not only statistically significant but also clinically relevant.

Results

A total of 594 patients were considered for recruitment. Of these, 195 initially met our inclusion criteria and made up the pool of candidates who were contacted and invited to participate in the study until 60 patients. The 60

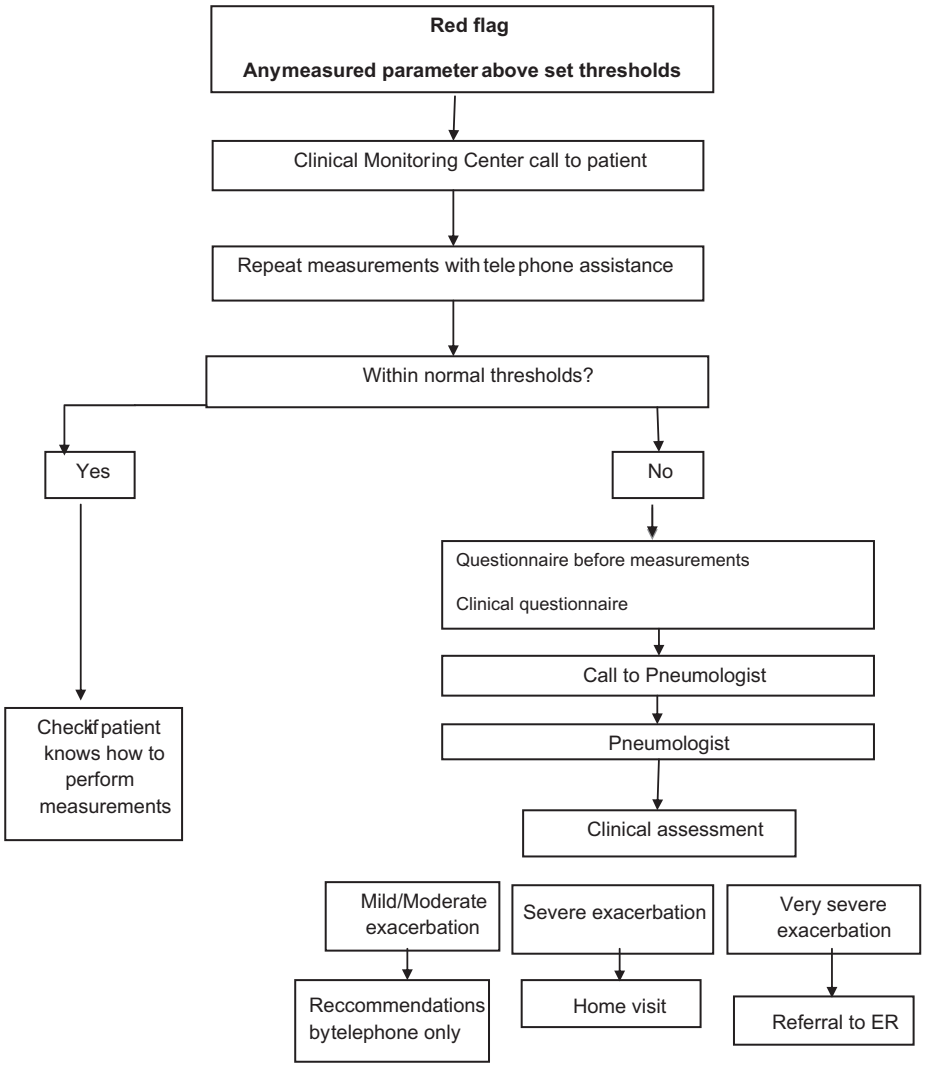

Figure 3 Step-by-step process after identification of a "Red flag", classification of a COPD exacerbation and response.

participants were recruited and assigned to the two groups: 30 patients to the CC group and 30 patients to the HT group (Fig. 1).

Their socio-demographic and clinical characteristics are shown in Table 1. The mean age was 73.8 years (standard deviation $\pm$ 9.5) and 44 patients (74.6%) were men. 62.7% of patients reported having an informal primary carer (IPC); in 60.5% of the cases this was the spouse, followed by the patients' children (15.7%).

The mean Charlson index score was 3.5 (SD $\pm$ 1.9) and the average number of drugs taken by the patients per day was 8.3 (SD $\pm$ 2.5). Regarding specific treatments for COPD, the most commonly used bronchodilators were a combination of an inhaled corticosteroid and a long-acting beta-adrenergic agonist together with a long-acting muscarinic receptors antagonist (Table 1).

All patients in the study could be classified into group D as defined by the revised 2011 GOLD classification (patients at high risk and with many comorbidities); mean post-bronchodilator FEV_1 was 39.1%, mean BODE index was 5.5, and CAT questionnaire was 19.3 (moderate impact on stable disease). All patients were long-term home oxygen therapy users, although seven of them used it erratically. At the study onset, the mean number of days of clinical stability per year (defined as days with no COPD exacerbation) was 166 days, and the mean number of hospitalizations was 1.8 per exacerbation in the previous year.

During the 7-months study period, we observed decrease in the number of emergency room visits in the HT group (20 visits) vs. the CC group (57 visits) ($p = 0.001$); number of hospitalizations: HT 12 hospitalizations vs. CC 33 hospitalizations ($p = 0.015$); length of hospital stay: HT 105 days vs. CC 276 days ($p = 0.018$) and need for NIV: HT 0 patients vs. CC 8 patients ($p < 0.0001$). We also found that the average number of days to first exacerbation requiring hospitalization was 77.28 days in the CC group and 141.07 days in the HT group ($p = 0.003$) (Fig. 4). Four patients in the CC group died (3 of causes related to COPD and 1 secondary to a retroperitoneal hematoma) vs. two patients in the HT group (1 of causes related to COPD and another secondary to an intestinal obstruction).

We identified a total of 50 Red Flags (clinical alerts), from which following our classification system: 39 (78%) were classified as moderate, 8 (16%) as severe, and 3 (6%) as

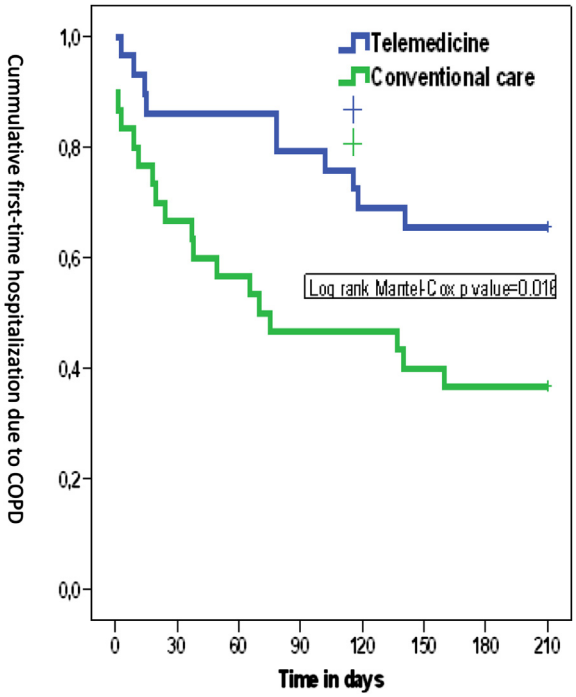

Figure 4 K—M survival curves of time to the first ER visit/observation/hospitalization, by group.

very severe. Clinical interventions were conducted primarily over the telephone (in 37 occasions) or in the patient's home (in 8 occasions). The main parameters that triggered Red Flags were oxygen saturation (in 30 occasions), followed by peak-flow (in 7 occasions). In 7% (4 occasions) of raised "red flag" were due to blood pressure alteration, though in our study blood pressure had a low predictive capacity to a COPD exacerbation. Importantly, in 12 cases a Red Flag was not raised although the patient had a COPD exacerbation. In the majority of these cases the exacerbation occurred out of office hours or during weekends (5 cases), the parameters received were correct (3 cases), the patient went to the emergency room department without being previously monitored and advised (4 cases).

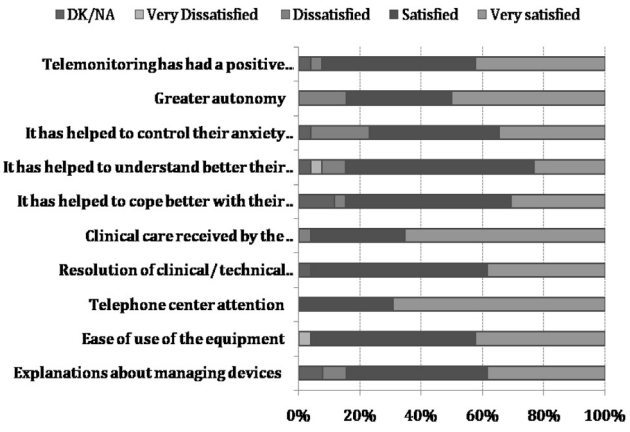

Figure 5 Patient satisfaction with the Home Telehealth program at the end of trial.

Overall, 78% of AECOPD in the HT group were classified as of a milder severity. In the CC we did not attend the patient's home or perform any other planned intervention, and for this reason we are unable to establish the severity of the AECOPD in this group.

We did not observe any withdrawals as a result of difficulties in using the devices and the technology, although in one case the data received were those of the carer and not from the patient. The overall patient satisfaction rate was high (median of telemonitoring time was 72.5%), with the HT programme being awarded a score of 9 out of 10 (Fig. 5). The average of telemonitoring days was 152,2 days (72.5% of the total study time). We defined adherence as the percentage of the total days the patient used the devices to monitor parameters during the study period. To improve the adherence each patient was provided with a user manual for each device and a "trial run" was performed to ensure the patient understood the proper functioning of the system. Additionally the CMC nurse called the patients who did not take their measurements on a dally bases.

Discussion

The PROMETE study is a novel and innovative home telehealth program that improved the care of severe COPD patients. It is the first study conducted in this population and demonstrated an improvement in many clinical outcomes.

The study combines telehealth resources with conventional care and early interventions after a detection of an AECOPD to improve the care of patients with severe COPD. The main results of this trial revealed a significant reduction in emergency room visits, hospitalizations and length of hospital stay of COPD patients enrolled in HT, with equivalent safety and high acceptance for patients receiving CC.

Our study population was made by COPD patients with severe airflow obstruction (mean FEV_1 38.9%), on long-term home oxygen therapy, with multiple comorbidities (Charlson index score of 3.57), limitations in activities of daily living (Barthel index 89.3 and 64% in need of a carer), using multiple medications (average of 8.30 drugs per day) and 46.7% of the HT group reported hospitalizations due to AECOPD in the previous year. Using HT for daily monitoring and follow-up allowed us to detect and treat exacerbations in their early stages. Overall, 78% of AECOPD were classified as moderate and interventions were conducted mainly over the telephone (74%), or as home visits (5%). We focused on care at the patient's home, initiating treatment for AECOPD from the home in 80% of the cases. We demonstrated that HT allows detecting early changes in measurable parameters and therefore identify an AECOPD prematurely. In fact, we detected more milder exacerbations with HT since we were able to monitor daily changes in the patient's condition.

In December 2011 the UK Department of Health published the results of the "Whole System Demonstrator" (WSD) program, a randomized clinical trial which involved 6191 patients, 3030 of whom had chronic diseases such as COPD, diabetes mellitus or heart failure, across 3 distant geographic areas [23]. Health parameters (blood pressure,

oxygen saturation and temperature) were telemonitored with a device installed at the patients' home. Early results showed at reduction of hospitalizations (20%), length of stay (14%) and time spent in emergency room (14%). The implementation of this program was planned to last about seven years and the potential maximum benefits were expected to be achieved in phase III (in about 3—4 years from start).

In a review published in 2010, HT was shown to reduce the number of hospitalizations and emergency room visits in comparison to CC, although the clinical characteristics of the studies reviewed were very heterogeneous [24]. Similar results were published in a Cochrane review in 2011 [25], which also found improvement in the quality of life of patients. No differences were found in mortality rates; possible explanations being that both study groups were composed of patients in the worst functional class, which in itself is associated with a poorer prognosis, and the short period of follow-up (total of 7 months). All these reports concluded that better-designed studies on specific populations are needed. To the date, studies in groups of patients with more severe disease are limited to Vitacca's work [26] in a population of 240 patients with severe respiratory failure, with a mean FEV_1 of 40%.

With respect to the utility of the telemonitoring parameters, there are few studies exploring the utility of PEF in COPD patients, especially in these patients without bronchial hyperactivity. Hurst [12] and van de Berge [16] linked the fall in the PEF with the probably to detect early COPD exacerbation. In our study, in 7 occasions PEF triggered clinical while oxygen saturation did in 30 occasions, and blood pressure only in 7% of the times (4 occasions).

To sum up the authors concluded that HT programs coordinated by primary and secondary care groups can improve the efficient delivery of the health services to chronic patients due to an easier and more effective follow-up of chronic patients.

Advantages and limitations

Adherence to the HT program in our trial was good, and there were no withdrawals due to complications of use, although one of the patients had difficulties taking the measurements, and in the end it was identified that data received were those of the carer. This reinforces the importance of selecting patients who may best benefit from a TH program [25]. An important aspect for patient adherence to a HT is the use devices that are not difficult to use; Finkelstein and Friedman showed that with a short training, elderly patients were capable of using a home monitoring system via videoconference [27].

Our study did not vary the schedule of the patients' appointments to visit the Pneumologist or PCCs, intervening only if there was some change in the monitored parameters that were recorded daily, and thereby ensuring patients did not lose their relationship with their regular doctors. Coordination with the PCC was essential to maintain continuity of care and to avoid duplicating clinical interventions and treatments. We dealt with a large amount of data and information, clinical and non-clinical; and in this case the CMC nurse played a key role in filtering the alerts. In this way in clinical alert, AECOPD were differentiated from other causes, and were able to detect false positives; And in technical alerts, false negatives were managed by the CMC nurses, all this reducing the burden of interventions by the, as the Pneumologist was only alerted when clinical alerts were confirmed by the CMC nurses.

We must emphasize that any integrated program for COPD care, with or without TH, requires the cooperation and coordination between primary and specialist care within the community and the hospital.

Finally, the main limitations of our study were: 1) the small sample size, albeit given the severity of the disease, it was sufficient to obtain significant clinically relevant and statistically significant differences between the two groups; 2) given the poor functional prognosis (COPD GOLD stage IV with multiple comorbidities) and only 7 months of monitoring period, we were unable to obtain significant differences in mortality between the two groups; 3) the study follow-up was less than one year; and hence we were unable to take into account seasonality of AECOPD 3) the patient selection could be better; although there were no withdrawals because of difficulties in using the devices and the overall satisfaction rate was high; 4) the lack of individual randomization, as mentioned above.

Future

Real-life effectiveness and economic feasibility studies are needed to implement HT programmes. In addition, larger, multicenter studies and the development of integrated care programs within the healthcare system are needed and no more repetitive "pilot projects". We must improve the selection process to better identify patients that are most likely to benefit from TH programs, define the roles of the staff involved, and assess the impact of these programs on the patient's carer.

In conclusion, the PROMETE study has shown clinical efficacy in monitoring COPD patients in GOLD group D [11] (severe airflow obstruction, respiratory symptoms, and at-risk of AECOPD), who also have multiple comorbidities, by reducing the number hospital visits through early detection and proactive intervention in the patient home before the AECOPD occur. This was possible with the coordination of Primary Care, Pneumologist, and nursing staff. However, we must carefully evaluate the population who meet inclusion criteria for HT programmes, as the majority of patients are elderly, some of them with cognitive, hearing, or visual defects that may hinder the continuity of TH on a daily basis [28]. Hence, HT programs in severe COPD patients are safe and efficacious in reducing healthcare resources utilization in elderly patients with multiple comorbidities.

Conflict of interest statement

All the authors have read the manuscript and have approved this submission. Cristina Gómez-Suárez, Ana Jordán and Elena Tadeo work at Linde Healthcare. The remaining authors have no conflict of interest.

The study was approved by the Ethics Committee of the HULP, study number was 1819. All patients signed an informed consent form prior to inclusion.

Acknowledgments

We thank Linde Healthcare for participating in this study, running the CMC and financing the medical equipment.

Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.rmed.2013.12.003

References

[1] Curry CW, De AK, Ikeda RM, Thacker SB. Health burden and funding at the centers for disease control and prevention. Am J Prev Med 2006;30:269—76.
[2] Yach D, Hawkes C, Gould CL, Hofman KJ. The global burden of chronic diseases: overcoming impediments to prevention and control. JAMA 2004;291:2616—22.
[3] Chapman KR, Mannino DM, Soriano JB, Vermiere PA, Buist AS, Thun MJ, Connell C, Jemal A, Lee TA, Miravitlles M, Aldington S, Beasley R. Epidemiology and costs of chronic obstructive pulmonary disease. Eur Respir J 2006;27:188—207.
[4] Lopez AD, Mathers CD, Ezzati M, Jamison DT, Murray CJ. Global and regional burden of disease and risk factors 2001: systematic analysis of population health data. Lancet 2006; 367:1747—57.
[5] Hurst J, Vestbo J, Anzueto A, Lacantore N, Müllerova H, Tal-Singer R, et al. Susceptibility to exacerbation in chronic obstructive pulmonary disease. N Engl J Med 2010;363: 1128—38.
[6] Soler-Cataluña JJ, Martínez-García MA, Catalán Serra P. Impacto multidimensional de las exacerbaciones de la EPOC. Arch Bronconeumol 2010;46:12—9.
[7] Ancochea J, coordinador científico. Estrategia nacional en EPOC del Sistema Nacional de Salud. Ministerio Sanidad y Política Social; 2009.
[8] Rabanales-Soto J, Párraga Martínez I, López-Torres J, Andrés-Pretel F, Navarro-Bravo B. Tecnologías de la información y las comunicaciones: telemedicina. Rev Clin Med Fam 2011;4: 42—8.
[9] Yohannes A. Telehealthcare management for patients with chronic obstructive pulmonary disease. Expert Rev Respir Med 2012;6:239—42.
[10] Sicotte C, Pare G, Morin S, Potvin J, Moreault M-P. Effects of home telemonitoring to support improved care for chronic obstructive pulmonary disease. Telemed J E Health 2011;17: 95—103.
[11] GOLD. The global initiative for chronic obstructive pulmonary disease. Last accessed in July 2012. Available at: http://www.goldcopd.com; 2011.
[12] Hurst J, Donaldson G, Quint J, Glodring J, Patel A, Wedzicha J. Domiciliary pulse-oximetry at exacerbation of chronic obstructive pulmonary disease: prospective pilot study. BMC Pulm Med 2010;10:52—63.
[13] Franquet J. Home telehealth for patients with chronic obstructive pulmonary disease (COPD): an evidence-based analysis. Ont Health Technol Assess Ser 2012;12:1—58.
[14] Koff PB, Jones RH, Cashman JM, Voelkel NF, Vandivier RW. Proactive integrated care improves quality of life in patients with COPD. Eur Respir J 2009;33:1031—8.
[15] Jódar-Sánchez F, Ortega F, Calderón CP, Gómez-Suárez C, Jordán A, Pérez P, et al. Implementation of a telehealth programme for patients with severe chronic obstructive pulmonary disease treated with long-term oxygen therapy. J Telemed Telecare 2013;19:11—7.
[16] van de Berge M, Hop W, van der Molen T, van Noord J, Creemers J, Schreurs A, et al. Prediction and course of symptoms and lung function around an exacerbation in chronic obstructive pulmonary disease. Respir Res 2012;33: 44—53.
[17] Abizanda-Soler P, Paterna-Mellinas G, Martínez-Sánchez E, López-Jiménez E. Comorbidity in the elderly: utility and validity of assessment tools. Rev Esp Gerontol 2010;45: 219—28.
[18] Agustí A, Soler JJ, Molina J, Muñoz MJ, García-Losa M, Roset M, Jones PW, Badia X. Is the CAT questionnaire sensitive to changes in the health status in patients with severe COPD exacerbations? COPD 2012;9:492—8.
[19] Meguro M, Barley EA, Spencer S, Jones PW. Development and validation of an improved COPD-specific version of the St. George respiratory questionnaire. Chest 2007;132:456—63.
[20] Cabañero-Martínez MJ, Cabrero-García J, Richart.Martínez M, Muñoz-Mendoza CL. The Spanish versions of the Barthel index (BI) and the Katz index (KI) of activities of daily living (ADL): a structured review. Arch Gerontol Geriatr 2009;49:77—84.
[21] Goldberg D, Bridges K, Duncan-Jones P, et al. Detecting anxiety and depression in general medical settings. Br Med J 1988;97:897—9.
[22] Early intervention and for COPD patients. Last accessed in September 2012. Available at: http://www.commonwell.eu.
[23] Polisena J, Tran K, Cimon K, Hutton B, McGill S, Palmer K, Scott RE. Home for chronic obstructive pulmonary disease: a systematic review and meta-analysis. J Telemed Telecare 2010;16:120—7.
[24] McLean S, Nurmatov U, Liu JLY, Pagliari C, Car J, Sheikh A. care for chronic obstructive pulmonary disease. Cochrane Database Syst Rev 2011;7:CD007718.
[25] Vitacca M, Bianchi L, Guerra A, Fracchia C, Spanevello A, Balbi B, Scalvini S. Tele-assitance in chronic respiratory failure patients: a randomised clinical trial. Eur Respir J 2009;33: 411—8.
[26] de Toledo P, Jiménez S, del Pozo F, Roca J, Alonso A, Hernández C. Telemedicine experience for chronic care in COPD. IEEE Trans Inf Technol Biomed 2006;10:567—73.
[27] Finkelstein J, Friedman RH. Potential role of telecommunication technologies in the management of chronic health conditions. Dis Manage Health Outcome 2000;8:57—63.
[28] Smith S, Elkin S, Partridge M. Technology and its role in respiratory care. Primary Care Respir J 2009;18:159—64.