

Télé médecine en BPCO : big promises, few details?

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12^{es}
12^{es} Journées
Francophones
Alvéole
15 & 16
mars
2018
Cité des Congrès de Nantes

Conflits d'intérêt: J Bourbeau

① Consultation fees	none
② Stock ownership/profit	none
③ Patent fees	none
④ Remuneration for lecture	Private: AZ, BI, Grifols, Novartis Public: UDM, RQESR, CTS, Chest, Respiplus
⑤ Manuscript fees	none
⑥ Trust research/ joint research funds	Private: Aerocrine, AZ, BI, GSK, Novartis Public: CIHR, CRRN, FRQS, RI MUHC
⑦ Affiliation with Endowed Department	none
⑧ Other remuneration such as gifts	none

Agenda

1. Définition(s)
2. Les études
 - Les évidences
 - Les recommandations
 - Les opportunités
3. L' étude COMET: le Canada visite l'Europe
4. 20 ans plus tard

Définitions

Table 1 *Definitions and applications*

→	Telemedicine	Distribution of health services in conditions where distance is a critical factor, by healthcare providers that use ICT to exchange information useful for diagnosis at distance
	Telecommunications	Use of cable connections, radio, optical means or other electromagnetic channels to transmit or receive signals, such as voice, data or video communications
	Telematics	Use of telecommunications to permit computers to transfer programs and data
	Teleconsultation	Second opinion on demand between patient/family and staff or among health operators; opinions, advice provided at distance between two or more parties separated geographically
→	Telemonitoring	Digital/broadband/satellite/wireless or Bluetooth transmission of physiological and other noninvasive data (i.e. biological storage data transfer)
→	Decision support systems	According to a sentinel value, an alert starts for health personnel, who call patient
	Remote diagnosis	Identifying a disease by the assessment of the data transmitted to the receiving party through instrumentation monitoring a patient away from the clinic
	Tele-evaluation	On-demand data transfer to use as biological outcome measures
	Telecare	Network of health and social services in a specific area; in case of emergency, patient calls medical personnel, emergency call service or members of family
→	Telerehabilitation	Allows reception of homecare and guidance on the process of rehabilitation through connections for point-to-point video conferencing between a central control unit and a patient at home
→	Telecoaching	Direct reinforcement or recorded messages/communications to improve adherence
	Teleconference, audio	Electronic two-way voice communication between two or more people located in different places

Ambrosino N, Vitacca M, Dreher M, et al. Tele-monitoring of ventilator-dependent patients:

4 a European Respiratory Society Statement. *Eur Respir J* 2016; 48: 648–663

Télémédecine: définition

American Telemedicine Association defines it as “the use of medical information exchanged from one site to another via electronic communications to improve a patient’s clinical health status.”

C'est un exercice de la médecine par le biais des télécommunications et des technologies qui permettent les prestations de santé à distance et l'échange de l'information médicale s'y rapportant.

Télémédecine en BPCO

Cochrane review de 10 RCTs

Aucune amélioration de la qualité de vie

Pourrait réduire les risques de visites en urgence et d'hospitalisations.¹

Méta-analyse plus récentes de 18 RCTs n'a pas démontré d'amélioration de la qualité de vie.²

1. McLean et al. Cochrane Review and meta- analysis. *Br J Gen Pract* 2012;62:e739-49.23
2. Gregersen et al. Do telemedical interventions improve quality of life in patients with COPD? A systematic review. *Int J Chron Obstruct Pulmon Dis* 2016;11:809-22

Télémédecine en BPCO

13 RCTs

Echantillon total de patients: 40-256

Technologies:

- Tel (quelques fois avec dispositifs médicaux) : 9
- Video conf: 1
- Dispositifs médicaux connectés par internet: 3

Mesures: questionnaires, VEMs, Saturation, TA

Resultats:

- Diminutions des admissions: 5
- Aucun effet: 6
- Déterioration des admissions: 2

Télémédecine en BPCO

Il y a un manque d'études de qualité et celles existantes sont:

- petites études,
- courte durée, et
- hétérogénéité des interventions et du traitement usuel de comparaison.

Les méta-analyses ont produit des résultats contradictoires.

Telemedicine COPD: Chest CTS Guideline

Telemonitoring comprised the following elements:

- (1) electronic transfer of self-report or biometric data (eg, oxygen saturation, pulse rate, BP) over a distance;
- (2) use of a device located in the patient's home or on his or her person (mobile device); and
- (3) personalized feedback from a health-care professional who exercises his or her skills and judgment in the provision of tailored advice to the patient or automated feedback based on a predetermined algorithm.

Telemedicine COPD: Chest CTS Guideline

Substantial variability in the telemonitoring interventions and equipment used, which included recording and electronic transmission of

- vital signs (spirometry, pulse oximetry, heart rate, and BP);
- technology platform for delivery of education and transmission of pedometer results;
- hand-held monitor, self-reported symptoms, and manually entered temperature and oximetry;
- sensor-containing wrist-bands for heart rate, physical activity, near body temperature, and galvanic skin response; commercial oximeter and cell phone coupled with a wristband;
- self-report data (EXACT-PRO questionnaire) transmitted through cell phones; and
- automated alert calls based on winter weather conditions.

Télémédecine en BPCO

11. We suggest that telemonitoring compared to usual care does not prevent acute exacerbations of COPD, as assessed by decreases in emergency room visits, exacerbations or hospitalizations over a 12-month period (Grade 2C)

Underlying values and preferences:

- There is insufficient evidence at this time to support the contention that telemonitoring prevents COPD exacerbations

Opportunité de combler les écarts pour mieux livrer et améliorer l'autogestion

1-Améliorer l'autogestion en la rendant disponible chez le patient dans son environnement de vie, et assurer le transfert d'info au moment le plus opportun: renforcer le lien entre info et action (**strengthens behavior change**).

2- Permettre au patient

- de communiquer avec son case manager et recevoir le soutien nécessaire;
- de recevoir l'éducation pertinent à sa condition.

3-Permettre au case manager de faire un monitoring continue et soutien d'un plus grand nombre de patients et ainsi réserver les visites en personne aux patients qui en ont le plus de besoin.

COPD patient Management European Trial (COMET)", initiated in 2006

COMET: an investigational home-based COPD disease management programme

- **To achieve the optimal daily life and health status for the individual patient**
- **To maintain independence and integration in the community**

Kessler R, Casan-Clara P, Koehler D, ...Bourbeau J et al. COMET: a multicomponent home-based disease-management programme versus routine care in severe COPD. *Eur Respir J*. 2018;51(1).

Will adopting positive home-behaviours improve the lives of patient with COPD?

COMET Global Objectives¹



**A home-based COPD
disease-management programme**

WILL HELP

**Patients with severe COPD learn
and adopt the behaviours needed
to cope with their disease**

AND CONSEQUENTLY

**Among important outcomes, it will result
in a reduction
in hospitalisations**

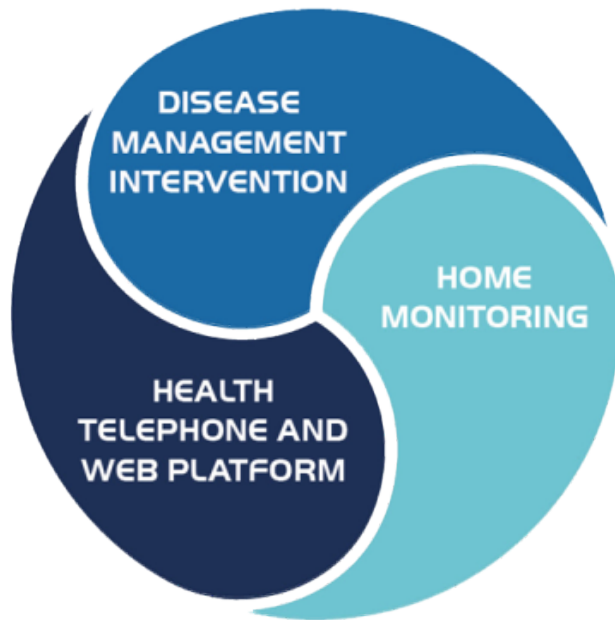
COPD, chronic obstructive pulmonary disease.

1. Bourbeau J et al. *Int J Chron Obstruct Pulmon Dis* 2016;28:1447–1451.

Disease management programme based on ‘Living Well with COPD’ and telemedicine platform

Components of the COMET trial^{1,2}

key interventions



Self-management program: involve patient self-management education LWWCOPD & coaching by case managers

Phone service with e-platform:

- weekly/daily reporting by patient with automatic analysis of clinical symptoms
- worsening triggers an alarm, standardized nurse intervention & transmission to the referent hospital physician for medical decision

COMET: control group

Usual management (control group)

Received the usual or routine COPD care and patient follow-up practices used at each investigational centre.

Site-specific usual management practices

- centre-specific COPD educational booklets or programme information.

were collected at the beginning and end of the patient inclusion period.

COMET: Quality control / Assurance

Quality Control / Assurance

Standardization of the program/content

- self-management program Living Well with COPD (LWWCOPD)

Case managers

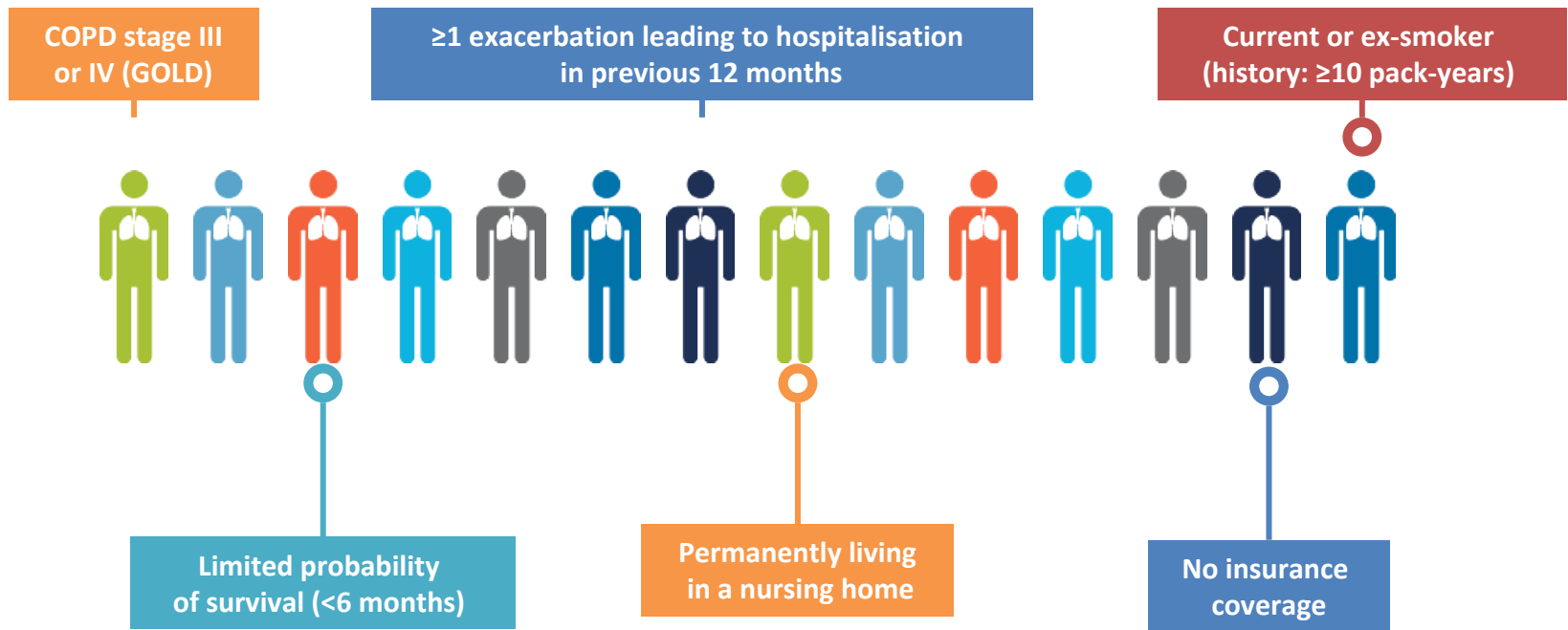
- experienced in taking care of home-based chronic patients;
- initial four-day training (+specific training MI);
- access given to 'reference guides' describing the objectives, interventions, suggested questions, expected results and resources;
- trainings at each country level during the study for new comers, program refreshing and experience sharing.

Monthly telephone contacts

- between the case managers and a pneumologist from the COMET study coordination center, in each country separately

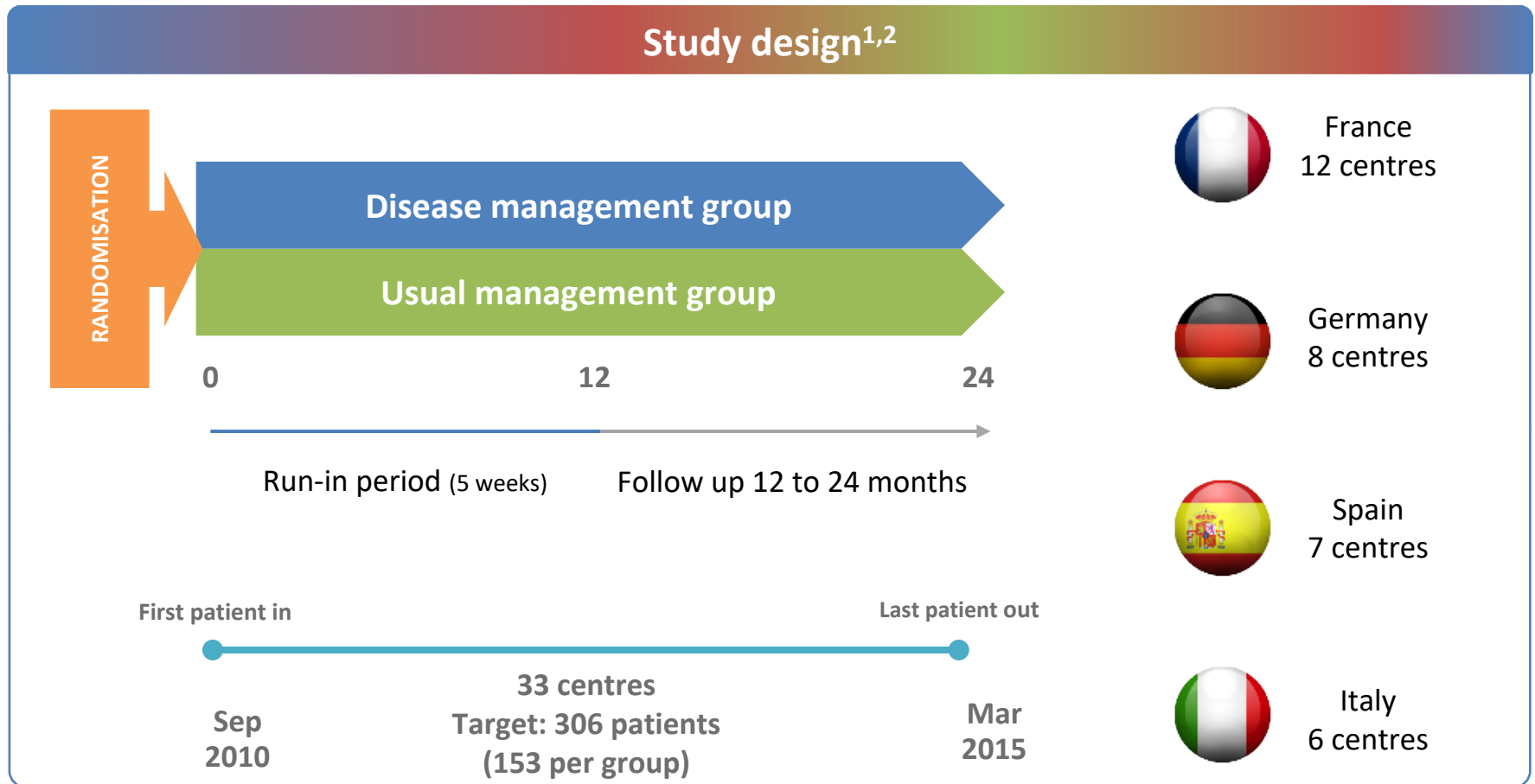
COMET was focused on patients with severe COPD treated at home¹

Main eligibility criteria



Main exclusion criteria

COMET is an international, randomised, home-based trial



1. Bourbeau J et al. *Int J Chron Obstruct Pulmon Dis* 2016;28:1447–1451; 2. COMET Clinical Study Report. July 2016.

Will adopting positive home-behaviours

Primary objective¹



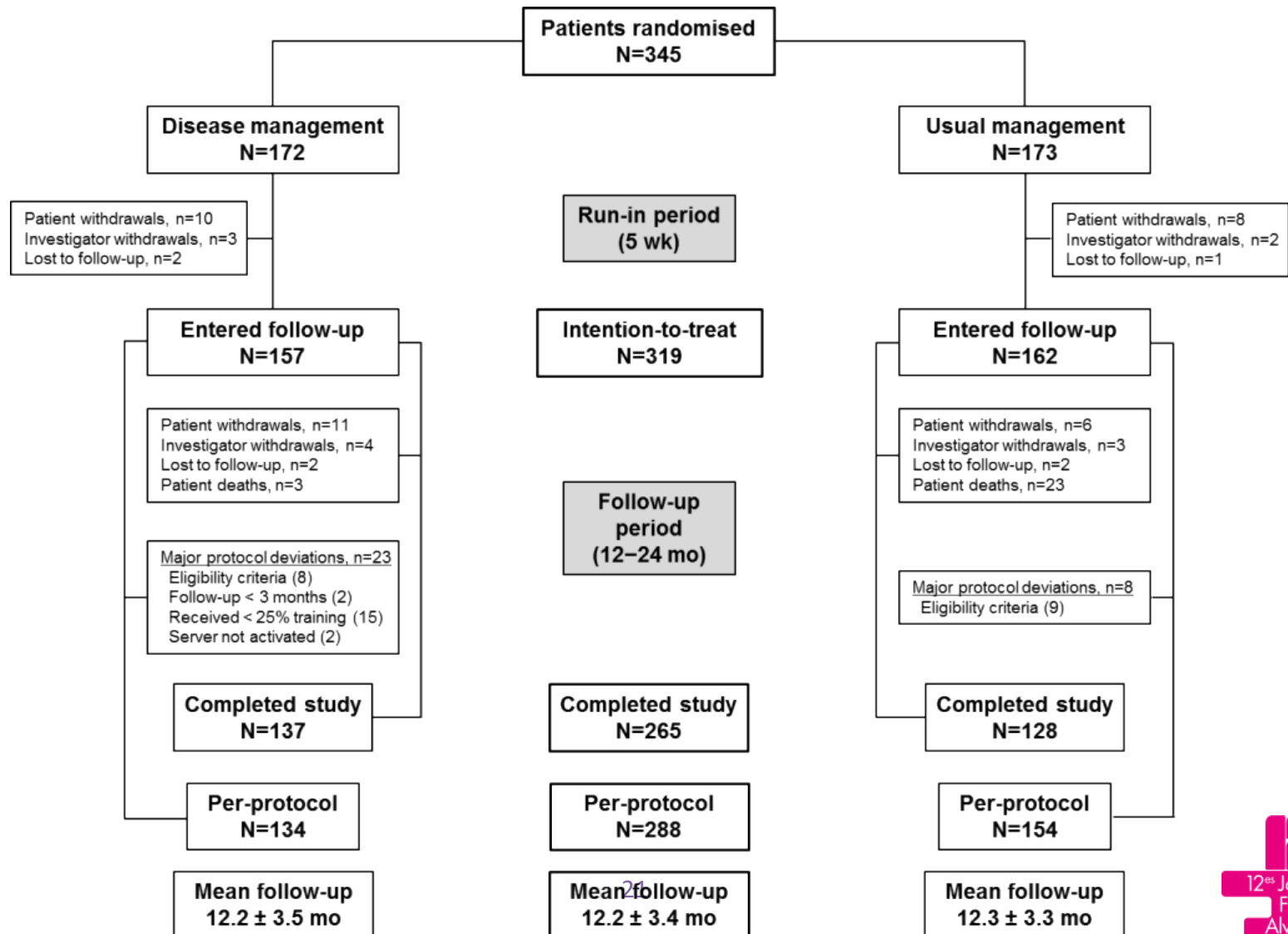
To compare the effect of a multicomponent, home-based COPD self-management programme versus usual care on **all-causes hospital days** in patients with severe COPD

Primary: all causes, acute care wards and subsequent nursing facilities, ITT

Supportive:

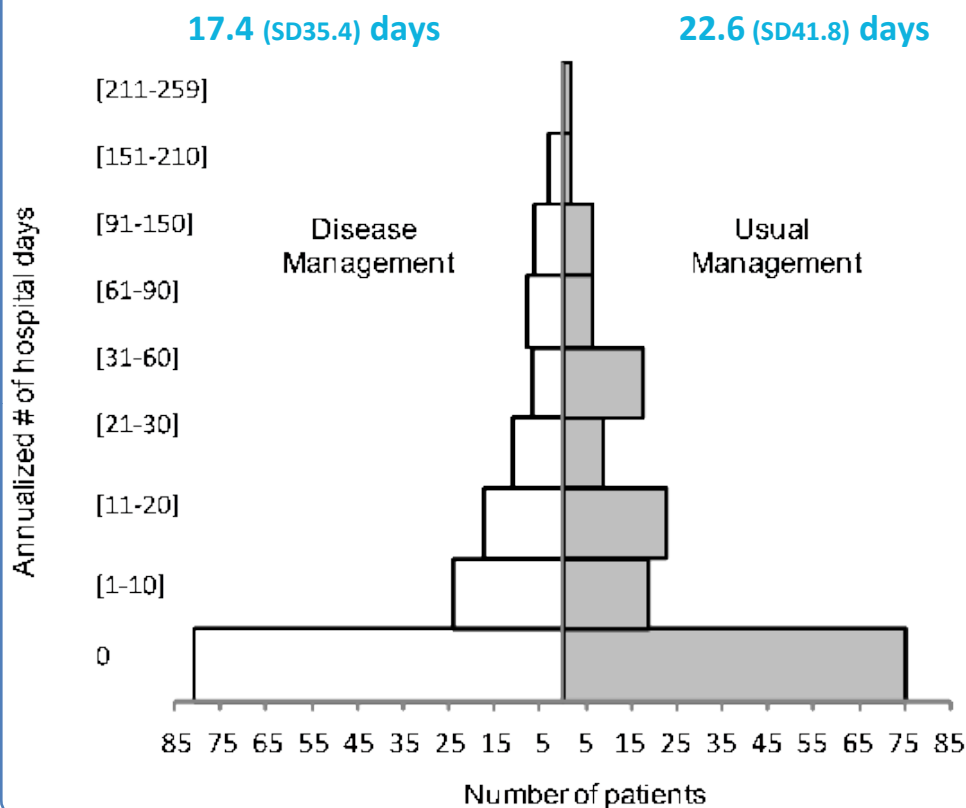
- Primary, per protocol (PP)
- All causes, acute care wards only, ITT and PP
- For AECOPD, ITT and PP

Patient flow



Primary efficacy endpoint: number of hospital days, all-cause, acute care + subsequent nursing facilities

In all countries, in the ITT population (n=319)



Reduction in the yearly number of hospital days

-5.32 days

[95% CI -13.69; 3.05]

not statistically significant

p=0.161

(Wilcoxon's test)

Primary efficacy endpoint: EVC assessment

In all countries, in the ITT population (n=319)

Primary Causes for Hospital Admissions According to EVC Assessments

	Disease Management (n=157)	Usual Management (n=162)
Respiratory	68 (43.3 %)	75 (46.3%)
Other Medical Reason	15 (9.6%)	17 (10.5%)
Cardiovascular	6 (3.8%)	7 (4.3%)
Surgical	2 (1.3%)	4 (2.5%)
Cancer	1 (0.6%)	2 (1.2%)
Not Assessable	0 (0.0%)	1 (0.6%)

All-causes, acute care and subsequent nursing facilities
yearly number of hospital days
15.5 (SD32.9) days (DM) vs 20.8 (SD38.8) days (UM)
not statistically significant
(p=0.150, Wilcoxon's test)

In the Per Protocol population (n=288): **13.2 (SD28.3) days (DM) vs 21.2 (SD39.5) days (UM)**
(p=0.106, Wilcoxon's test)

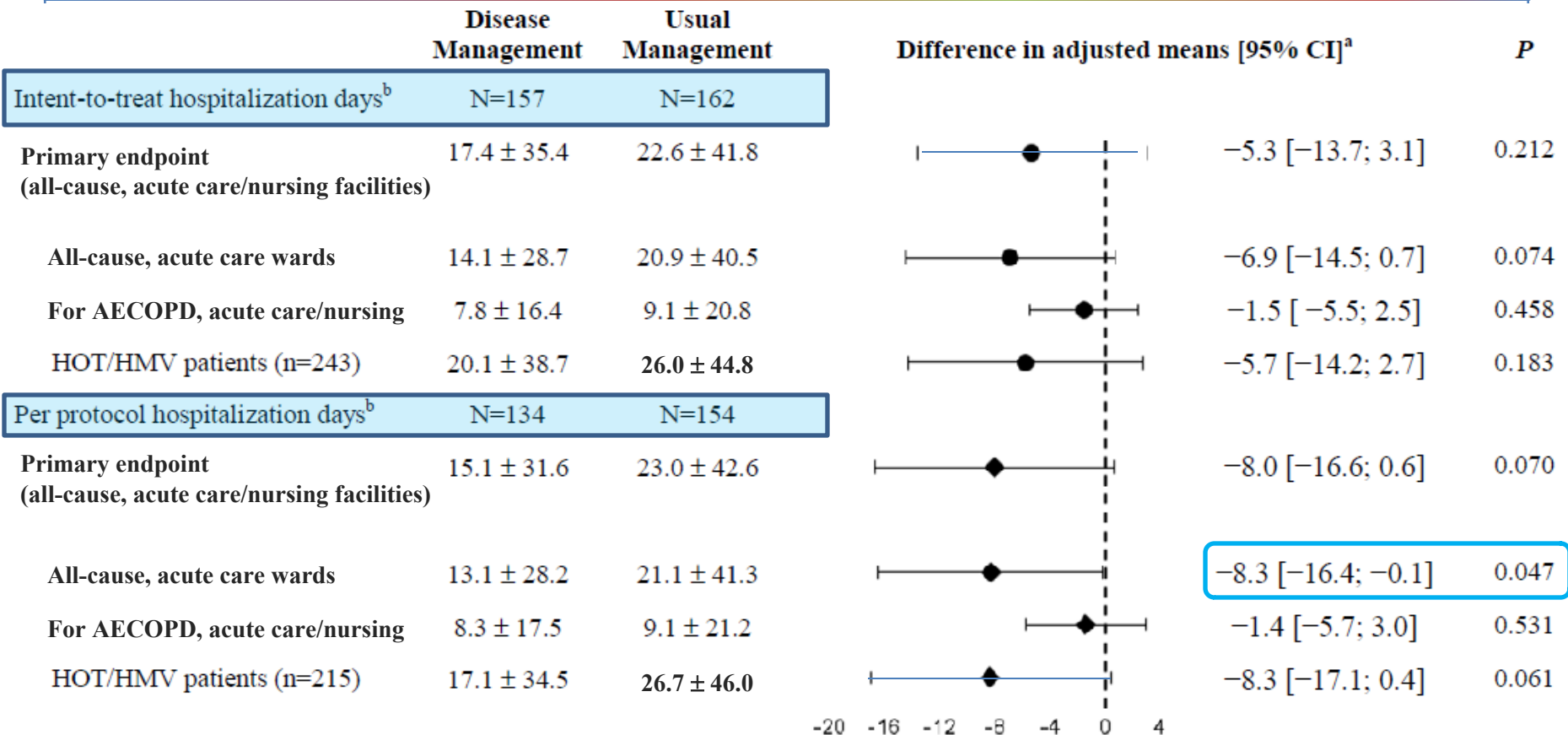
ITT, intention-to-treat.

Categories were exclusive (e.g., lung cancer surgery was categorised in surgery but was not included in cancer and respiratory).

Other medical reason includes anxiety, asthenia, diarrhoea, fall, thermal burn, syncope.

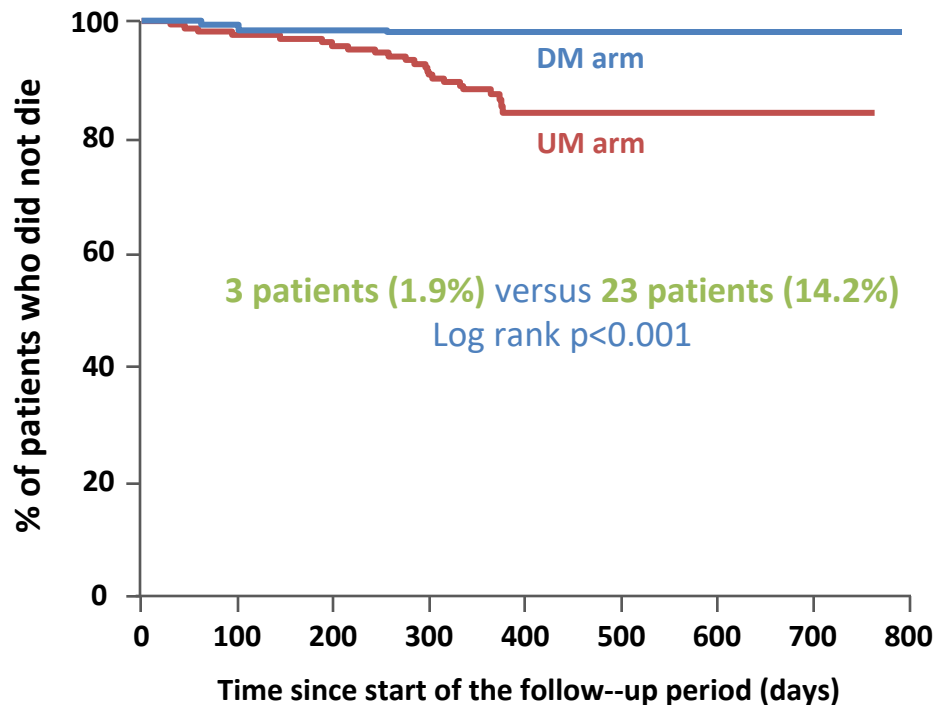
Secondary efficacy endpoint: Fewer all-cause Acute Care hospital days

In all countries, supportive and secondary analyses of hospitalisation endpoint



Safety endpoint: Significantly fewer deaths in the DM

In all countries, all-causes deaths during the follow-up period



Cause of death was **respiratory** in 62% of cases and occurred in **hospital** settings

Prognostic factors for death were **baseline BODE index**, and the **total number of days of hospitalisation** after selection whatever their reason

1 patient died prior to randomisation from sudden death (unknown cause).

BODE, Body mass index, degree of airflow Obstruction, Dyspnoea and Exercise capacity; DM, disease management;

UM, usual management.

Other secondary efficacy endpoints: Favorable impact on chronic COPD condition

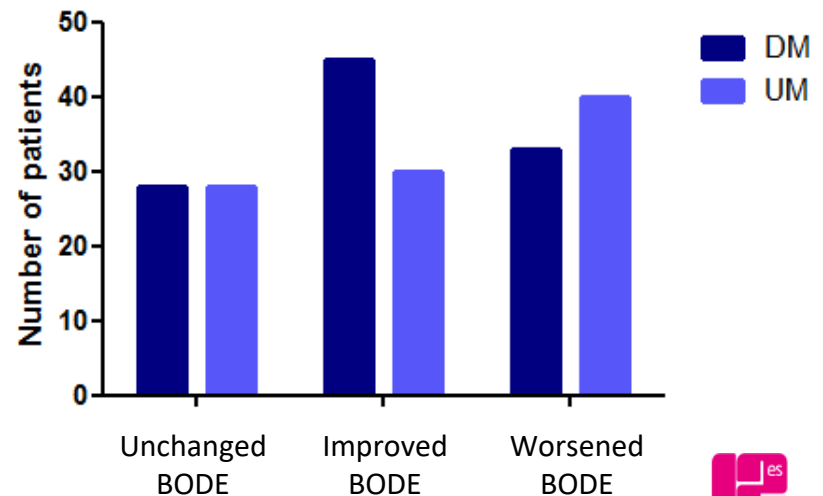
Significant cessation of smoking:

9/34 (DM) vs 2/34 (UM) current
smokers at baseline
 $p=0.021$

Significant reduction in the BODE index at 1 year:

difference in adjusted means
 -0.5 [95% CI: -0.9 ; -0.1], $p=0.010$

1-yr BODE index response rate



BODE, Body mass index, degree of airflow Obstruction, Dyspnoea and Exercise capacity; improvement or worsening is change ≥ 1
DM, disease management; UM, usual management.

COMET: program adherence

- Two-thirds to 90% of the DM group patients received at least 80% of the planned number of coaching sessions;
- 80% compliant with the weekly phone calls to transmit health status, and most acquired disease management skills.

Take-home messages

- COMET showed that it is possible to improve the management of patients with severe COPD and this could have impact on patient outcome
- More specifically: COMET provides key learnings in home-management of severe COPD patients with self-management intervention and the support of health care professional (case manager)
 - All-cause hospital days were decreased but not statistically significant (ITT)
 - All-cause Acute Care hospital days were decreased and statistically significant (PP)
 - Deaths were significantly less
 - Self-management skills, smoking habits and BODE index were favourably modified
- Novel aspects of the disease management intervention included an e-health platform for reporting frequent health status updates, rapid intervention when necessary, and oxygen therapy monitoring

Télémédecine... 20 ans plus tard

Surprise et déception!

Cependant:

- Beaucoup d'études ont rapporté des résultats positifs dans les essais cliniques randomisés
- Les effets bénéfiques sont probablement dus à l'attention donnée, l'éducation thérapeutique et le case manager dans l'intervention « télémédecine »
- Peu d'étude économique

Future work:

- Il est nécessaire que les études futures distinguent l'apport réel de la télémédecine
- **Opportunité de combler les écarts pour mieux livrer et améliorer l'autogestion**