INNOVACIÓ EN TECNOLOGIES DE LA COMUNICACIÓ APLICADES A LA GESTIÓ DEL MALALT RESPIRATORI CRÒNIC

Sala Geron 3, Planta -1. Edifici Montseny. Parc Sanitari Pere Virgili. Avinguda de Vallcarca, 169-205

8 de maig 2018

BRN SEMINARS

Scientific workshops to foster collaborative research

Organized by: Barcelona Respiratory Network Collaborative research

PROMETE II: Un assaig clínic aleatoritzat i controlat de telemedicina en MPOC greu

En nom dels investigadors PROMETE II:

Julio Ancochea, Francisco García-Río, Emma Vázquez-Espinosa, Ascensión Hernando-Sanz, Luis López-Yepes, Raúl Galera-Martínez, Germán Peces-Barba, Mª Teresa Pérez-Warnisher, Gonzalo Segrelles-Calvo, Celia Zamarro, Pablo González-Ponce, M. Inmaculata Ramos, Jose Ignacio Conforto & Syed Jafri

H. U. La Paz, H. U. La Princesa, Fundación Jiménez Díaz, H. U. 12 de Octubre, y H.U. Rey Juan Carlos

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THE LINDE GROUP Linde

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Declaració de Potencials Conflictes d'Interès

JB Soriano informa referent (o no) a aquesta presentació que:

-JBS ha rebut finançament per realitzar investigació mèdica i beques de GSK en 2011 i Chiesi en 2012, vía su antigua afiliación CIMERA; y desde 2016 a 2018 de Linde y GSK vía el IIS del Hospital Universitario de La Princesa

-JBS ha participado en actividades formativas, conferencias, comités asesores y/o consultoría durante el periodo 2011-2018 patrocinades per: AirLiquide, Almirall, AstraZeneca, Boehringer-Ingelheim, CHEST, Chiesi, ERS, GEBRO, Grifols, GSK, Linde, Lipopharma, Menarini, Mundipharma, Novartis, Pfizer, RiRL, Rovi, SEPAR i Takeda

-JBS no ha rebut (ni directament ni indirectament) fons de la indústria del tabac o els seus afiliats

JB Soriano declara no tenir conflictes d'interès, reals o percebuts, en relació amb aquesta conferència

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- PROMETE I resum
- PROMETE II resultats

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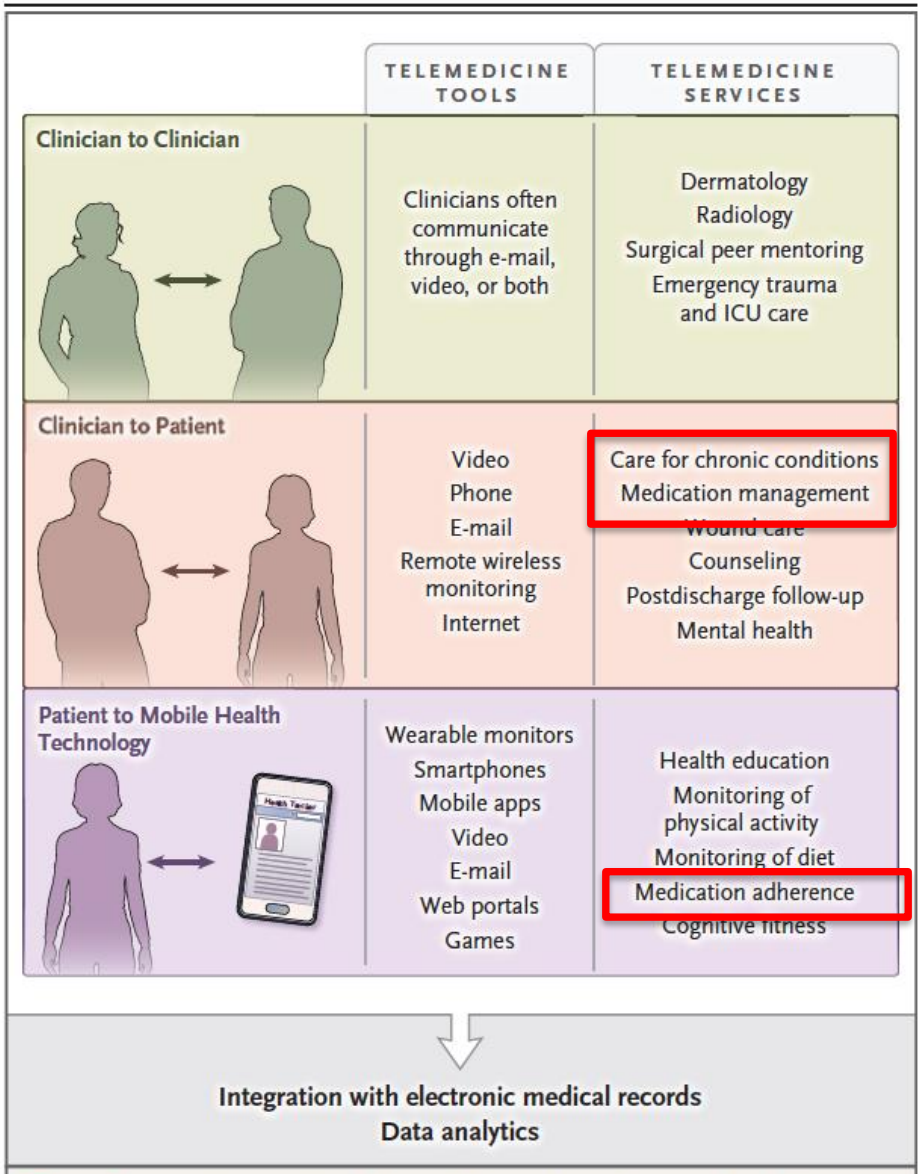

Figure 1. How Doctors Use Telemedicine and How Patients Benefit.
Adapted from the American Telemedicine Association. ICU denotes intensive care unit.

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL REPORT

Telehealth

Reed V. Tuckson, M.D., Margo Edmunds, Ph.D., and Michael L. Hodgkins, M.D., M.P.H.

Table 2. Recommendations for Telehealth Research.

Topic	Recommendation
Physician leadership	Physicians should seek to enhance telehealth care delivery through collaborations with telehealth technology and service providers and contribute to the evidence base by comparing telehealth outcomes with usual care.
Reimbursement	Current Procedural Terminology codes should be updated to facilitate reimbursement-related research in fee-for-service settings, and the effect of alternative payment models that use bundled telehealth services should be studied to determine purchaser returns on investment.
Licensure	The necessary facilitation of interstate licensure should be supported by ongoing research regarding any quality-of-care issues that may arise.
Liability	Evidence is necessary to better understand what, if any, quality and safety risks may differentiate telehealth service delivery from traditional in-person care.
Human factors	Research on user-centered design is needed to facilitate the integration of telehealth into clinical workflows and to optimize patient engagement.
Device interoperability and data integration	Evidence-based best practices and standards that support the most effective integration of devices and data streams from clinician and patient telehealth engagement should be widely shared.
Privacy and security	Standardized guidelines are necessary and should be based on evidence and best practices to support appropriate safeguards and regulatory oversight.
Performance measurement	Enhanced evidence is required to address gaps in existing telehealth-related clinical performance measures and enhance those currently available.
Patient engagement and the evolving patient–physician relationship	Evidence-based guidance is needed to support health professional counseling and engagement with patients and caregivers across the full spectrum of telehealth services and technologies.
Research design and methods	Telehealth research in real-world settings requires alternative research designs, new research methods, and innovative analytic techniques that supplement traditional randomized, controlled trials and should be supported with enhanced funding and an expanded workforce.

Tuckson RV, et al. NEJM 2017.

Table 1. Quality-of-Life and Patient-Reported Outcome Measures among Elderly Patients with Chronic Disease.*

Measures	Baseline (N=32)	3 Months (N=18)	Absolute Difference	P Value
Quality-of-life measures				
EQ-5D global quality†	0.4612	0.5093	0.0481	0.03
EQ-5D quality dimension‡				
Mobility	3.16±0.2	2.95±0.3	−0.21	0.04
Self-care	2.63±0.8	2.58±0.6	−0.05	>0.05
Daily activities	2.79±0.6	2.95±0.5	0.16	>0.05
Pain or discomfort	2.32±1.1	2.26±0.9	−0.05	>0.05
Anxiety and depression	2.42±0.3	2.11±0.2	−0.32	0.04
Global satisfaction§		9.50		
Patient-reported outcome measures (%)	**Very Satisfied**	**Satisfied**	**Less Satisfied**	**Unsatisfied**
Health care	86.4	13.6	0	0
Abatement of symptoms	77.3	22.7	0	0
Knowledge of disease	81.8	18.2	0	0
Reduction of anxiety	81.8	18.2	0	0
Improvement in autonomy	86.4	9.1	0	0
Adaptation to abatement of disease	54.5	40.9	0	0
Benefit for family	72.7	9.1	0	0

* Plus–minus values are means ±SD.

† The European Quality of Life–5 Dimensions (EQ-5D) global-quality measure evaluates the global quality of life in Europe. The answers provided data for 243 health states and can be converted into an index indicating a range of scores in which 0 denotes death and 1 perfect health.

‡ The EQ-5D quality-dimension measure evaluates quality of life in the five dimensions listed. Scores range from 1 to 5, with 1 denoting perfect health and 5 the worst health.

§ Global satisfaction denotes the general satisfaction of patients who received care through the Telehealth assistance program. Scores range from 1 to 10, with higher scores denoting greater satisfaction with outcomes.

Fernández-Moyano A, et al. NEJM 2018.

REVISIÓN

Continuidad asistencial. Evaluación de un programa de colaboración entre Atención Hospitalaria y Atención Primaria

A. Fernández Moyano[a], J. L. García Garmendia[b], C. Palmero Palmero[a], B. García Vargas-Machuca[c]
J. M. Páez Pinto[d], M. Álvarez Alcina[a], R. Aparicio Santos[a], M. Benticuaga Martines[a],
J. Delgado de la Cuesta[a], R. de la Rosa Morales[a], C. Escorial Moya[a], R. Espinosa Calleja[a],
J. Fernández Rivera[a], C. González-Becerra[a], E. López Herrero[a], Y. Marín Fernández[a],
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Fernández-Moyano A, et al. Rev Clin Esp 2007.

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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]

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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 $p < 0.05$).

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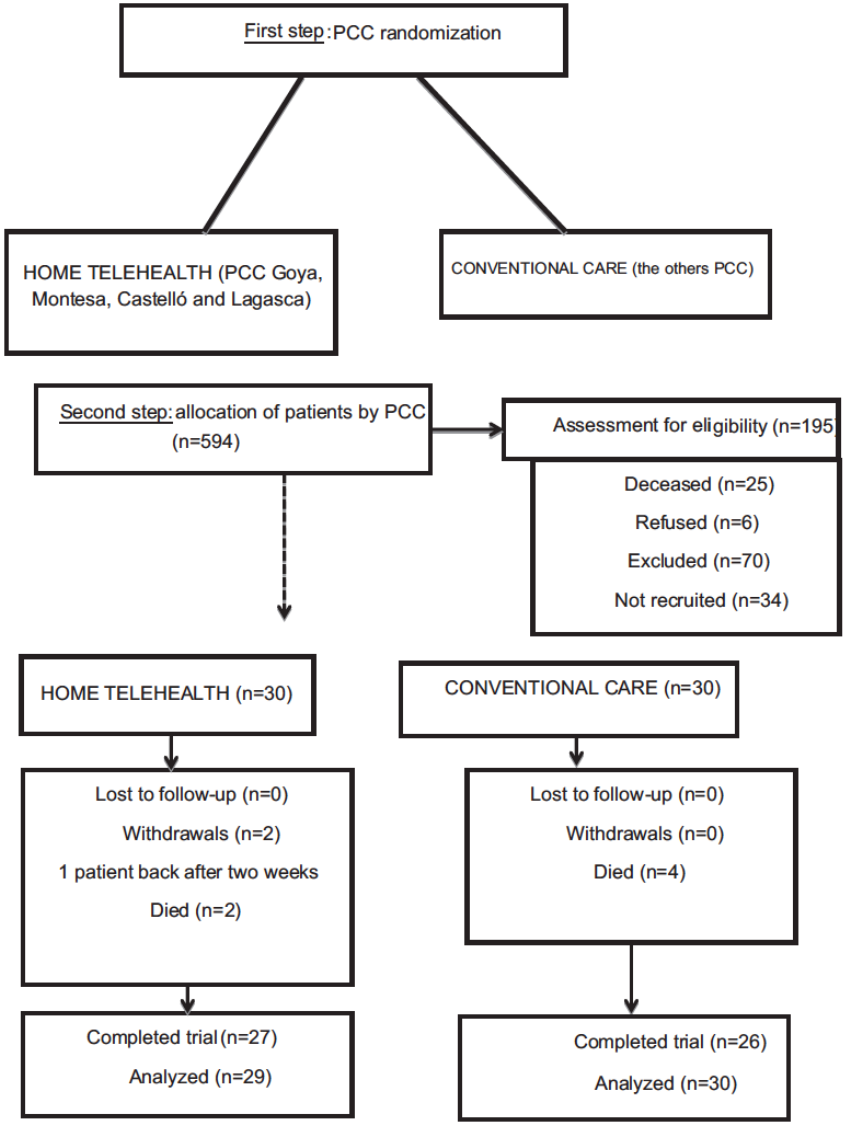


Figure 1 CONSORT flow chart of trial participation.

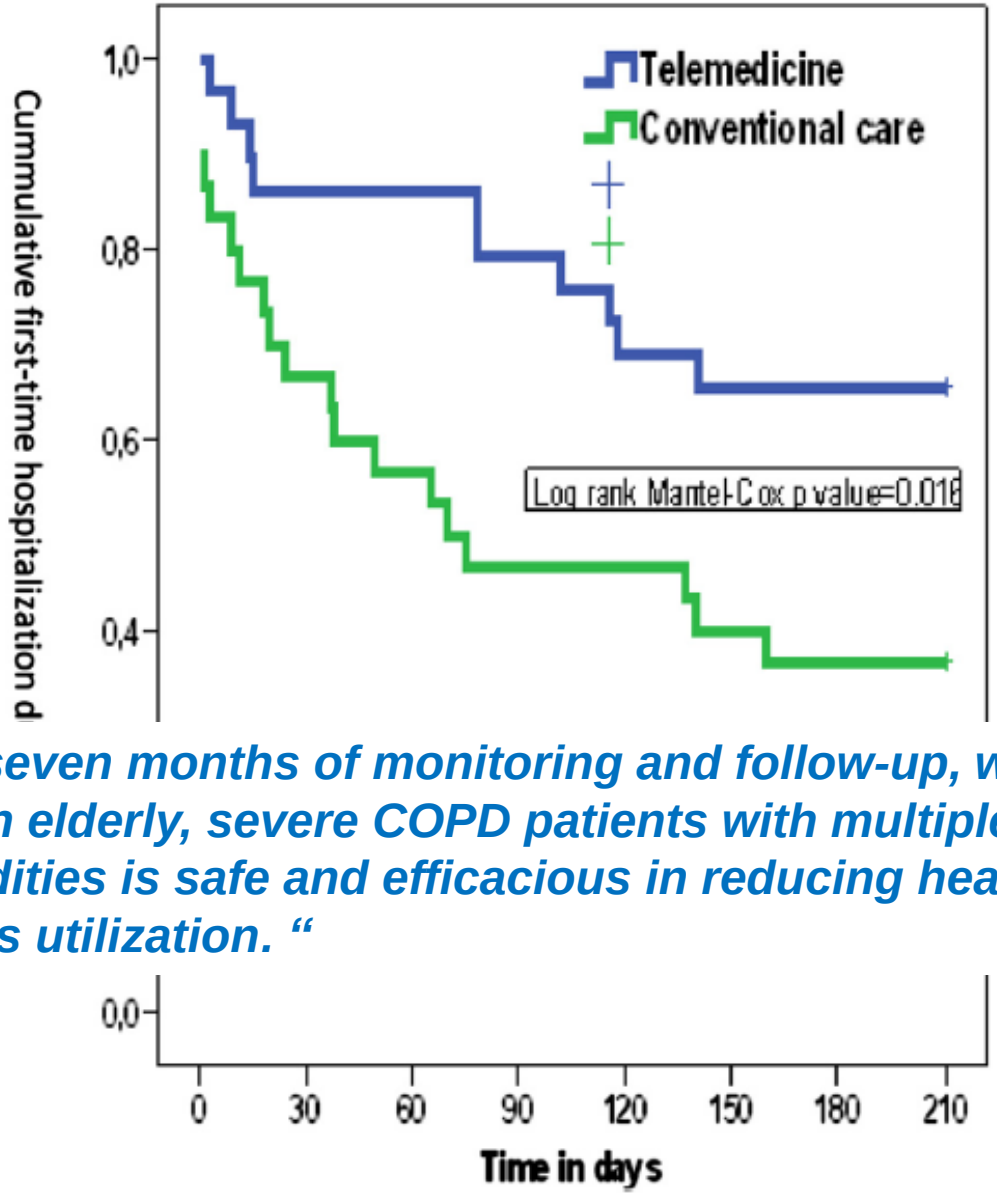
Segrelles G, et al. Respir Med 2014.

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.



… After seven months of monitoring and follow-up, we conclude that HT in elderly, severe COPD patients with multiple comorbidities is safe and efficacious in reducing healthcare resources utilization. "

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

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Efficacy and costs of telehealth for the management of COPD: the PROMETE II trial

Julio Ancochea[1], Francisco García-Río[2,3], Emma Vázquez-Espinosa[1], Ascensión Hernando-Sanz[4], Luis López-Yepes[4], Raúl Galera-Martínez[2,3], Germán Peces-Barba[3,5], Maria Teresa Pérez-Warnisher[3,5], Gonzalo Segrelles-Calvo[6], Celia Zamarro[6], Pablo González-Ponce[7], M. Inmaculata Ramos[8], Jose Ignacio Conforto[8], Syed Jafri[9] and Joan B. Soriano[1,10]

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ClinicalTrials.gov Identifier: NCT02499068

Ancochea J, et al. Eur Respir J 2018 (in press March 29).

Criteris d'Inclusió / Exclusió

Criteris d'Inclusió

- Tenir més de 50 anys i menys de 90 anys.
- Ser diagnosticat amb MPOC d'acord amb els criteris de GesEPOC, amb limitació de flux d'aire **FEV_1 <50%** del nivell teòric.
- Teniu un **"fenotip exacerbador"** definit segons els criteris de la guia GesEPOC: un pacient amb MPOC que té dues o més exacerbacions moderades o greus per any. Aquestes exacerbacions han de ser separades almenys 4 setmanes després de finalitzar el tractament per a l'exacerbació prèvia o 6 setmanes des de l'inici de l'exacerbació anterior en cas de no rebre tractament, per diferenciar el nou esdeveniment d'un fracàs terapèutic anterior.
- Estar en una **situació d'estabilitat clínica**, definida com 6 setmanes sense símptomes clínics des de l'última exacerbació de la MPOC.
- En **oxigenoteràpia crònica al domicili**.

Criteris d’Exclusió

- Tenir una esperança de vida inferior a un any.
- Disfunció cardíaca terminal (classe funcional NYHA III-IV).
- Insuficiència renal avançada (aclariment de creatinina <30%) o en un programa de diàlisi.
- Cirrosi hepàtica o en un programa de trasplantament de fetge.
- Atenció domiciliària pal·liativa.

Disseny de l'estudi

Inclusion criteria:
COPD III – IV, LTOT,
moderate exacerbation
previous year

Aim to randomize (n=240)

Home Telemonitoring HTM (n=120)

Routine Clinical Practice (RCP n=120)

Clinic visit at Month 0

HTM group took daily measurements
- **Pulse oximeter**
- **Blood pressure**
- **Respiratory rate & LTOT usage (Visionox®)**
- **Spirometry**

Remote Patient Mgmt

Clinic visits when needed

Clinic visit at Month 3

Clinic visit at Month 6

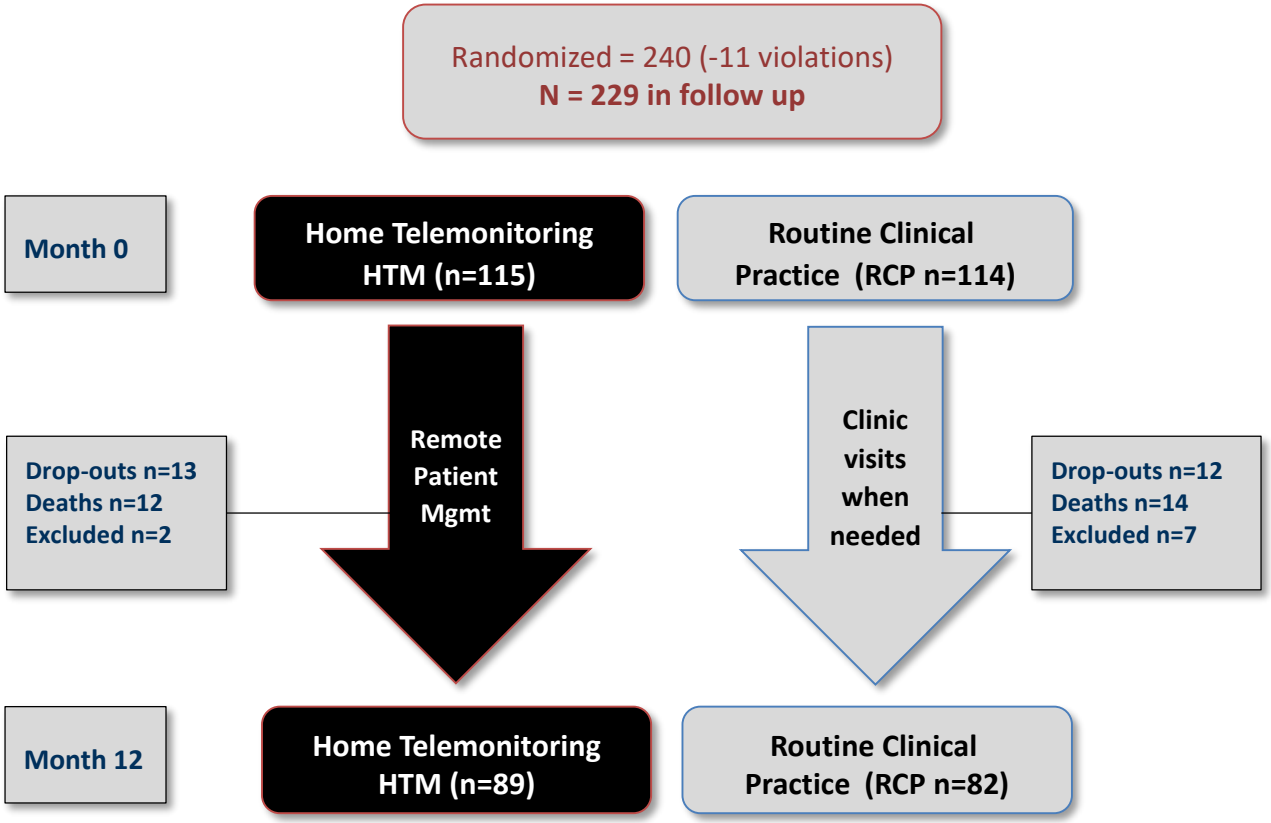
Clinic visit at Month 9

HTM Close out

RCP Close out

Clinic visit at Month 12

Diagrama de fluxe CONSORT



Característiques basals

		RCP* (N=114)	HTM (N=115)	p-value
Male, n (%)		94 (82.5)	90 (78.3)	0.424
Age (years), mean ± SD		71.3 ± 8.94	71.5 ± 7.97	0.845
Education level. n (%)	Illiterate	9 (7.9)	19 (16.5)	0.185
	Primary	58 (50.9)	47 (40.9)	
	Secondary	30 (26.3)	30 (26.1)	
	University	17 (14.9)	19 (16.5)	
Employment status, n (%)	Active	---	---	---
	Retired			
	Disabled/unable			
With caretaker, n (%)		79 (69.3)	88 (76.5)	0.219
Dyspnea mMRC, n (%)	II	28 (24.6)	35 (30.4)	0.549
	III	56 (49.1)	51 (44.3)	
	IV	19 (16.7)	22 (19.1)	
COPD hospitalizations in the last year, mean ± SD		2.0 ± 1.2	2.0 ± 1.31	0.8940

Característiques basals (2)

		RCP* (N=114)	HTM* (n=115)	p-value
COPD hospitalizations last year, n (%)	Total	75 (65.8)	86 (74.8)	0.136
Home status, n (%)	Alone	---	---	0.783
	With partner	75 (65.8)	84 (73.0)	
	With other relatives	15 (13.2)	10 (8.7)	
	With caretaker	---	---	
Barthel Index, mean ± SD		94.6 ± 10.84	95.0 ± 9.86	0.7730
Charlson Comorbidity Index, mean ± SD		2.4 ± 1.51	2.4 ± 1.53	0.7090
Cote Index, mean ± SD		1.6 ± 2.16	1.7 ± 2.08	0.7010
Respiratory medications, n(%)	LAMA + LABA + ICCI	---	---	---
	LAMA	108 (94.7)	107 (93.0)	0.593
	LABA	110 (96.5)	115 (100.0)	**0.043**
	ICCI	106 (93.0)	110 (95.7)	0.383
	PDE4 inhibitors	16 (14.0)	21 (18.3)	0.385
	Mucolythics	---	---	---
	Theophyllines	16 (14.0)	17 (14.8)	0.872
	Oral steroids	4 (3.5)	5 (4.3)	0.744
Lung function, mean ± SD	FEV1 post-BD	32.24 ± 8.798**	34.25 ± 9.085**	0.0900
Home oxygen	hours/day	18.8 ± 3.54	18.9 ± 3.69	0.7680
	flow in L/minute	1.98 ± 0.500	2.01 ± 0.628	0.6840

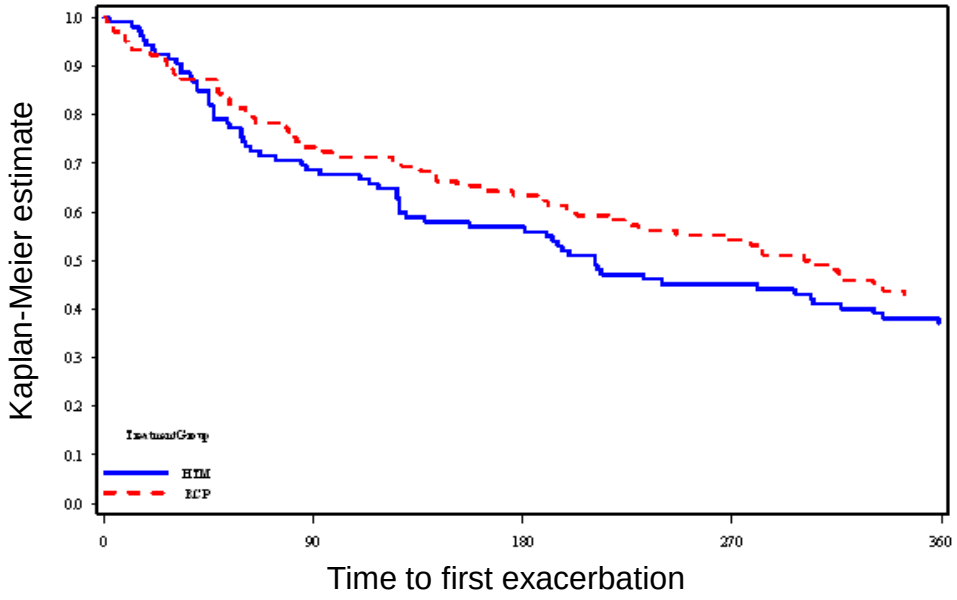
Característiques basals (i 3)

		RCP* (N=114)	HTM* (n=115)	p-value
Quality of life and other assessments	CAT	18.6 ± 6.45	18.6 ± 6.76	0.9950
	euroQOl	0.78 ± 0.179	0.79 ± 0.175	0.5330
	Goldberg anxiety	1.8 ± 2.55	1.5 ± 2.27	0.4180
	Goldberg depression	2.9 ± 2.47	2.5 ± 2.45	0.2210

L'objectiu primari no s'ha aconseguit

The number of patients experiencing hospitalisations or ER visits was not significantly different between the groups different

Per Protocol Population	HTM N = 109	RCP N = 106	p-value
# Patients with at least 1 ER visit	65 (59.6%)	59(55.7%)	0.556
# Patients with at least 1 ER visit leading to hospitalization	54 (49.5%)	47 (44.3%)	0.445



No matter how the endpoints were expressed, there was no significant difference between the two groups

Tampoc es va aconseguir la majoria d'Objectius Secundaris

Duration of stay in hospital/ICU did appear to be shorter in the HTM group

Per Protocol Population	HTM N = 109	RCP N = 106	p-value
Mean duration of hospitalisation in days	18.9 ± 16.40	22.3 ± 19.69	0.3490
Number of ICU Admissions	3 (2.8%)	3 (2.8%)	0.972
Number of days in ICU	6.0 ± 4.58	13.3 ± 11.6	0.349
Presence of non-invasive ventilation	15 (13.8%)	16 (15.1)	0.781
Presence of orotracheal ventilation	2 (1.8%)	3 (2.8%)	0.628
Anxiety level at 12 months	0.9 ± 1.9	1.0 ± 2.4	0.911
Depression at 12 months	1.8 ± 2.21	2.2 ± 2.64	0.316
Daily activity at 12 months	95.3± 8.41	96.3 ± 9.13	0.46
COPD symptoms at 12 months	21.5± 5.62	21.4± 6.07	0.855

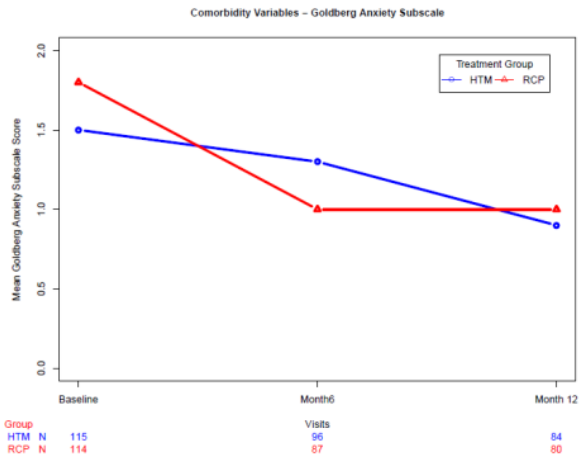
No significance

Two parameters stuck out:

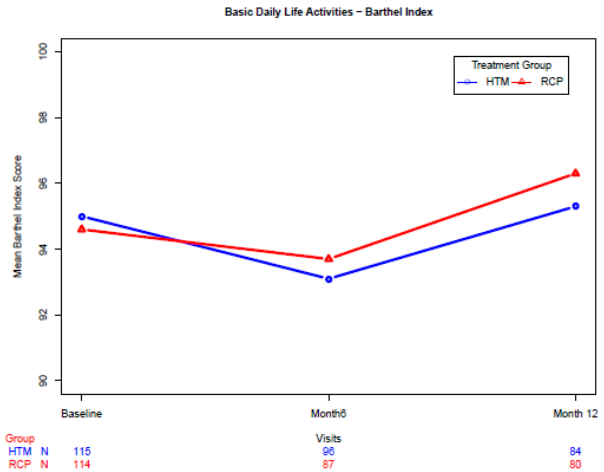
- **Mean duration of hospitalization in days was lower by approx 4 days**
- **Mean ICU stay was about 7 days less in an ICU**
- **Neither difference in parameters is statistically significantly different but suggests positive effect of telehealth.**

Qualitat de Vida i Símtomes

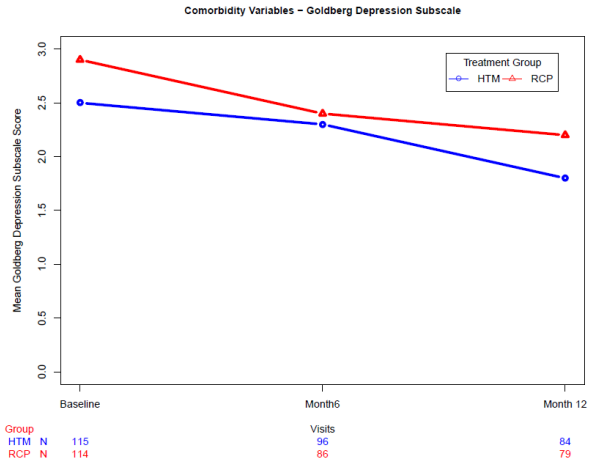
Goldberg Anxiety Index



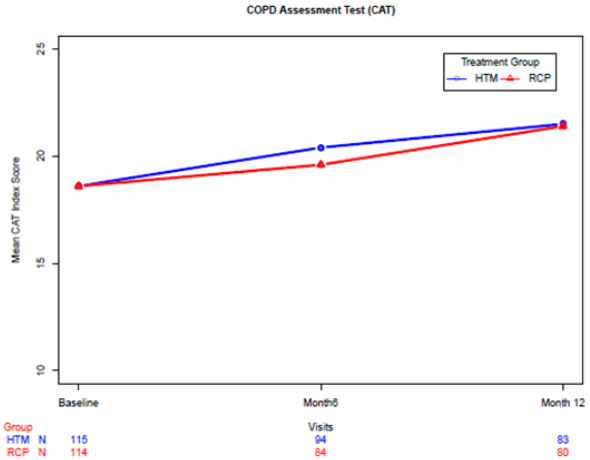
Barthel Index Daily Activity



Goldberg Depression Index

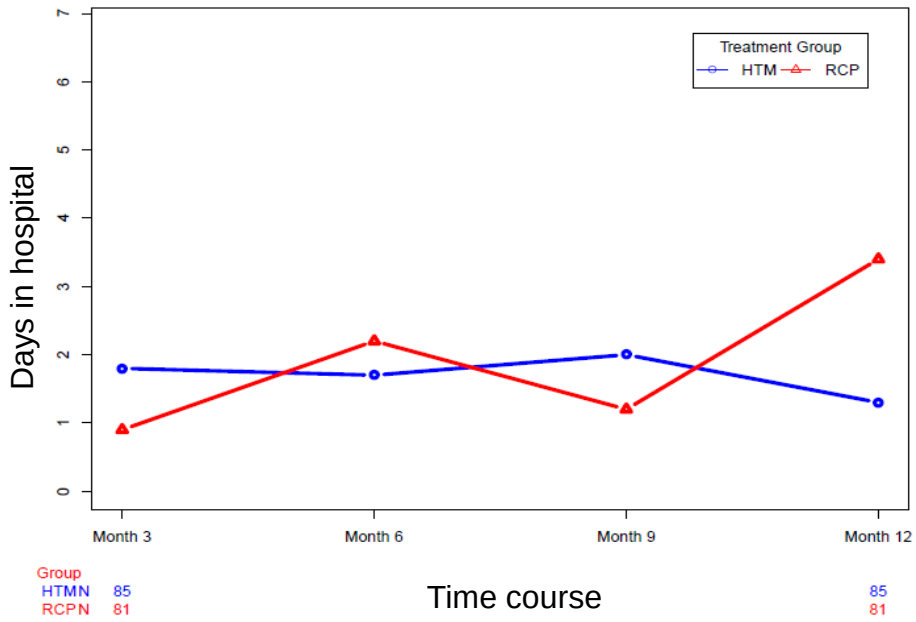


CAT Score COPD Symptoms



La durada de les hospitalitzacions en pacients en TM va ser significativament inferior durant els darrers tres mesos

Only patients who survived 12 months	HTM N = 85	RCP N = 81	p-value
Number of days in hospital per patient (month 9 to 12)	1.3	3.4	0.038*



- The number of days in hospital per HTM patient was less than half that of patients in the RCP group

La TM va ser ben tolerada. Les puntuacions d'adherència i satisfacció van ser molt elevades

- Patients remained compliant on the program despite being asked to use 3 different devices every day.
- Compliance was generally very high with only episodic non adherence - only 28.4% of patients missed one or more measurements due to a lack of motivation.
- They were highly satisfied with the telehealth intervention (satisfaction questionnaire at the end of the study).
- The clinicians were also highly satisfied with the telemonitoring solution.

Evolució del programa de TeleMedicina PROMETE - similituds i diferències

	Telehealth Pilot Start 2011	Promete I Start 2012	Promete II Start 2014
Design	Proof of concept - RCT	Pilot -RCT	RCT
# patients	50	60	240
Follow-up	3 months	7 months	12 months
Set-up	Single-center study	Multi-center study	Multi-center study
Outcome	Reduction of ER visits by 55%	60% reduction of hospitalization 65% reduction of ER visits Extended time to first hospitalization by 55%	Signifcant reduction in respiratory related mortality
Points of differentiation	Small trial Run in community centers, with close communication to community nurses Patients were “hand picked”	Small trial Run with community service and home visits by pulmonologists! Patients still handpicked	HTM intervention was expedited referral to hospital pulmonologist via ER Out of hours managed as per ER patient

While the objectives of the studies were similar, the study design and protocol evolved considerably and these may have contributed the results of the study

PROMETE II – Conclusions

Efficacy and costs of telehealth for the management of COPD: the PROMETE II trial

Julio Ancochea[1], Francisco García-Río[2,3], Emma Vázquez-Espinosa[1], Ascensión Hernando-Sanz[4], Luis López-Yepes[4], Raúl Galera-Martínez[2,3], Germán Peces-Barba[3,5], Maria Teresa Pérez-Warnisher[3,5], Gonzalo Segrelles-Calvo[6], Celia Zamarro[6], Pablo González-Ponce[7], M. Inmaculata Ramos[8], Jose Ignacio Conforto[8], Syed Jafri[9] and Joan B. Soriano[1,10]

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*In countries like **Spain**, where a well-developed health system ensures COPD patients have rapid, effective access to appropriate care, **it may well prove challenging to demonstrate that telehealth further improves outcomes**.*

*To conclude, **remote patient management** using this monitoring protocol **in PROMETE II did not reduce the COPD-related ER visits or hospital admissions compared to RCP within 12 months**.*

Ancochea J, et al. Eur Respir J 2018 (in press March 29).

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