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ORIGINAL RESEARCH

Does Home Telemonitoring after Pulmonary Rehabilitation Reduce Healthcare Use in Optimized COPD? A Pilot Randomized Trial

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ABSTRACT

Aim. **To see if home telemonitors reduce healthcare use in those with optimized chronic obstructive pulmonary disease (COPD).** ***Methods.*** **We randomized 40 stable patients with moderate to severe COPD, who had completed at least 12 sessions of outpatient pulmonary rehabilitation (PR), to receive standard care (Controls) for 52 weeks or standard care plus Docobo HealthHUB monitors at home for 26 weeks followed by 26 weeks standard care (Tm Group). During the monitoring period, the Tm Group completed symptoms and physical observations twice daily which were stored and then uploaded at 2 am through a freephone landline. Nurses could access the data through a secure web site and received alerting e-mails if certain combinations of data occurred.** ***Results.*** **There were fewer primary care contacts for chest problems ($p < 0.03$) in the Tm group, but no differences between the groups in emergency room visits, hospital admissions, days in hospital or contacts to the specialist COPD community nurse team, during the monitoring period. After the monitors were removed, there were no differences between the groups for any of the health care contacts ($p > 0.20$ throughout).** ***Conclusion.*** **In stable, optimized COPD patients who have already completed PR, telemonitoring in addition to best care, reduces primary care chest contacts but not hospital or specialist team utilization.**

INTRODUCTION

Despite better understanding of disease mechanisms and treatment standardization, (1) Chronic Obstructive Pulmonary Disease (COPD) remains a leading cause of death and morbidity worldwide (1, 2) with patients remaining extensive healthcare users (3). Integrated case management has improved outcomes in COPD (4, 5) and information technologies have helped integrated case management reduce hospitalisations for COPD (6). Telemonitoring has also been used to reduce admissions and overall costs in the home management of chronic respiratory failure (7, 8).

Home monitoring by a specialist team may help patients feel more secure and avoid unnecessary doctor visits if they know their oxygen levels and heart rate are stable and clinical status is being checked. As worsening symptoms are usually present for days before patients with COPD are admitted to hospital with an exacerbation, (9) there could be a window of opportunity for remote monitoring to detect changes sooner and allow earlier intervention to ameliorate exacerbations which themselves

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worsen outcome in COPD (10). Alternatively, such an active monitoring process may make patients feel there is an increased sense of control from clinical staff, cause inconvenience or even increase health care contacts if they become aware of (asymptomatic) changes in their pulse oxygenations, temperature or heart rate or have a daily reminder of their illness when completing uploads.

The Better Breathing Project (11) is a European Union-funded market validation project under the eTEN program, with ten partners from five European countries aiming to reconfigure the normal care pathway for COPD by implementing integrated supported home-hospital and rehabilitation services. As one of the field-trial sites for Better Breathing, we wanted to see if telemonitoring technologies placed in the home are feasible and useful. Our aim was to see if telemonitoring in stable, and optimized COPD patients affects their health care utilization.

MATERIALS AND METHODS

This was a randomized trial for 6 months (intervention), followed by a 6-month passive (observational) period. Loco-regional ethical approval was obtained (Ref: 07/WMW01/53) and the trial registered (ISRCTN 41424840).

Participants

Ninety-nine still-living subjects were identified from our PR database. The exclusion criteria are shown in Figure 1 and we approached remaining patients until we obtained 40 patients with the following inclusion criteria: a primary diagnosis of moderate to severe COPD, according to a standard definition and prescribed optimal medication (1) and who had completed at least 12 of 18 sessions of our PR program.

The program includes outpatient multidisciplinary input from occupational therapists, physiotherapists, dietetics staff, physicians, specialist respiratory nurses, social workers and a smoking cessation counselor. This PR program is closely based on a model with a strong evidence base for a range of beneficial clinical outcomes (12). They were enrolled in the present study a median of 8 months after completing PR (range 2–19 months). To help ensure standardization, all patients also had to be known to our community-based Chronic Disease Management Team (CDMT). This local service consists of 2 specialist nurses, a respiratory physiotherapist and nurse manager.

If contacted by patients, a member of the CDMT would visit them at home usually within one working day for clinical assessment, pulse oximetry, to take sputum cultures, and recommend treatment escalations (e.g., home steroids or home antibiotics). The CDMT liased with primary care doctors and had weekly contacts with the hospital-based respiratory consultants (specialists) to discuss any problems. Doctors wrote prescriptions on CDMT advice and the CDMT could take these medications directly to the patient's homes.

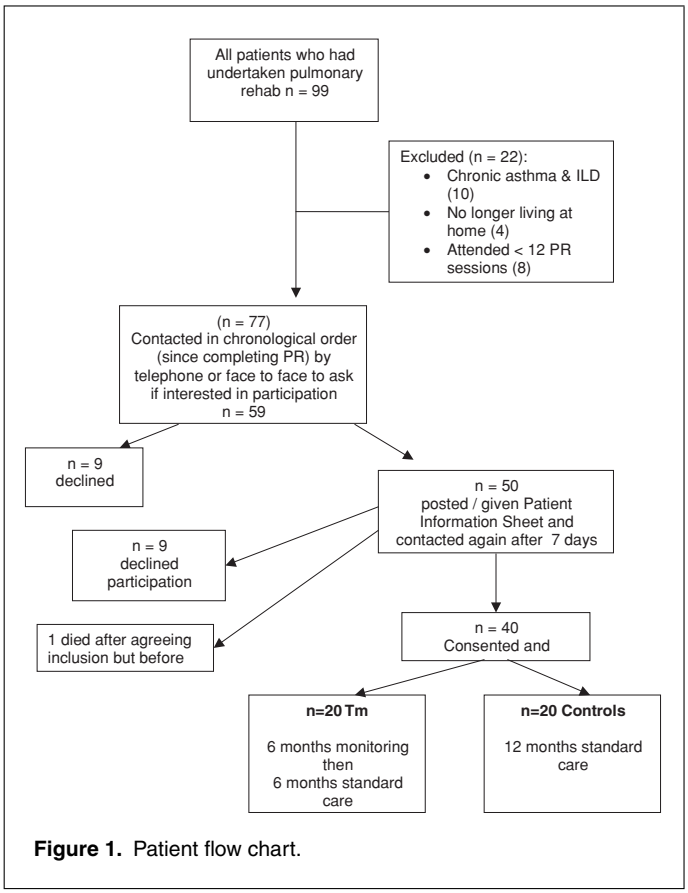

Figure 1. Patient flow chart.

Procedure

After consent, subjects completed baseline demographic questions. Occupation was used to estimate socioeconomic grouping according to established criteria (13). Subjects were randomized using the Statistical Package for the Social Sciences (SPSS) (Chicago, Illinois), version 12.0, random number generator, into 2 groups and allocated using sealed opaque envelopes. Twenty subjects received standard care, including continued CDMT and hospital / primary care support at the discretion of their clinical teams for 12 months (Controls). The 20 subjects in the intervention arm (Tm Group) received standard care plus a handheld telemonitor – the Docobo® Health HUB™ (Docobo Ltd, Bookham, UK), (HUB) for 26 weeks. Users do not need Internet connections as the HUB integrates through a freephone landline with the doc@HOME care management system (Docobo Ltd, Bookham, UK), a generic web-based telemonitoring system that can be pre-configured to specific needs. The CDMT received two training sessions each lasting approximately 1 hour from the HUB manufacturers before the project started.

A generic community, telecare team (separate from the clinical staff), installed the monitors and trained subjects in their own homes in January 2008. Each patient-training session took less than 1 hour. The installation team dealt with any technical problems and visited only 2 patients over 6 months, when the signal was lost. Twice daily, patients completed button screen

answers to the following clinical questions, regarding their chest over the preceding day or night.

Completed from 0600 until 12.00

1. **Did you awake during the night due to breathlessness?** Yes or No
2. **How is your wheeze today?** Much worse than usual, worse than usual, same as usual, none
3. **How is your cough today?** Much worse than usual, worse than usual, same as usual, none
4. **How able are you to do your normal daily activities (washing, dressing etc)?** Much worse than usual, worse than usual, same as usual, none
5. **Please insert your finger into the oxygen sensor**. Was this finger oxygen taken on room air, your normal oxygen or extra oxygen?
6. **Please take your temperature and enter the value using the number pad**.

Completed from 1201 until 23.00

1. **How is your breathless today?** Much worse than usual, worse than usual, same as usual, none
2. **How is your wheeze today?** Much worse than usual, worse than usual, same as usual, none
3. **Have you produced sputum today?** Much worse than usual, worse than usual, same as usual, none
4. **How often are you using your reliever medications?** Much more than usual, more than usual, same as usual, none
5. **Please insert your finger into the oxygen sensor.** Was this finger oxygen taken on room air, your normal oxygen or extra oxygen?

They recorded their oral temperatures, using a manual thermometer (model FT04-1, Beurer, Ulm, Germany) and typed the result into the HUB. They placed their index finger into a pulse oximeter probe (part no. 3831-001, Nonin Inc, Minnesota, USA) connected to the HUB. The HUBs were pre-configured for the pulse oximeters and although all equipment was British safety approved, hospital technicians checked it prior to home installation.

Data were not accessed 'live' by the CDMT but were transferred in a 'store and forward model' to the central server at 2 am daily. Health professionals (primarily the CDMT but also a respiratory consultant and a specialist hospital nurse) could access the server, via a secure Internet connection at any time, or if the patient phoned with worsening symptoms. The final number of individual data points completed on the central server was divided by the total number of data points possible (max 13 data points per person per day over the 6 months) to estimate HUB usage. If there were 24 hours without data upload to the central server, a member of the CDMT phoned the patient.

In addition to regular reviews of the results (daily, Monday-Friday) on the doc@home web site, an alerting e-mail was sent to the CDMT and hospital respiratory nurses if there were a combination of *2 or more* of any of the following recordings on a single session upload:

a) Any question scoring 'much worse than usual'
b) Pulse rate greater than 120 beats per minute
c) Oxygen saturations less than 88% (on their usual air/oxygen)
d) Temperature greater than 38.5 degrees centigrade

The CDMT telephoned the patient on receipt of this alerting e-mail during working hours (Mondays-Fridays, 9 am–5 pm). After 6 months the telemonitors were removed from the Tm group to see if withdrawal would lead to increased healthcare usage possibly after patients become accustomed to their use. The first 26 weeks of the study was the active intervention, then the monitors were removed and this was followed by 26 weeks of (passive) observation in both groups.

Both patient groups were instructed to seek help from their primary care or emergency doctor if they felt urgent treatment was needed and it was emphasized that the HUB was *not* a replacement for but was to work in conjunction *with* standard support.

All patients were treated according to the clinical discretion of their primary care doctors, specialist nurses and hospital specialists. Apart from the CDMT, these other health care providers were all unaware of the Telemedicine allocation, unless the patient told them during the consultation. Hospital, CDMT and primary care contacts were collected from medical records and hospital computers and primary care data were collected from their computerized databases corroborated by a researcher (blinded to group allocation) phoning each primary care practice monthly during the monitoring periods.

A senior respiratory clinician (separate from the research team) independently reviewed the medical records of any deaths or withdrawals to determine if telemonitoring contributed towards adverse consequences e.g., unusual delays in treatment. At the end of whole 12 months, those allocated to the Tm, who were still living, were posted a simple questionnaire asking if they thought the Tm was helpful or inconvenient. A committee from the Better Breathing Project performed a site inspection after 6 weeks and received progress reports at 26 weeks and completion.

Statistics

We used SPSS version 13.0. Following distribution plots (with Lilliefors correction) parametric data were compared with *t*-tests and other data evaluated with either Mann–Whitney or Wilcoxon signed rank test. Categorical data were compared with Chi Square. Throughout, $p < 0.05$ was deemed significant. Based on the assumption that our patients with severe COPD who we had targeted with the CDMT service, previously had a mean of 1.2 admissions per year (standard deviation 0.9) and we could reduce this rate by two thirds, to 0.4 admissions per year with Tm — we estimated we would need around 22 patients per group to show a significant difference, with a Type 1 (alpha) error rate 0.05 and power 0.80. We had funding for 20 Tm machines for this pilot.

Primary Outcomes

To test the null hypothesis that there is no difference in the number of hospital admissions for COPD, during the 6-month monitoring period between those receiving Tm versus Controls.

Secondary outcomes

- To test the null hypotheses that there is no difference in primary care contacts (for chest and non-chest symptoms), emergency room attendances, length of hospital admissions, CDMT phone calls and CDMT visits during the 6 month monitoring period between those receiving Tm versus Controls.
- To test the null hypotheses that there is no difference in primary care contacts (for chest and non-chest symptoms), emergency room (ER) attendances, length of hospital admissions, CDMT phone calls and CDMT visits *within* the Tm Group and Controls between their 6 month active monitoring period and the later 6-month (passive) observation period.
- To record Tm usage / concordance during the 6-month monitoring period.

RESULTS

Table 1 describes the two study groups immediately prior to the telemonitoring period: Data are presented as means (standard deviations) or median (interquartile ranges).

Table 1. Comparison of both groups at baseline

Variable (Mean ± standard deviation)	Controls ($n = 20$)	Telemedicine ($n = 20$)	*p*-value
Male	50%	50%	—
Current smokers	5%	5%	—
Mean age (years)	70 ± 10	67 ± 9	0.34
Socioeconomic Group 1 or 2	25%	25%	—
Proportion living alone	30%	20%	0.72
Mean score computer confidence	1.8 ± 1.5	1.4 ± 0.9	0.39
Regular Internet users	20%	15%	0.68
Hospital admissions for COPD preceding 12 months*	0(0,1.0)	0(0,0.8)	0.40
FEV_1 predicted	40 ± 15%	38 ± 16%	0.73
BMI (kg/m^2)	29.0 ± 5.7	25.8 ± 4.1	0.052
Oxygen Saturations (on air)	89 ± 9%	93 ± 3%	0.36
Known co-morbidity	88%	92%	0.73
PR sessions completed	14.8 ± 2.5	15.2 ± 2.0	0.53
Months since PR	7.4 ± 5.2	12.1 ± 6.6	0.02
Anxiety (HAD)	6.3 ± 3.5	5.6 ± 3.5	0.56
Depression (HAD)	5.9 ± 2.8	6.3 ± 3.5	0.70
SGRQ (total)	59.9 ± 15.2	60.7 ± 15.3	0.83
EQ-5D (total)	0.51 ± 0.27	0.54 ± 0.27	0.60
MRC dyspnoea score	3.4 ± 0.8	4.0 ± 0.7	0.01

*Median (interquartile range).

Table 2. Other health car utilization during the first 6 months (telemonitoring period)

Variable	Controls	Tm Group	Z score	*p*-value
ER attendances for COPD	0 (0, 1.0)	0 (0, 0.8)	−1.40	0.24
Days in hospital	0 (0, 1.5)	0 (0, 0)	−0.64	0.66
Primary Care Contacts (chest)	4 (2, 6)	2 (1, 3.8)	−2.18	0.03
Primary Care Contacts (non-chest)	1 (1, 3)	1 (0, 2)	−1.26	0.23
CDMT phone-calls	2 (0, 10.5)	5 (0, 16.5)	−1.06	0.31
CDMT home-visits	0 (0, 3)	1.5 (0, 4)	−0.86	0.44

Data presented as medians (IQR).

Primary clinical outcome

There were a total of 7 hospital admissions in the Controls and 4 hospital admissions in the Tm Group during the telemonitoring period. The Controls had a median (IQR) of 0 (0, 0.75) and mean 0.35 hospital admissions for COPD, the Tm Group had a median of 0 (0,0) and mean 0.20 admissions, during the monitoring period ($Z = -1.397$, $p = 0.16$).

Secondary clinical outcomes

Table 2 lists the secondary outcomes comparing both groups during the first 6 months tele-monitoring period. Table 3 lists the secondary outcomes comparing both groups in the second 6 months, during the passive intervention period (i.e., after the monitors were removed form the intervention group).

Looking at each group individually over time, there were no changes in ER attendances, hospital admissions, days in hospital, CDMT contacts nor primary care contacts *within* the Controls or particularly the Tm Group when they had the monitors and when the monitors were removed ($p > 0.12$ throughout). The only exception was a significant reduction in CDMT phone-calls from a median of 5 phone calls during telemonitoring to

Table 3. Health care utilization during the second 6 months (passive monitoring period)

Variable	Controls	Tm Group (Machines removed)	Z score	*p*-value
COPD admissions	0 (0, 1.0)	0 (0, 1.0)	−.78	0.54
ER attendances for COPD	0 (1.0, 1.0)	0 (0, 1.5)	−1.23	0.26
Days in hospital	0 (0, 3.8)	0 (0, 2.0)	−0.59	0.62
Primary Care Contacts (chest)	3 (2.0, 4.5)	3 (2.0, .3.0)	−0.70	0.51
Primary Care Contacts (non-chest)	3 (1.5, 5.0)	2 (0, 3.0)	−1.22	0.23
CDMT phone-calls	1 (0, 8.5)	3 (0, 9.8)	−0.55	0.60
CDMT home-visits	0 (0, 4.8)	0.5 (0, 4.8)	−0.17	0.89

Data presented as medians (IQR).

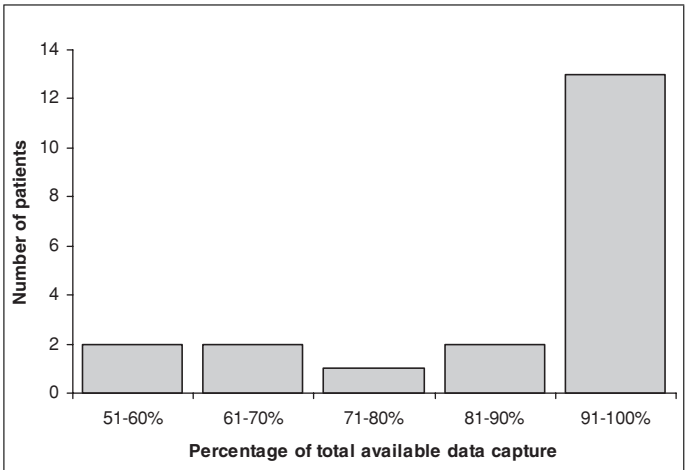

Figure 2. Number of Tm patients by HUB monitor usage.

3 phone calls per patient after the monitors were removed ($p = 0.045$).

Secondary outcomes — telemonitors usage:

On an intention to monitor analysis, the patients uploaded a median 97% of total available data during the first 6 months (monitoring period). Figure 2 shows the distribution of data points uploaded as a percentage of total available data, during the monitoring period in the Tm Group. None of the 17 Tm patients, who completed the study, reported difficulties using the monitors. 15 from 17 found it 'helpful' or 'very helpful'.

Safety

There were 2 deaths in the Tm Group – one man died after 15 days in hospital of multi-organ failure following a gastrointestinal haemorrhage; one lady was withdrawn when she went into a nursing home, where she died 2 months later of 'old age.' Neither had used their monitors for at least 15 days before their death and neither death (nor preceding deterioration) was attributed to the telemonitors. There was 1 other withdrawal in the Tm Group after 3 months, because the patient found it too cumbersome, when she wanted to travel. All 3 had been good users prior to withdrawing and their last recorded symptoms, heart rate and oximetry showed no worrying trend. We had no user satisfaction ratings on these 3 subjects.

DISCUSSION

For stable COPD patients, who have completed PR and who are actively engaged with and supported by a specialist CDMT team, continuous home telemonitoring and alerts to provide reassurance and avoid clinical worsening, is associated with reduced contacts to the primary care physicians for chest /respiratory problems, but we found no statistically significant differences in hospital admissions, or utilization of hospital or specialist community team resources. In particular, we cannot reject the null hypothesis that there is no difference in the number of hospital admissions over a 6-month period.

The reduction in primary care contacts during telemonitoring is biologically feasible and this was not at the expense of increased CDMT or hospital usage. The difference of 2–3 primary care visits per 6 months may still be clinically important and should be included in any cost-effectiveness modeling. The reduction in phone calls in the Tm group when the monitors were removed is interesting; this may be because patient confidence has built up or because the CDMT were not checking up on occasional e-mail alerts. At least it can be argued that withdrawal of Tm is not associated with any surge in health care usage as patients feel less secure following the HUB's removal.

Although we found no statistically significant reduction in hospital admissions it could be argued that our 'usual clinical support' is above standard and doesn't leave much room for the telemonitor to help. Nevertheless, the Tm group did better with 4 hospitalizations compared to 7 in the control group and this approximate halving of admissions is actually similar to other studies of telemedicine in COPD (14, 15). Our primary event rate (admissions) was much lower than expected.

If we were to plan a repeat study of such an optimized population who had completed PR and who already have ongoing CDMT support, with a 'mean' admission rate 0.35 admissions per patient per 6 months and achieve an estimated mean of 0.20 admissions per 6 months in the Tm group, we would need to study around 138 patients in each arm, to find a statistically significant difference in hospital admissions for COPD. These power calculations assume the admission data is parametric (which it usually isn't), an alpha level of 0.05 and power 0.80, without Fisher's correction (or 151 patients per group if we apply a corrected chi-square). Such a pivotal study of around 150 patients per arm seems feasible compared with other studies of medications designed to show reductions in hospital admissions in COPD.

Other studies have applied different types of telemedicine in COPD. Mair et al. reported technical difficulties (16) and patient reticence (17) in implementing a real-time home video monitoring at set times for COPD patients so we chose simpler equipment, offered telemedicine *in addition to* rather than *instead of* home nurse visits; as we did not require real time monitoring, our patients had greater time flexibility in inputting data. Finally, we recruited from patients well known to the specialist teams, rather than from emergency departments (17) where patient engagement may be lower. For these reasons, our recruitment and installation was complete within 4 weeks of receiving ethical approval. Our 18 'refusers' had similar sociodemographics and QoL scores post PR, as the participants (details omitted). We hoped that continuous monitoring might ameliorate exacerbations or reduce unnecessary visits to or by caregivers. The docobo HUB is compact, simple to use and has been used successfully in conditions other than COPD (18–20). A small study from Portugal using the docobo HUB in remote home monitoring for COPD, reported reductions in symptoms and demand activity on the hospital. This was a conference abstract reported in a magazine and more details are awaited. Dale

et al. reported the effects of a different home monitoring system (recording pulse, saturations and body weight) for patients with COPD over a 3-month period (21).

This seemed to avert some of the predicted increase in hospital admissions but it is difficult to tease out the effects of the monitoring from the protocol's additional daily telephone calls that are not feasible in most settings. Vontetsianos et al. used telemedicine monitoring via a visiting nurse in 18 'well-motivated' patients with advanced COPD who had previous admissions. They reported a decrease in hospitalizations, emergency visits and use of health services but the patient's disease knowledge and self-management also improved (15).

Again, it is difficult to see what additional benefit the real-time video link offered on its' own as it was only set up during the nurse home visits. Maiolo *et al* studied 30 patients with various respiratory illnesses, on long-term oxygen. 23 completed the study and they found that twice weekly home monitoring of heart rate and arterial oxygen saturations was associated with 50% reduction in hospital admissions, 56% reduction in acute exacerbations and overall cost savings of 17% (14).

Importantly, none of these studies were randomized control trials but a 'before and after' trial design, akin to one of our secondary endpoints. Such studies could be influenced by other changes in clinical and social care and treatment of co-morbidity.

We emphasize that our system was not 'real' time, but a store and forward' type of monitoring with usually a 12–24-hour delay between patient upload and the data being accessed by the CDMT. Equipment offering *immediate* interaction with a nurse may have different effects on health care utilization. However, we do not believe this is the reason for our lack of benefit because most COPD exacerbations develop over several days rather than minutes or hours (9).

We were not using telemedicine to deliver a home exercise program or other intervention to improve health outcomes. Such an active process of educational approach, rehabilitative prescription and life style change is difficult to deliver effectively through a simple device alone, but a change in at least quality of life and fitness leading to reduced health care utilization may occur if this was combined with a continuous educational reinforcement by nurses.

Did we choose the most appropriate target population? It was a pre-requisite of the Better Breathing Study that participants had completed PR, which itself can influence study selection, enrollment, and outcome measures (22) so whether the results can be generalized to other patients remains a question. In addition, our home CDMT service is multifaceted and evidence-based (23). Hospital at home is recommended in national guidelines (24) and our local CDMT's creation has very recently been evaluated and itself associated with reduced COPD admissions, from a mean of 1.14 (median 1.0, IQR 0, 2.0) admissions, in the year preceding CDMT to a mean of 0.79 per patient (median 0.0, IQR 0, 1.0) in the year following. CDMT ($p < 0.005$) (25). It is therefore very likely that our participants were already optimized so that additional telemonitoring (or other treatments) may add little clinical benefit and we believe this is the main reason for our negative result. The relatively (and unexpectedly) persistent low number of healthcare contacts in both groups, especially hospital admissions, reflect the optimization and selection of our study population and the importance of applying a randomized trial rather than a 'before and after' that is more influenced by concurrent developments.

Strengths of our study include the randomized design with overall good matching for most confounders. However, we did not match on all baseline variables (as n = 20) and we did not have enough numbers to stratify the randomisation. The Tm group had lower BMI, besides longer time from PR and worse MRC and these could work against showing benefit in the Tm group results. Our subject demographics are typical of those with moderate-to-severe COPD, and although we included only those who agreed to and completed PR, our PR program is based on well-researched models.

Although many rural COPD services do not have access to PR it is recommended for people with chronic lung disease who remain symptomatic despite optimal medication in all guidelines. We are based in a non-teaching hospital unit serving a town and rural population so our findings can be generalized to both settings. Those collecting health care utilization data were unaware of group allocation and we used more than 1 measure of health contacts that all showed similar patterns. Our Tm technology was simple, readily deployed with minimum training and widely used hence providing excellent data capture in the monitoring period. We had 85–90% response rate of QoL questionnaires throughout the study, so lack of usage /engagement was not a reason for the negative result.

The main weakness of the study is its small size; we chose 40 patients mainly due to funding (machine) constraints but also because both staff and patients had never used home monitors before and there was no funding for additional personnel. We wanted to create a sustainable model in a real world setting and asking inexperienced staff to start monitoring daily data on up to 100 people in addition to their normal duties would not be successful. Based on certain assumptions, we hoped that 20 patients per group would be enough to show differences in hospital admissions as well as simultaneously establishing safety and feasibility. By having a small (pilot) study we cannot exclude the possibility especially of a Type 2 statistical error, i.e., of failing to reject the null hypothesis when a true difference really exists.

Certainly a reduction in admissions from 7 to 4 is encouraging and even avoiding one severe hospital acquired infection and prolonged stay on intensive care could still be clinically important. We have not performed a cost-effective analysis. There have been calls for better-designed studies of telemedicine, noting in particular the lack of randomized controlled trials (26). This is the first such study of telemedicine in the home monitoring of stable, optimized COPD patients who have all had PR. It is important because although it shows telemonitoring is safe and very feasible in this group, and despite being well used, it is not associated with significant changes in specialist healthcare utilization. To avoid the possibility of statistical errors, we believe that a 1:1 randomised controlled

trial of around 150 patients per group is needed to establish a good argument for Tm in optimized patients.

In summary, we believe that their primary care physicians, without telemonitoring, can probably follow up such a stable population. However, we do not want to throw the baby out with the bath water! It is important that future studies on telemonitoring in COPD also look more closely at other (less optimized) groups such as those with multiple hospital contacts, those unable to complete PR and those without community team support or use telemedicine to deliver an intervention such as PR. However, until adequately designed studies are performed, telemedicine may never become fully accepted by most clinicians or purchased by providers with increasingly limited resources.

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Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

REFERENCES

1. **Rabe KF, Hurd S, Anzueto A**, *et al.* Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: GOLD executive summary. Am J Respir Crit Care Med 2007; 176:532–555.
2. **Murray CJ, Lopez AD**. Mortality by cause for eight regions of the world: Global Burden of Disease Study. Lancet 1997; 349:1269–1276.
3. **Menzin J, Boulanger L, Marton J**, *et al.* The economic burden of chronic obstructive pulmonary disease (COPD) in a U.S. Medicare population. Respir Med 2008; 102:1248–1256.
4. **Chavannes NH, Grijsen M, Van Den Akker M**, *et al.* Integrated disease management improves one-year quality of life in primary care COPD patients: a controlled clinical trial. Prim Care Respir J 2009.
5. **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; 33:1031–1038.
6. **Casas A, Troosters T, Garcia-Aymerich J**, *et al.* Integrated care prevents hospitalisations for exacerbations in COPD patients. Eur Respir J 2006; 28:123–130.
7. **Koizumi T, Takizawa M, Nakai K**, *et al.* Trial of remote telemedicine support for patients with chronic respiratory failure at home through a multistation communication system. Telemed J E Health 2005; 11:481–486.
8. **Vitacca M, Bianchi L, Guerra A**, *et al.* Tele-assistance in chronic respiratory failure patients: a randomised clinical trial. Eur Respir J 2009; 33:411–418.
9. **Seemungal TA, Donaldson GC, Bhowmik A, Jeffries DJ, Wedzicha JA**. Time course and recovery of exacerbations in patients with chronic obstructive pulmonary disease. Am J Respir Crit Care Med 2000; 161:1608–1613.
10. **Esteban C, Quintana JM, Moraza J**, *et al.* Impact of hospitalisations for exacerbations of COPD on health-related quality of life. Respir Med 2009; 103:1201–1208.
11. **Better Breathing**. http://www.betterbreathing.org/home.html. last updated May 17th, 2007. (accessed 8th June, 2009).
12. **Griffiths TL, Burr ML, Campbell IA**, *et al.* Results at 1 year of outpatient multidisciplinary pulmonary rehabilitation: a randomised controlled trial. Lancet 2000; 355:362–368.
13. **The National Statistics Socio-economic Classification User Manual**. London: United Kingdom Office for National Statistics, 2005.
14. **Maiolo C, Mohamed EI, Fiorani CM, De Lorenzo A**. Home telemonitoring for patients with severe respiratory illness: the Italian experience. J Telemed Telecare 2003; 9:67–71.
15. **Vontetsianos T, Giovas P, Katsaras T**, *et al.* Telemedicine-assisted home support for patients with advanced chronic obstructive pulmonary disease: preliminary results after nine-month follow-up. J Telemed Telecare 2005; 11 Suppl 1:86–88.
16. **Mair F, Boland A, Angus R**, *et al.* A randomized controlled trial of home telecare. J Telemed Telecare 2002; 8 Suppl 2:58–60.
17. **Mair FS, Goldstein P, Shiels C**, *et al.* Recruitment difficulties in a home telecare trial. J Telemed Telecare 2006; 12 Suppl 1:26–28.
18. **Brownsell S, Blackburn S, Hawley MS**. An evaluation of second and third generation telecare services in older people's housing. J Telemed Telecare. 2008; 14:8–12.
19. **Port K, Palm K, Viigimaa M**. Self-reported compliance of patients receiving antihypertensive treatment: use of a telemonitoring home care system. J Telemed Telecare 2003; 9 Suppl 1:S65–66.
20. **Port K, Palm K, Viigimaa M**. Daily usage and efficiency of remote home monitoring in hypertensive patients over a one-year period. J Telemed Telecare. 2005; 11 Suppl 1: 34–36.
21. **Dale J, Connor S, Tolley K**. An evaluation of the west Surrey telemedicine monitoring project. J Telemed Telecare 2003; 9:S39–S41.
22. **Springmeyer SC, Casaburi R, Make B, Jones P, Wise R**. Pulmonary rehabilitation and clinical trial design in patients with severe COPD. COPD 2008; 5:305–309.
23. **Adams SG, Smith PK, Allan PF, Anzueto A, Pugh JA, Cornell JE**. Systematic review of the chronic care model in chronic obstructive pulmonary disease prevention and management. Arch Intern Med 2007; 167:551–561.
24. **British Thoracic Society**. Management of exacerbations of COPD. Thorax 2004; 59:i131–i56.
25. **Hurlin C, Annandale J, Lewis K**. Specialist Chronic Disease Management for COPD reduces admissions in a semi-rural setting. Thorax 2008; 63:A127.
26. **Whitten P, Johannessen LK, Soerensen T, Gammon D, Mackert M**. A systematic review of research methodology in telemedicine studies. J Telemed Telecare 2007; 13:230–235.