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**Insufficient Evidence of Benefit:
a Systematic Review of Home Telemonitoring for COPD**

Charlotte E Bolton ², Cerith S Waters¹, Susan Peirce ¹, Glyn Elwyn ¹ on behalf of the
EPSRC and MRC Grand Challenge Team

1. Department of Primary Care and Public Health, Clinical Epidemiology Interdisciplinary
Research Group, Cardiff University, Heath Park, Cardiff, CF14 4YS

2. NIHR Nottingham Respiratory Biomedical Research Unit, Clinical Sciences Building,
University of Nottingham, City Hospital, Hucknall Road, Nottingham. NG5 1PB

Address for correspondence:

Charlotte E Bolton

NIHR Nottingham Respiratory Biomedical Research Unit, Clinical Sciences Building,
University of Nottingham, City Hospital,

Hucknall Road, Nottingham. NG5 1PB

Email: Charlotte.bolton@nottingham.ac.uk

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Grand Challenge Team Members: Omnia Allam, Charlotte Bolton, Edward C Conley, W.
Alex Gray, Alex Hardisty, Tim Maughan, David Owens, Alun Preece, Omer Rana, Zaheer
Yousef.

ABSTRACT

The evidence to support the effectiveness of home telemonitoring interventions for patients with COPD is limited yet there are many efforts made to implement these technologies across healthcare services.

A comprehensive search strategy was designed and implemented across 9 electronic databases and 11 European, Australasian and North American telemedicine websites. Included studies had to examine the effectiveness of telemonitoring interventions, clearly defined for the study purposes, for adult patients with COPD. Two researchers independently screened each study prior to inclusion.

Two randomised trials and four other evaluations of telemonitoring were included. The studies are typically underpowered, had heterogeneous patient populations and had a lack of detailed intervention descriptions and of the care processes that accompanied telemonitoring. In addition, there were diverse outcome measures and no economic evaluations. The telemonitoring interventions in each study differed widely. Some had an educational element that could itself account for the differences between groups.

Despite these caveats, the study reports are themselves positive about their results. However, given the risk of bias in the design and scale of the evaluations we conclude that the benefit of telemonitoring for COPD is not yet proven and that further work is required before wide scale implementation be supported.

INTRODUCTION

Interest in using home telemonitoring interventions to help manage patients with chronic obstructive pulmonary disease (COPD) is increasing, yet the evidence to support the effectiveness of these practices is limited.[1] By 2020, COPD is predicted to become the third leading cause of death worldwide, and the fifth most common source of disability.[2] In order to try and facilitate the management of the growing number of patients with COPD and to reduce pressures on health services, providers have sought to implement telemonitoring for patients with COPD. However, whilst there are several substantive evaluations of the efficacy of telemonitoring interventions for conditions such as heart failure,[3,4,5] this is not the case for COPD and it is not clear whether these interventions are effective.

A number of systematic reviews have evaluated the effectiveness of telemonitoring interventions for patients diagnosed with a heart failure and other long-term conditions.[6,7,8,9] The reviews are in the main positive and suggest that there is tentative evidence that telemonitoring may offer clinical benefit by reducing burden on services by reducing admissions. Yet the case for cost-effectiveness remains unsubstantiated and there is no evidence that telemonitoring efforts become part of routine practice after the protected funding and evaluations are completed.[10] There is interest in adopting telemonitoring for patients with COPD given the possibility that technology could help diagnose exacerbations in time to reduce morbidity and perhaps admission to hospital. There are few studies however and scoping searches revealed only a handful of publications and no systematic reviews.[7,8,9] In addition, it is likely,[8] that the clinical and economic effectiveness of telemonitoring interventions would vary across the different chronic diseases and there is a need to examine the evidence for the effectiveness of telemonitoring specifically for COPD.

We therefore conducted a systematic review of studies that have addressed the effectiveness of telemonitoring practices for patients with COPD. Our aim was to examine

the evidence for the clinical and economic benefit of telemonitoring interventions in this condition.

METHOD

The search strategy

A comprehensive literature search was conducted January 1990 to July 2009 using the methods recommended by the NHS Centre for Reviews and Dissemination and the Cochrane Collaboration.[11,12] Nine electronic databases (Medline, Scopus, INSPEC, the Science Citation Index, Embase, CINAHL, BNI, the Cochrane Library, the WHO Library) and 11 European, Australasian and North American telemedicine websites (www.teis.port.ac.uk; www.library.nhs.uk; www.telemedicine.scot.nhs.uk; www.telemedicine.org.uk; www.nlm.nih.gov; www.dh.gov.uk/www.pasa.nhs.uk; www.nordictelemedicine.org; www.ehto.org; www.tie.telemed.org; www.uq.edu.au; www.cst-sct.org) were searched for published articles. In order to identify in press and recently published articles, authors of included studies were contacted. The table of contents of selected relevant journals were manually screened and the bibliographies of all retained articles examined for relevant studies.

Inclusion and exclusion criteria

To be included, studies had to examine the effectiveness of telemonitoring interventions for adult patients with COPD. Scoping searches had indicated a paucity of research in this area and we therefore included uncontrolled and non-randomised as well as randomised controlled studies. All published studies reporting economic and clinically related outcomes (e.g. hospital admissions, number of exacerbations) were considered. Non-systematic review articles, single case, or case series reports were excluded. Articles that included additional medical conditions as well COPD were retained if the outcomes specific to the COPD group were reported separately. All English and non-

English language studies identified during the search were considered. Non-English language titles and abstracts were reviewed by colleagues able to apply the criteria.

A definition of telemonitoring

Telemonitoring has been defined as “the use of telecommunication technologies by patients for the timely transmission of data (e.g. spirometric measures, vital signs and symptoms) from home to a healthcare service centre.[9] In this study we operationalised the definition further. In order to qualify as telemonitoring, the intervention had to; (1) require the patient or their carer to periodically measure physiological indicators (e.g. arterial oxygen saturation & heart rate) and/or record their symptoms/vital signs in a standardised format, (2) use telecommunication technologies (e.g. telephone, internet, web-phone) that either manually or automatically transferred the patients health status data from home to a healthcare service, (3) lead to the automated or manual review of the patient’s health status data, (4) involve an automated or manual response when the patients health status data crossed a pre-defined threshold. Studies were excluded if healthcare professionals conducted the measurement of physiological signs.

The screening process

Two researchers independently screened each citation identified during the search and decided on the articles to retrieve for full text analysis. CSW extracted the data and attributed an evidence score to each study using the evidence levels suggested by the Oxford Centre for Evidence-based Medicine (<http://www.cebm.net/index.aspx?o=1025>). CSW also conducted a risk of bias assessment for each individual study according to the Cochrane Collaboration criteria. GE checked the data extraction; independently allocated a level of evidence score, and reviewed the bias assessments. Differences in opinion were resolved by discussion until consensus was achieved.

Data extraction

The following information was collated and tabulated from the included studies: description of patient population, sample size, presence of power calculation, duration of follow-up period and the type of economic evaluation (if any). The nature of the intervention and the outcomes reported were also summarised.

RESULTS

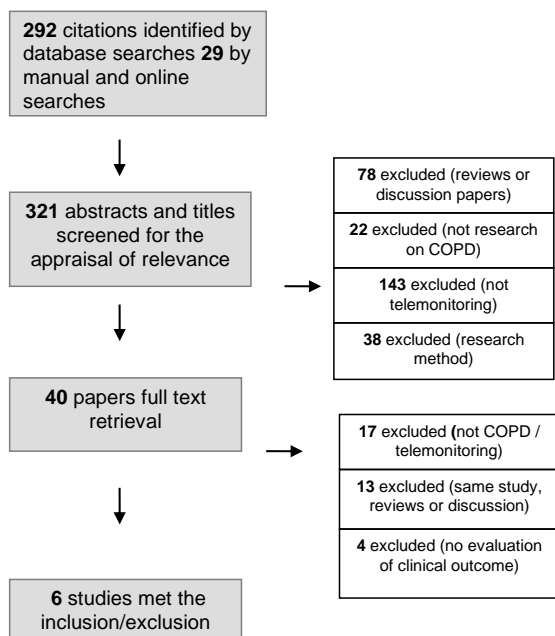
The search results are reported in Figure 1.

Characteristics of the included studies

Table 1 summarizes the characteristics and results of the 6 included research studies. Two of the six studies were randomised controlled trials,[13,14] two studies used a non-randomised design with a control group,[15,16] and two used a non-randomised design without a control group.[17,18] All of the studies were conducted on relatively small samples. The follow-up period during the intervention ranged from three to twelve months. One study followed-up their participants for 12 months, three for six months, one for three months, and one study conducted a variable follow-up period of 3 to 12 months. All the articles were published after 2002.

The patient populations recruited varied between studies. Most studies recruited patients during or following a hospital admission for COPD exacerbation or from secondary care clinics. Mean ages for participants ranged from 61 yrs to 73 yrs. Information regarding disease severity was variable. Mean FEV₁ and proportion of patients on long term oxygen therapy (LTOT) were the most commonly reported measures of disease severity. Two of the studies specifically recruited patients who were on LTOT or home ventilation. [14,17]

Figure 1 Summary of the review process



<<Insert Table 1 about Here>>

Methodological quality

All of the studies had methodological limitations. The quality of the study reports did not provide sufficient data for a risk of bias assessment. However, we do comment on methodological limitations in Table 1. Largely due to the small sample sizes, no study was classed higher than a level 2b in the hierarchy of evidence and only one trial by Koff *et al.* reported a sample size power calculation.[13] Of the randomised controlled trials, both report

the method of randomisation.[13,14] Due to the nature of the intervention, no study reported on allocation concealment. Attrition rates across the included studies were variable. Retention rates ranged between 70% [16] and 98% [14]. More recent studies tended to use larger samples and randomised designs, reflecting an improvement in design quality over time. The quality of the study reporting was low and it was difficult to establish clarity on many telemonitoring processes and outcome. None of the trials reported their results using the CONSORT guidelines.[19]

The nature of the telemonitoring intervention

Four of the six studies had an educational component to their intervention programme. The trial by Par e provided a 1 to 2 hour educational session that offered information on the nature of COPD and strategies for the effective management of the condition.[15] The other three studies provided ongoing information throughout the course of the intervention on disease management and illness education via a web-based computerised programme.[13,16,18] The studies were in effect assessment of complex interventions that were composed of multiple components. It is not clear whether the educational strategies, the increased professional contact or the monitoring technologies had the most impact. It is likely that there is a synergistic effect of the different components and we need to be cautious about making inferences based on the role of the technology alone.

Only Koff *et al.*, Dang *et al.* and Vitacca *et al.* report any information about the type of symptom information collected or describe how this relates to the generation of alert situations and the healthcare professional's response, [13,14,18] with Koff *et al.* and Vitacca *et al.* providing the most information.[13,14] Koff *et al.* reported a table of criteria by which green, yellow and red 'flags' were generated for each indicator.[13] Observing staff were alerted to contact patients with red flags and to use "discretion" for persistent yellow and red. Vitacca *et al.* used a card-based questioning by nurses to collect systematic health information and assign numerical scores and the criteria by which this information was categorised for each indicator was reproduced in their article.[14] A change of more than

three points from baseline would initiate a referral to a pulmonologist. None of the studies report the collected data in the results or assess the usefulness of the collected data in achieving the reported outcomes.

The frequency of telemonitoring assessment or contact with the health care provider over the course of the follow-up period varied greatly across the included studies. In four studies, the intervention group was remotely monitored on a daily basis.[13,15,16,18] In one study the patients were monitored twice weekly.[17]

<<Insert Table 2 about Here>>

Table 2 summarises the telemonitoring components used in the included studies. Five of the six studies required the patients to record physiological indices of their health status (e.g. arterial oxygen saturation, pulmonary functioning).[13,14,15,17,18], four of the six studies relied on the patient's subjective report of their symptoms and vital signs.[13,14,15,17] In these studies, the staff at a call centre recorded the patient's responses to a set of questions that assessed the likelihood of an exacerbation given the severity of the patient's symptoms. In the remaining studies, the physiological measures and/or the patients' self-reported symptoms were recorded at home and transmitted via the internet to the healthcare provider.

The effectiveness of the telemonitoring intervention.

The effectiveness of the telemonitoring interventions were evaluated in terms of improvements in the patient's medical condition and quality of life, reductions in health service utilisation and economic savings. The specific findings of each study are summarised

in Table 1. General trends are as follows. Four of the six studies examined whether participation in the telemonitoring intervention reduced the number of COPD exacerbations.[13,14,16,17] Two of these four studies reported a statistically significant reduction.[14,16] Two of the six studies examined the patient's self-reported quality of life:[13,16] only one of these studies observed a significant improvement.[13] Only one of the six studies reported mortality as an outcome and did not find any reduction in mortality rate with the intervention.[14]

Regarding health service utilisation, all six reported hospital admissions with four observing a reduction in the number of hospital admissions among the patients enrolled in the intervention programme.[14,15,16,17] Often this related the admissions in the study period to the preceding comparative number of months. It is also not clear in the results whether the admissions were due to COPD exacerbations or not and to what degree treatment has been initiated early by virtue of telemonitoring. The two studies that conducted detailed cost-minimisation analyses reported savings of 15% and 50% per patient.[14,15] Two studies analysed direct costs,[13,17] one reported savings.[17] Where savings were found, the reduction in the number of hospital admissions was considered to be the greatest source of economic gain.

DISCUSSION

Principal findings

The principal findings of this systematic review is that the evaluations of home telemonitoring to date are of low quality and are undertaken by those who are enthusiastic about the potential of remote patient assessment. The low quality does not stem entirely from the finding that the trials are small and therefore underpowered – they also suffer from a lack of

clarity about a clear patient population. This lack of clarity results in heterogeneous populations where patients with COPD who are at risk of winter exacerbations are combined with other susceptible patients who are on oxygen or sometimes on mechanical respiratory support, as in Vitacca's study.[14] These patients are not comparable in terms of the potential impact of remote monitoring ~~because the disease profile is so different.~~

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The telemonitoring interventions in each study differed widely. Some had an educational element directed at the patients and their carers that could itself account for the differences between groups. Few studies had a clearly stated aim for the telemonitoring intervention implemented. In general the telemonitoring intervention is poorly described, especially in terms of the assessment of the data transferred and how this assessment leads to a service response or not. The lack of a clear aim for the use of the intervention is manifested in the difficulty the trials have in specifying a clear primary outcome. The assumed, but not often declared, motive for using remote monitoring is to identify COPD exacerbations at a point in which it might be possible to intervene successfully, i.e. to reduce the risk of hospital admission by using appropriate therapy as soon as possible.

The outcomes of a telemonitoring intervention are therefore: exacerbations (recognised and unrecognised) and their eventual outcome in terms of treatment (e.g. antibiotics, steroids, possible admission), and its eventual impact on service use. None of the trials included in the review ~~made a distinction between~~ distinguished health service contacts that were related specifically to COPD exacerbations. The studies examined patient attendance at outpatient and emergency admissions (all cause), and so lack the ability to interpret the intended effect of the telemonitoring interventions. Many different outcome measures were reported. Only four of the six studies included physiological measures and the monitoring methods were not standardised or automated.

Despite these significant caveats, all the studies are positive about their results. However, given the inherent risk of bias in research of this nature and the low quality of the studies overall, with heterogeneous populations and diverse outcome measures, we conclude that the benefit of telemonitoring for COPD is not yet proven and that further work is required before wide scale implementation be considered.

Strengths and weakness of this review

Recently, there has been a systematic review and meta-analysis of telehealth in COPD,[20] with different inclusion criteria and importantly including telephone support studies (n=6). We are not aware of any previous attempt to conduct a systematic review of telemonitoring alone. Our search process was extensive and rigorous.[12] Although we did not include unpublished articles, given the paucity of research we did include quasi-experimental studies. We did not conduct a meta-analysis due to the heterogeneity of the data and study designs. Systematic reviews of telemonitoring used in a range of other conditions have concluded that telemonitoring is a promising approach and conclude that using technology to remotely monitor patients at home is acceptable and easily implemented;[7,8,9] and yet there is little progress on integrating telemonitoring into mainstream care. Moreover, unlike the situation in heart failure,[3,4,5] fewer rigorous studies have evaluated the efficacy of telemonitoring for COPD patients.

Results in context

There are no other systematic reviews of telemonitoring for COPD. Smith has however published a narrative review recently which came to the view that although there was 'potential for telemonitoring' to improve care for patients with COPD the evidence to data does not confirm clear benefits.[1]. This view was echoed by McKinstry who has called for more 'effectiveness' trials and is part of a collaboration who have published a protocol describing a trial which has been designed to address the outstanding issues of exacerbation

definition, outcome measurement and cost-effectiveness.[10,21] Cooper draws similar conclusions in an editorial targeted at respiratory specialists which indicates the need to define very clearly what is meant by monitoring technology and what degree of automation of data collection and analysis would be consistent with the view that the technology is independent of clinical judgement or whether in the final analysis, the data from sensors will never be sufficient to guide the need or not to take clinical action.[22]

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Implications

We therefore agree that the potential for telemonitoring is tangible but that there is much more work needed to determine the clinical benefit of early detection and the eat "one glove fits all" approach seems too simplistic for this heterogeneous population of patients. A constellation of changing set of symptoms and signs that reveal themselves from a baseline, which itself shifts over time, and which can reliably establish the patient clinical status in order to enable a specific management plans demands detailed attention to a diagnostic, or even a prognostic, signature. Future trials involving telemonitoring for COPD need to have improved designs and more rigorous attention to intervention specification and overall aim, to outcome definition, measurement and economic analyses. We note that there is no evidence that these interventions are being embedded in routine clinical care.

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Conflicts of interest: Nil.

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Contributorship: CSW searched the literature, selected the studies and conducted the data analysis. GE and CSW drafted the manuscript. CEB contributed to the interpretation, writing

and editing of the manuscript. SP contributed to developing the search strategy and editing the manuscript. GE initiated the review and is the PI of the study.

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Table 1. Characteristics of Studies on Home Telemonitoring in Patients with COPD

1 st Author (Year)	Design (Evidence Score)	Included patients, Sample & Power Calculation	Intervention	Follow-up months	Economic Evaluation	Results
Dang (2006) (18)	UBA (4)	Overall sample 59 † (COPD, DM and CHF). COPD N=17 male veterans aged ≥ 60 yrs. Power calculation not performed.	Automated system logged patients' self-reported symptoms and provided illness education. Referral alerts were generated if patients' status changed.	6	No	No significant differences in the number of bed days of care, outpatient visits, hospital admissions or emergency department visits.
Koff (2009) (13)	RCT (2b)	COPD Gold Stage 3 or 4.: Intervention: N = 19, 55% female, mean age = 67 yrs	Intervention: Patients transmitted self-reported symptoms, oximetry and spirometry readings to a central record system. Daily	3	RC	Significant difference in St George's Respiratory Questionnaire scores between groups. Data on exacerbations in control group not collected. No savings in medical

		Control: N = 19, 50% female, mean age = 65 yrs	completion of illness education and disease management modules.			costs reported; no adjustment for intervention costs.
		Power calculation reported.	Contact with coordinator via mobile phone.			
Maiolo (2003) (17)	UBA (4)	N=20 †, with COPD and on long-term oxygen, 9% female, mean age = 73 yrs.	Twice weekly nocturnal pulse oximetry readings sent via telephone line to a central storage system. Scheduled calls by physician to patient after analysing the oximetry data.	12	RC	Significant decrease in the number of hospital admissions (2.15 vs 1.21 admissions, in Phase 1 vs. Phase 2 respectively. (p<.01).
		No power calculation reported.				
Pare (2006) (15)	NCBA (4)	Patients with respiratory failure, emphysema and asthma. intervention: N = 19, 37% female, mean age = 69 yrs	Intervention: Patients transmitted peak flow symptoms and medication data. Control: Usual homecare. Both groups had access to a	6	CMA	Significantly fewer hospital admissions in the intervention group than the control in the 6 month study, 2 vs. 6, (p<.05). However, when the intervention patients were admitted, the duration was significantly

		Control: N = 10, 50% female, mean age = 72 yrs No power calculation reported.	nurse-led telephone service.			longer, 13.5 vs. 7.3 days (p<0.01). Reported cost saving of \$355 per person.
Trappenburg (2008) (16)	NCBA (4)	COPD patients GOLD 3 and 4: Intervention: N = 59, 54% female, mean age = 69 yrs Control: N = 56, 39% female, mean age = 70 yrs No power calculation reported.	Intervention: Patients transmitted symptoms and medication data. Illness education and disease management training was provided. Control: Usual care.	6	No	Reported statistical difference in number of exacerbations (p<0.004) and hospital admission in intervention group compared to control group p<0.02) but the numbers of events are low. No significant differences in quality of life scores, number of inpatient days or outpatient visits.
Vitacca (2009) (14)	RCT (2b)	Patients on home mechanical ventilation or	Intervention: Regular telephone appointments with a nurse where	3-12	CMA	Significant decrease in the average number of hospital admissions in the intervention

on long term oxygen therapy. Intervention: N = 57
Control: N = 44. †
No other details by diagnosis.
Power calculation not performed.

patients gave oximetry readings and reported their symptoms.
Access to call centre.
Control: Usual care.

group ($p < 0.02$). Patients in the intervention group showed a greater probability of remaining free of emergency visits ($p < .001$), GP calls ($p < .02$) and exacerbations ($p < .001$). No differences in mortality rates. Telemonitoring costs 50% cheaper per patient.

Abbreviations:

- UBA Uncontrolled Before and After Study
- NCBA Non-Randomised Controlled Before and After Study
- RCT Randomised Clinical Trial
- CMA Cost Minimization Analysis
- RC Reported Costs
- † Study including patients with multiple diagnoses: results reported here only for COPD patients.

Table 2 The components of the telemonitoring intervention among the included studies

Reference	Measurement Parameters				Recording of Biomarkers		Call/ Web Centre Access ^a	Data Transmission			Assessment Process		
	Spirometer	Pulse Oximeter	Peak Flow	Symptom Report	Nurse	Patient		Auto	Video	Verbal	Auto Alert	Lay Person	Clinician
Dang (2006) (18)				•			•	•		•	•	•	
Koff (2009) (13)	•	•		•		•		•			•		•
Maiolo (2003) (17)		•		•		•		•		•			•
Pare (2006) (15)			•	•		•	•	•		•	•		•
Trappenburg (2008)				•				•			•		•

(16)													
Vitacca (2009) (14)		•		•		•	•			•			•

^a Patients could contact these centres with a health related query when required. Typically, call centres were staffed for 8 hours a day, 5 days a week. Outside of these hours, an automated service was provided

Cells are left blank where information on the components was not available