Effectiveness of telemonitoring integrated into existing clinical services on hospital admission for exacerbation of chronic obstructive pulmonary disease

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RESEARCH

Effectiveness of telemonitoring integrated into existing clinical services on hospital admission for exacerbation of chronic obstructive pulmonary disease: researcher blind, multicentre, randomised controlled trial

Hilary Pinnock *reader*[1], Janet Hanley *principal research fellow*[2], Lucy McCloughan *programme manager*[3], Allison Todd *research nurse*[3], Ashma Krishan *statistician*[4], Stephanie Lewis *reader in medical statistics*[5], Andrew Stoddart *health economist*[6], Marjon van der Pol *professor of health economics*[7], William MacNee *professor of respiratory and environmental medicine*[8], Aziz Sheikh *professor of primary care research and development and directorHarkness fellow in healthcare policy and practice*[1 9], Claudia Pagliari *senior lecturer in primary care and health informatics*[3], Brian McKinstry *professor of primary care ehealth*[3]

[1]Allergy and Respiratory Research Group, Centre for Population Health Sciences, University of Edinburgh, Edinburgh EH8 9AG, UK; [2]School of Nursing, Midwifery and Social Care, Edinburgh Napier University, Edinburgh, UK; [3]eHealth Research Group, Centre for Population Health Sciences, Edinburgh, UK; [4]Edinburgh Clinical Trials Unit, University of Edinburgh, UK; [5]Centre for Population Health Sciences, Edinburgh, UK; [6]Health Services Research Unit, University of Edinburgh, UK; [7]Health Economics Research Unit, University of Aberdeen, Aberdeen, UK; [8]Centre for Inflammation Research, University of Edinburgh, UK; [9]Division of General Internal Medicine and Primary Care, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA

Abstract

Objective To test the effectiveness of telemonitoring integrated into existing clinical services such that intervention and control groups have access to the same clinical care.

Design Researcher blind, multicentre, randomised controlled trial.

Setting UK primary care (Lothian, Scotland).

Participants Adults with at least one admission for chronic obstructive pulmonary disease (COPD) in the year before randomisation. We excluded people who had other significant lung disease, who were unable to provide informed consent or complete the study, or who had other significant social or clinical problems.

Interventions Participants were recruited between 21 May 2009 and 28 March 2011, and centrally randomised to receive telemonitoring or conventional self monitoring. Using a touch screen, telemonitoring participants recorded a daily questionnaire about symptoms and treatment use, and monitored oxygen saturation using linked instruments. Algorithms, based on the symptom score, generated alerts if readings were omitted or breached thresholds. Both groups received similar care from existing clinical services.

Main outcome measures The primary outcome was time to hospital admission due to COPD exacerbation up to one year after randomisation. Other outcomes included number and duration of admissions, and validated questionnaire assessments of health related quality of life (using St George's respiratory questionnaire (SGRQ)), anxiety or depression (or both), self efficacy, knowledge, and adherence to treatment. Analysis was intention to treat.

Results Of 256 patients completing the study, 128 patients were randomised to telemonitoring and 128 to usual care; baseline characteristics of each group were similar. The number of days to admission did not differ significantly between groups (adjusted hazard ratio 0.98, 95% confidence interval 0.66 to 1.44). Over one year, the mean number of COPD admissions was similar in both groups (telemonitoring 1.2 admissions per person (standard deviation 1.9) *v* control 1.1 (1.6); P=0.59). Mean duration of COPD admissions over one year was also similar between groups (9.5 days per person (standard deviation 19.1) *v* 8.8 days (15.9); P=0.88). The intervention had no significant effect on SGRQ scores between groups (68.2 (standard deviation 16.3) *v* 67.3 (17.3); adjusted mean difference 1.39 (95% confidence interval −1.57 to 4.35)), or on other questionnaire outcomes.

Correspondence to: H Pinnock hilary.pinnock@ed.ac.uk

Extra material supplied by the author (see http://www.bmj.com/content/347/bmj.f6070?tab=related#webextra)

Web appendix: Supplementary material

Conclusions In participants with a history of admission for exacerbations of COPD, telemonitoring was not effective in postponing admissions and did not improve quality of life. The positive effect of telemonitoring seen in previous trials could be due to enhancement of the underpinning clinical service rather than the telemonitoring communication.

Trial registration ISRCTN96634935.

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Introduction

Potentially affecting one in four adults by the age of 80 years,[1] chronic obstructive pulmonary disease (COPD) is already a leading cause of death and disability in high, middle, and low income countries.[2 3] Telemonitoring has attracted interest as a potential solution to the global challenge of providing care for ageing populations living with long term conditions such as COPD,[4] leading to its enthusiastic promotion by policy makers.[5 6] The recent UK Whole Systems Demonstrator (WSD) evaluation analysed a cohort of patients with conditions including COPD, diabetes, and heart failure.[7] The study's findings lend some support to the assertion that a service redesign that included telemonitoring can reduce admissions and mortality in people with long term conditions, although not cost effectively.[8]

Despite calls for robust effectiveness trials of telemonitoring in COPD,[9] five systematic reviews have reported inconclusive results.[10-14] Patients' attitudes and receptiveness towards this approach are "promising,"[13] but the evidence is insufficient to draw firm conclusions about clinical effectiveness[10 12 13] or cost effectiveness.[13] The heterogeneity of interventions that use telemonitoring contributes to the difficulty in interpreting outcomes—ranging from "simple" telephone follow-up to daily telemonitoring of physiological or symptom scores or to more complex telemonitoring interventions with greatly enhanced clinical support.[10 14] This heterogeneity has led to calls for further research to clarify the specific role of telemonitoring (as opposed to the additional clinical services created to support it) in managing people with COPD.[10]

To inform the ongoing debate, we designed a study in which telemonitoring was integrated into existing clinical services, such that monitoring was provided by clinical teams who already had (or were about to assume) clinical responsibility for the patients. Both intervention and control groups had access to the same clinical care: the only difference between the groups was the use of telemonitoring.[15]

Methods

We conducted a 12 month, researcher blinded, randomised controlled trial in primary care in the United Kingdom, which recruited participants between 21 May 2009 and 28 March 2011. A detailed protocol has been published.[15] We did not make any substantive changes to the trial procedures, but after pilot work,[16] we made some minor procedural changes to enhance recruitment and to streamline the collection of data from participants' healthcare records. A detailed statistical analysis plan was submitted to the trial sponsor before completion of data collection.

Participants

We recruited adults registered with Lothian general practices who had been admitted to hospital with an exacerbation of COPD in the previous year and who were thus at risk of future admissions.[17] Our eligibility criteria were as inclusive as possible, including patients of all ages and with a range of comorbidities.[18] Thus, we only excluded people with other significant lung disease; who were unable to provide informed consent, use the technology, or complete the questionnaires; or, on the advice of their general practitioner (GP), for other significant social or clinical problems.

Participant recruitment

We used three strategies to identify potentially eligible participants. Community respiratory and nursing teams screened their caseloads. Respiratory consultants identified and contacted potentially eligible patents from hospital admission data from the Information Services Division (www.isdscotland.org/). Finally, supported by the Scottish Primary Care Research Network, 96 primary care practices searched for patients in their databases. With GP agreement, the responsible clinician sent trial information to all eligible patients inviting them to express interest in participating in the trial.

Potentially interested participants were invited, with one reminder, to a baseline assessment with a research nurse in their home at least six weeks after the most recent exacerbation (whether an admission or managed at home). The research nurse provided further information about the trial and obtained consent. Diagnosis of COPD was confirmed by the presence of chronic airflow limitation on spirometry normally performed at the baseline assessment by the research nurse trained in spirometry. COPD was confirmed if the post-bronchodilator forced expiratory volume in one second (FEV_1) divided by the forced vital capacity was less than 0.7.[19] Recordings undertaken by a specialist respiratory service within the previous three months were accepted if spirometry at the baseline assessment was not possible or declined. All consenting participants meeting the eligibility criteria were enrolled into the trial.

Primary outcome measure

The primary aim of the intervention was to reduce the frequency of admissions. Therefore, our primary outcome measure was the time to first hospital admission with a primary diagnosis of an exacerbation of COPD up to one calendar year after randomisation. We defined an exacerbation as a sustained worsening of the participant's symptoms from their usual stable state that was beyond normal day-to-day variations, was acute in onset, and necessitated a change in treatment.[20] An exacerbation was considered the "primary diagnosis" if the presenting symptoms were consistent with and the participant was treated for an acute exacerbation of COPD, and if no other disease was treated as a priority.

Secondary outcome measures

Full details of the secondary outcome measures are in the published protocol.[15] Briefly, we measured the difference of the items listed in the box at one year after randomisation.

Baseline assessment

We undertook a baseline assessment comprising current smoking status, UK Medical Research Council dyspnoea score,[26] history of COPD, presence of comorbidity, and baseline questionnaires.

Secondary outcome measures

Exacerbations, admissions, and deaths

Time until first hospital admission with an exacerbation of COPD or all cause death

Number and duration of hospital admissions with an exacerbation of COPD; number and duration of admissions in which COPD was a factor (for example, listed as a significant comorbidity, or as an overnight admission for minor surgery that might otherwise have been a day case)

Number and duration of admissions for any cause

Number of deaths at one year

Number of exacerbations self reported by participants on quarterly questionnaires. This included all exacerbations treated with steroids or antibiotics, whether commenced by the patient, primary care, or secondary care including during an admission.

Questionnaire assessment of health related quality of life, anxiety and depression, participant knowledge, and self efficacy and adherence with treatment

St George's respiratory questionnaire (SGRQ)[21] (both mean difference and proportion of participants with scores improving by the minimum clinically important difference (defined as four units))

Hospital anxiety and depression scale (HADS)[22]

Self efficacy for managing chronic disease 6 item scale (SECD6)[23]

Lung information needs questionnaire (LINQ)[24]

Medication adherence report scale (MARS).[25]

Healthcare resource use

Number and duration of contacts (telephone, clinic visits, or home visits) with community services

Randomisation and protection against bias

Existing clinical care varied in intensity and organisation throughout the four regions of Lothian. Therefore, consenting participants were stratified by the clinical service providing their existing COPD care (see below for clinical care arrangements) and centrally randomised to either control or intervention with a 1:1 allocation using randomised blocks of two or four. This process was managed by the telephone randomisation service of the Edinburgh Clinical Trials Unit, ensuring concealment until the treatment was assigned. The research nurse phoned the randomisation service, informed the participant of the allocation, and referred intervention participants for installation of the telemonitoring equipment. The research nurse responsible for follow-up assessments was different to the nurse who performed randomisation, and data entry was undertaken by trial administrators blinded to allocation. All primary outcome assessors were blind to the allocation.

Trial intervention: telemonitoring

Figure 1⇓ illustrates the model of telemonitoring. The telemonitoring equipment and secure broadband link was installed in the homes of intervention participants. The clinical team responsible for their care then visited the participant at home to explain how to use the technology and provide self management education. Participants had access to technological advice and support throughout the trial.

Using the touch screen telemonitoring equipment, the participant recorded and transmitted a daily questionnaire about symptoms and use of treatment (web appendix 1), and monitored oxygen saturation using linked validated instruments. The symptom score was based on validated diary cards,[28] and the patient was asked to assess if their dyspnoea, sputum purulence and volume, cough, wheeze had increased or if they had developed an upper respiratory tract infection or had a fever. The responses were weighted as described in the validation studies: positive answers to cardinal symptoms of an exacerbation of COPD scored 2, the remaining questions scored 1.[28]

This information was sent by a secure internet connection to a password protected server at the UK's health service, which was accessible to the supporting clinical team. The supporting clinical team (a specialist respiratory team in Edinburgh, a nurse specialist in long term conditions in Midlothian, or a trained call handler working with general practices for patients living in East or West Lothian) monitored the daily online data. Algorithms, based on the symptom score, alerted the clinical monitoring team if daily readings had not been submitted or if a score of 4 or 5 had been recorded (web appendix 2).[15]

The action taken was the responsibility of the monitoring clinician who normally knew the patient and was able to interpret the monitoring data in the light of the patient's history.[29] Typically, this involved contacting the patient by telephone (although the system could support a video link) and undertaking a further clinical assessment to enable a decision about further management (for example, commencing rescue treatment, a home visit, immediate admission, or reviewing the following day). Although a video link was available, poor reception meant that it was only used on two occasions. Pulse oximetry data were available to inform the clinical assessment, and clinicians were able to define an "oxygen saturation" alert on an individual patient basis.

Control group

To ensure that our trial specifically tested the effect of the telemonitoring technology, intervention and control groups were provided with the same clinical care (including self management advice) according to the region in which they lived (see below). The only difference between the intervention and control groups was the provision of the telemonitoring service.

Clinical care in both groups

Clinical care in both groups was in accordance with the Lothian protocols, which were based on national and international guideline recommendations.[19 20] Education on self management of exacerbations was provided for all participants, reinforced by a copy of the British Lung Foundation's booklet about living with COPD,[30] which includes a written management plan, and an emergency supply of antibiotics and steroids were made available.

Different service models operated in the four regions of Lothian. A dedicated respiratory physiotherapy service was available seven days a week for participants in the city of Edinburgh.

Nurse specialists in long term conditions provided a weekday service for participants in the mixed urban and rural population of Midlothian. In East and West Lothian, care was provided by the participants' registered GP: telemonitoring data were monitored by a trained administrative assistant who referred participants to their GP according to the algorithm used in our pilot study (web appendix 2).[16] Randomisation was stratified by these different services to allow for the possibility that outcomes might not be comparable in the different areas.

Data collection

Data on admissions were extracted from the hospital records at the end of the trial. The number of admissions identified was cross referenced with the admissions reported by the patients to ensure that we captured events occurring away from the patients' usual hospital. The cause of the admission (and thus whether the event counted as a primary outcome) was assessed independently from the hospital discharge summary by HP and BM with disagreements resolved by discussion (with WM arbitrating, if necessary). Questionnaires were administered by a research nurse at a home visit arranged within two weeks of the calendar year during which the participant was in the trial. Healthcare resource use was collected by questionnaire posted to the participants three, six, and nine months (one reminder) and by the research nurse at baseline and the 12 month assessment. Healthcare resource use included consultations with GPs and nurses, respiratory and nursing teams, out of hours services, emergency services, telephone calls to the NHS 24 health information and self care advice service, and courses of oral steroids and antibiotics. The respiratory physiotherapy service in Edinburgh and the nurses in Midlothian maintained detailed timesheets of all patient contacts. All data were entered manually onto the trial database, with 10% checked for accuracy by an external assessor.

Sample size calculations

We estimated that 125 participants in each arm would allow us to detect a difference in the primary outcome of time to admission from a median of 200 days in the control group to 300 days in the intervention group, with 80% power, using a significance level of 5% (log rank test). This estimate was based on data from the largest study of telemonitoring available at the time (n=155), which showed an increase in the time to admission from a median of about 200 days to 400 days.[31] Because effectiveness in that trial varied between centres, we opted for a conservative estimate of effect size. To allow for 10% withdrawal from follow-up and 7% of deaths occurring before admission to hospital with COPD, we increased our target recruitment to 150 per arm. We monitored withdrawals and deaths before admission with an exacerbation of COPD, which proved considerably lower than our estimates, enabling us to stop recruitment at 128 participants in each group.

Data analysis

All participants who were randomised were followed up and included in the analysis in their allocated treatment groups regardless of the treatment actually received (intention to treat analysis). Survival data were presented using Kaplan-Meier curves,[32] analysed using Cox proportional hazards models[33] adjusting for potentially important confounders. These confounders were service (stratification variable), age, sex, severity (post-bronchodilator FEV_1% predicted), current smoking status, presence of comorbidity, SGRQ score, HADS score, social class (based on postcode and the Scottish Index of Multiple Deprivation), and number of previous admissions. Binary outcomes were analysed using logistic regression and continuous outcomes were analysed using generalised linear models. However, for the majority of the analyses on number and duration of hospital admissions, a Poisson distribution function was used owing to the data being heavily skewed, adjusting for the stratification variable and potential confounders. Unadjusted analyses were also performed. Where appropriate, adjustments were made for baseline measurements using analysis of covariance.

Because the primary outcome and majority of the secondary outcomes were analysed using survival analysis, any missing data were censored at the point when the data became missing. Participants who died without having had an admission with a primary diagnosis of COPD were censored in the final analysis. For other analyses, participants with missing data were omitted as necessary.

Subgroup analyses

For the primary outcome, planned subgroup analyses were performed based on age, sex severity, presence of any comorbidity, and SGRQ and HAD scores, because these could be hypothesised to affect the impact of the intervention.[34] Subgroup analyses were performed by adding the interaction between these factors and treatment into the survival analysis model and by observing whether the change in the model log likelihood was statistically significant. All analyses were agreed a priori. We did not plan or undertake any interim analysis.

Results

Recruitment

Figure 2⇓ details the flow of participants through the trial. Of 422 patients identified by clinical services, the GP refused permission to approach three patients for significant clinical or social reasons, leaving 419 who were potentially eligible and were sent an invitation letter by the clinical team. Of these, 314 patients expressed an interest in participating and 258 provided informed consent. Two patients withdrew consent (for personal reasons) before randomisation, so that 256 were randomised equally between the two groups. Two participants withdrew their consent during the course of the trial (one in each group).

Baseline characteristics

Demographic characteristics of participants, social deprivation, markers of disease severity (including admissions in the previous year), presence of comorbidities, smoking status, and baseline questionnaire scores were similar in both groups. However, slightly fewer patients in the intervention group than in the control group had one or more comorbid conditions (61% *v* 71%; table 1⇓). The demographic profile of the participants (mean age 69.4 (standard deviation 8.6) years; 45% male) was similar to that of the population referred by their clinician as potentially eligible and willing for their contact details to be passed to the research team (69.8 (9.1) years; 43%).

Hospital admission with an exacerbation of COPD

The median time to the first hospital admission with an exacerbation of COPD was 362 days (interquartile range 131 to >365) in the telemonitoring group and 361 days (113 to >365; fig 3⇓) in the control group. There was no significant difference in the hazard ratio for admission in the telemonitoring group compared with the control group (adjusted hazard ratio 0.98

(95% confidence interval 0.66 to 1.44)). Similarly, there was no significant difference in the number of admissions with an exacerbation of COPD, or the total number of days spent in hospital (table 2⇓). Unadjusted results (data not shown) were similar to the adjusted analyses.

Four deaths occurred before admission to hospital with COPD (one in the telemonitoring group) and were censored in the primary analysis. Using a composite outcome of time to first COPD admission or all cause death, the adjusted hazard ratio for admission in the telemonitoring group was 0.87 (95% confidence interval 0.61 to 1.26) compared with the control group.

Self reported COPD exacerbations, all cause admissions, and deaths

The telemonitoring group showed a non-significant increase in the number of self reported exacerbations per patient during the calendar year compared with controls (mean 15.0 (standard deviation 12.7) *v* 12.8 (11.8); adjusted mean difference 2.29 (95% confidence interval −0.78 to 5.37)). A self reported exacerbation was defined as a patient report of an episode of taking antibiotics or steroids. The number and duration of admissions for which an exacerbation was not the primary cause were similar in both groups (table 2). The number of deaths did not differ significantly between the telemonitoring and control groups (16 *v* 21; adjusted odds ratio 0.66 (95% confidence interval 0.29 to 1.48)).

Questionnaire responses

There was no significant difference between the groups in any of the questionnaire scores, and no differences from baseline to one year in either group. The intervention made no significant difference to health related quality of life the telemonitoring and control groups (mean SGRQ score at one year, 68.2 (standard deviation 16.3) *v* 67.3 (17.3); adjusted mean difference 1.39 (95% confidence interval −1.57 to 4.35)), anxiety or depression, self efficacy, knowledge, or adherence to treatment (table 3⇓). The proportion of participants whose SGRQ[20] score improved by more than four units (the minimum clinically important difference) was 25% in the telemonitoring arm and 25% in the control group.

Installation of telemonitoring equipment, training, and withdrawals

Table 4⇓ details the logistics of installing and training participants to use the equipment and reasons for withdrawals. The mean time from randomisation to commencing monitoring was 79 days (standard deviation 48 days), with nearly three quarters of the delay related to the installation of a dedicated broadband line and setting up of the telemonitoring equipment. Of 128 participants allocated to telemonitoring, 113 had the equipment successfully installed and 109 completed training. Eight participants withdrew from telemonitoring during the trial, mostly because of changes in clinical circumstances.

Contacts with clinical monitoring teams

Table 5⇓ details the contacts with healthcare monitoring services for the 189 patients under the care of the Edinburgh Community Respiratory Team and the Midlothian nurses. Data for East and West Lothian services were incomplete because care was provided by a number of general practices and contacts were not recorded consistently. The community teams dealt with 2441 telemonitoring alerts from the 97 telemonitored patients under their care, 113 of which required home visits. This represented an average of 25 contacts per patient over the year of the trial—about one contact every two weeks, in addition to the 510 telephone calls and 821 home visits to telemonitored patients that were not directly associated with alerts. The 92 patients in the control group received fewer telephone calls and home visits than those in the telemonitoring group (353 and 681, respectively).

Subgroup analyses

Figure 4⇓ shows the subgroup analyses. The only significant result was that the intervention was less effective for participants with mild or moderate COPD than for those with severe or very severe COPD. Although this was an a priori analysis, severity was one of seven subgroups tested and was based on a small number of patients in the mild or moderate group; therefore, it is subject to considerable uncertainty.

Discussion

In participants with a recent history of admission for exacerbations of COPD, telemonitoring over one year did not have a significant benefit on time to a hospital admission, duration of admissions, or health related quality of life when both intervention and control groups had access to the same clinical care. Furthermore, telemonitoring was associated with a large increase in the number of telephone consultations and home visits, and a non-significant increase in participant reported exacerbations. Telemonitoring thus did not represent an effective use of NHS resources.

Strengths and limitations

Our researcher blinded pragmatic trial, which built on relevant conceptual and systematic review work,[10 15] reports clinical effectiveness and workload implications of telemonitoring for COPD. We obtained the primary outcome data from the clinical records of all but two participants, and thus achieved our target sample size. There was some attrition of questionnaire completion, principally because of deaths during the trial year, and because several participants felt it was too burdensome given their state of health at the time.

The confidence intervals for our primary outcome were wide (0.66 to 1.44) and we cannot be confident of ruling out a clinically meaningful difference that was smaller than the one we were powered to study. Our admission related secondary outcomes, however, similarly showed no significant effect. Our sample size was based on a study conducted a decade ago.[31] However, in the intervening years, there has been a considerable drive to reduce the number and duration of admissions (including the development of community respiratory teams who provided clinical care for the majority of our participants), thus limiting the potential for further reduction.

We ensured that both groups had access to the same clinical care, which in our UK setting was facilitated by the availability of established community specialist respiratory teams, specialist nurses for long term conditions, or primary care teams. The clinical services into which the telemonitoring was integrated varied between the four Lothian regions, which may have influenced the effect of the intervention and the potential for improvement; we therefore stratified randomisation by service model. Most participants lived within 10 miles of secondary care facilities: outcomes might have been different in rural areas where telemonitoring might have had a greater effect on enhancing access to care.

Blinding of participants and treating clinicians was not possible, but central randomisation ensured concealment and the primary outcome was assessed by two clinicians unaware of allocation. To achieve blinding of data collection, outcome data were collected by a different member of the research team from the nurse who had randomised the patients, but we acknowledge that participants could have mentioned telemonitoring, or equipment might have been visible during the home visit for data collection, making it impossible to maintain blinding in all cases.

Interpretation of findings

Our findings highlight the importance of defining the nature of usual care delivered to a control group when evaluating a complex intervention. Previous studies that have introduced an enhanced clinical service to support the telemonitoring arm of a trial have achieved improved outcomes compared with the usual care available to people with COPD.[10 12] For example, telemonitoring in the context of an integrated care service[31]—incorporating case management[35] or providing additional home visits[36]—reduced hospital admissions. Similarly, in the recently published WSD trial, telemonitoring supported by specialist community care, case management, or specific arrangements with general practices according to local service preferences was compared with usual care (that is, without the specific services or arrangements developed to support the telemonitoring).[7] In this context, telemonitoring for participants with diabetes, COPD, or heart failure was associated with lower rates of emergency admissions, although the authors noted that the difference was due to a short term increase in emergency admissions in the control group.[7] In our trial, the same clinical service was available to participants in both groups (albeit accessed considerably more frequently as a result of the telemonitoring) and showed no difference in any outcomes. The WSD trial with 3230 participants showed a significant reduction in mortality,[7] by contrast with Takahashi and colleagues, who found a substantial increase in deaths.[37] Our trial, however, was not powered for this outcome and our estimate of mortality is thus imprecise and cannot contribute to the debate.

Our nested qualitative study suggested that patients were very positive about the benefits of telemonitoring,[16 27 29] but this was not reflected by an improvement in respiratory-related quality of life. Similarly, the lack of change in the HADS score suggested that the intervention neither relieved nor exacerbated overall levels of anxiety or depression. Our theoretical framework for the telemonitoring intervention emphasised the importance of empowering self management, improving confidence of professionals by providing ongoing monitoring data, and improving access to clinical services.[15] Our nested qualitative data suggested that continuity of care,[29] facilitating access to care,[29] and supporting self management[27] were all perceived to be important facets of the intervention. However, this did not translate into a difference in measured self efficacy (a mediator of self management).

Our data did not allow us to distinguish telemonitoring alerts triggered by clinically confirmed exacerbations requiring treatment from false alarms that needed no additional intervention. We observed a non-significant increase in the number of self reported, treated exacerbations in the telemonitoring group, although it is not clear whether this finding was due to improved recognition of early exacerbations or over treatment of "bad" days. Our results challenge previous findings from a cohort study concluding that early recognition and treatment improved exacerbation recovery, reduced risk of admission, and was associated with a better health related quality of life.[38] Despite frequent prompt responses to changes in symptom scores, and a trend to increased treatment of exacerbations, we found no benefit in any of these clinical outcomes.

A key factor that could increase the number of false alerts and limit the effectiveness of telemonitoring in COPD is the lack of clear early predictors of an exacerbation.[39] Physiological parameters have not proved to be sufficiently predictive. This is because they either change late in the course of the exacerbation (for example, FEV_1, oxygen saturation, heart rate, temperature)[39] or cannot be measured reliably (for example, respiratory rate). Developing predictive algorithms with clinically useful levels of sensitivity and specificity is thus a priority for the future development of telemonitoring of COPD.

The substantial workload generated by the telemonitoring alerts underlines the importance of piloting and assessing workforce implications for both technological and clinical support services during the planning and implementation phase of reconfiguration. Crucial decisions about economies of scale and the relative importance of continuity of care will be needed and their effect monitored.[29]

Logistical issues with installation bedevilled the early months of the intervention and will potentially have reduced any effectiveness of our intervention. For telemonitoring to become mainstream, the technology needs to adapt seamlessly to variations in local connectivity as well as provide flexibility in monitoring capability to meet individual clinical need. Use in more specific contexts (such as to support early discharge until the risk of readmission has receded[40]) could then be possible.

Conclusions and implications

Integration of telemonitoring into existing clinical services—such that both intervention and control groups had access to the same clinical care—had no effect on delaying time to a hospital admission, and had a substantial impact on workload. The positive effect of telemonitoring seen in previous trials could thus be due to enhancement of the underpinning clinical service rather than the telemonitoring communication. Specific developments that could improve the performance of telemonitoring in COPD in the future include the validation of measures and algorithms that can predict potentially serious exacerbations more reliably, and an understanding of clinical contexts in which telemonitoring is most effective. In the meantime, long term telemonitoring of people with COPD is unlikely to reduce admissions unless it is a means of enhancing clinical services.

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What is already known on this topic

Telemonitoring has attracted interest as a potential solution to the global challenge of providing care for ageing populations living with long term conditions such as COPD

A Cochrane systematic review of telemonitoring in COPD reported a reduction in hospital admissions over 12 months, although telemonitoring in these trials had been supported by enhanced clinical care which could reduce admissions in its own right

The specific role of telemonitoring in managing people with COPD, as opposed to the additional clinical services created to support it, needs to be clarified

What this study adds

Integration of telemonitoring into existing clinical services—such that both intervention and control groups had access to the same clinical care—did not delay time to a hospital admission, and had a substantial effect on workload

The positive effect of telemonitoring seen in previous trials could be due to enhancement of the underpinning clinical service rather than the telemonitoring communication

Long term telemonitoring of people with COPD is unlikely to reduce admissions unless it is a lever for enhancing clinical services

Contributors: BM initiated the idea for the study, and with HP, led the development of the protocol, securing of funding, study administration, data analysis, interpretation of results, and writing of the paper. JH, SL, ASh, WM, and CP were grant holders who contributed to development of the protocol, securing of funding, study administration, data analysis, interpretation of results, and writing of the paper. AT undertook the data collection. LM provided liaison between the research and clinical teams, and provided the regulatory oversight for the trial. SL and AK were the trial statisticians. MvdP and ASt undertook the health economic analysis. All authors had full access to all the data, and were involved in interpretation of the data. HP and BM wrote the initial draft of the paper, to which all the authors contributed. HP and BM are study guarantors.

Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: support from the Chief Scientist Office of the Scottish government and NHS Lothian for the submitted work; HP is supported by a primary care research career award from the Chief Scientist's Office of the Scottish government; BM and JH are supported via NHS Lothian through the Edinburgh Health Services Research Unit; AS is supported by the Commonwealth Fund, a private independent foundation based in New York City; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: Ethical approval was granted by the Lothian research ethics committee (reference 08/S1101/60), and NHS management approval was provided by NHS Lothian, Scotland.

Data sharing: No additional data available.

HP and BM are study guarantors and affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Tables

Table 1| Baseline characteristics of trial participants

	Telemonitoring (n=128)	Control (n=128)
Age in years (mean, SD)	69.4 (8.8)	68.4 (8.4)
Female sex (No of participants, %)	75 (59)	65 (51)
FEV_1 % predicted (mean, SD)*	44.0 (18.8)	40.0 (17.0)
GOLD classification of severity of airflow limitation (No of participants)		
Mild/moderate	46	42
Severe	45	42
Very severe	37	44
MRC dyspnoea score (No of participants, %)†		
1 (least breathless)	4 (3)	1 (1)
2	23 (18)	26 (20)
3	31 (24)	27 (21)
4	24 (19)	31 (24)
5 (most breathless)	45 (35)	43 (34)
One or more comorbid conditions (No of participants, %)	78 (61)	91 (71)
No COPD admissions in previous year (mean, SD)‡	2.3 (2.1)	2.5 (2.6)
Smoking status (No of participants, %)		
Never smoked	2 (2)	0 (0)
Ex-smoker	89 (70)	98 (77)
Current smoker	37 (29)	30 (23)
Scottish Index of Multiple Deprivation (No of participants, %)§		
1 (most deprived)	39 (31)	33 (26)
2	36 (28)	37 (29)
3	26 (20)	17 (13)
4	9 (7)	20 (16)
5 (least deprived)	17 (13)	21 (16)
Questionnaires (mean, SD)		
SGRQ	68.6 (16.6)	68.8 (15.2)
HADS (anxiety)	9.8 (5.2)	9.6 (4.6)
Depression	8.9 (4.4)	8.2 (4.1)
SECD6	5.0 (2.2)	5.2 (2.3)
MARS	24.0 (2.1)	23.8 (1.8)
LINQ	7.8 (3.3)	7.8 (3.4)

SD=standard deviation; GOLD=Global Initiative for Chronic Obstructive Lung Disease.

*Telemonitoring n=126, control n=128.

†Telemonitoring n=127, control n=128.

‡Telemonitoring n=127, control n=127.

§Telemonitoring n=127, control n=128.

Table 2| Admissions and deaths per patient over one year

	Telemonitoring (n=128)*	Control (n=128)	Adjusted point estimate (95% CI)	P
Time to first hospital admission (days; median, IQR)				
Admission with an exacerbation of COPD	362 (131 to >365)	361 (113 to >365)	0.98 (0.66 to 1.44)†	0.92
Admission with an exacerbation of COPD or death	339 (131 to >365)	287 (102 to >365)	0.87 (0.61 to 1.27)†	0.46
No of hospital admissions (mean, SD)				
Admission with a primary diagnosis of COPD exacerbation	1.2 (1.9)	1.1 (1.6)	1.10 (0.78 to 1.56)	0.59
Admission in which COPD was the primary reason or a factor in the admission	1.5 (2.3)	1.3 (1.8)	1.14 (0.82 to 1.60)	0.43
All cause admissions	2.2 (2.9)	2.0 (2.2)	1.08 (0.80 to 1.45)	0.63
Duration of hospital admissions (days; mean, SD)				
Admission with a primary diagnosis of COPD exacerbation	9.5 (19.1)	8.8 (15.9)	1.03 (0.71 to 1.50)	0.88
Admission in which COPD was the primary reason or a factor in the admission	11.9 (22.7)	10.5 (18.5)	1.04 (0.71 to 1.51)	0.85
All cause admissions	16.2 (27.2)	14.0 (20.8)	1.05 (0.75 to 1.48)	0.78
Deaths (No, %)	16 (13)	21 (16)	0.66 (0.29 to 1.48)‡	0.31

IQR=interquartile range; SD=standard deviation.

*Reference group.

†Adjusted hazard ratio (95% confidence interval) for time to hospital admission.

‡Adjusted odds ratio (95% confidence interval) for number of deaths.

Table 3| **Questionnaire data**

Questionnaire and trial group	At baseline (mean, SD)	At 12 months after randomisation (mean, SD)
SGRQ*		
Telemonitoring (n=105)	67.2 (16.6)	68.2 (16.3)
Control (n=100)	68.0 (16.0)	67.3 (17.3)
HADS (anxiety)†		
Telemonitoring (n=105)	9.8 (5.3)	9.6 (5.0)
Control (n=100)	9.4 (4.7)	9.1 (5.1)
HADS (depression)‡		
Telemonitoring (n=105)	8.8 (4.3)	9.1 (4.6)
Control (n=100)	8.3 (4.3)	8.4 (4.2)
SECD6§		
Telemonitoring (n=105)	5.1 (2.1)	5.0 (2.2)
Control (n=100)	5.3 (2.2)	5.3 (2.5)
LINQ¶		
Telemonitoring (n=104)	7.9 (3.3)	6.9 (3.1)
Control (n=96)	7.7 (3.5)	6.8 (3.6)
MARS**		
Telemonitoring (n=104)	24.0 (2.0)	24.0 (1.7)
Control (n=101)	23.6 (1.9)	23.7 (1.9)

Data include only participants who had complete information for each respective questionnaire at both time points. Non-completion at one year was due to death (n=37), withdrawals from trial (n=4), and participants who declined to complete final questionnaires (n=10).

*Measures respiratory health related quality of life on a scale of 100 (greatest impairment) to 0.

†Assesses anxiety: scores ≤7 are normal, ≥11 indicate significant anxiety.

‡Assesses depression: scores ≤7 are normal: ≥11 indicate significant depression.

§Assesses confidence in ability to self manage symptoms on a scale of 1 (low self efficacy) to 10 (high self efficacy).

¶Measures information needs of people with COPD on a scale of 0 (low needs) to 25 (high needs).

**Assesses adherence to treatment on a scale of 0 (low adherence) to 5 (high adherence).

Table 4| Logistics of installing telemonitoring equipment and training participants

	No of days or participants
Time period (days; mean, SD)	
Time from randomisation to installation of broadband line and telemonitoring equipment	56 (30)
Time from installation of equipment to completion of training	20 (21)
Time from randomisation to commencing telemonitoring	79 (48)
Participants	
Participants randomised to telemonitoring	128
Participants for whom equipment was successfully installed	113
Reasons for non-installation of equipment: moved to nursing home, residential care, or staying with relatives (n=3); participant declined (n=6; four participants were unhappy with equipment or installation process); died before equipment was installed (n=2); participant was too ill when equipment was due to be installed (n=2); installation was unsuccessful or too expensive to install broadband (n=2)	—
Participants who received training	109
Reasons for no training: participant declined training and equipment was withdrawn (n=2), participants was too ill when training was scheduled (n=2), training was unsuccessful and equipment was withdrawn (n=1)	—
Participants whose equipment was withdrawn	8
Reasons for withdrawal: repeated malfunctioning of equipment (n=1); participant felt restricted by the home based equipment (n=1); on advice of clinician because of inconsistent readings, increasing anxiety (n=3); additional health problems made use of telemonitoring impossible or inappropriate (n=4)	—

SD=standard deviation.

Table 5| **Contacts with the telemonitoring services for patients under the care of the Edinburgh Community Respiratory Team and Midlothian nurses**

	Telemonitoring (n=97)	Control (n=92)
Contacts not related to alerts from telemonitoring		
Total No of contacts		
Telephone consultations	510	353
Home visits	821	681
Video link	2	—
Other contacts	6	6
No of contacts per patient (mean, SD)		
Telephone consultations	5.26 (4.70)	3.84 (5.73)
Home visits	8.46 (8.72)	7.40 (7.72)
Video link	0.02 (0.14)	—
Other contacts	0.06 (0.24)	0.07 (0.29)
Duration of contacts (minutes; mean, SD)		
Telephone consultations	6.70 (6.82)	7.95 (9.71)
Home visits	33.69 (16.02)	34.58 (16.13)
Video link	25.00 (7.07)	—
Other contacts	36.67 (41.55)	45.00 (42.31)
Contacts in response to alerts from telemonitoring		
Total number of contacts		
Telephone consultations	2326	—
Home visits	113	—
Video link	0	—
Other contacts	2	—
No of contacts per patient (mean, SD)		
Telephone consultations	23.98 (22.34)	—
Home visits	1.16 (2.02)	—
Video link	0 (0)	—
Other contacts	0.02 (0.14)	—
Duration of contacts (minutes; mean, SD)		
Telephone consultations	4.44 (3.84)	—
Home visits	28.71 (16.99)	—
Video link	—	—
Other contacts	4.50 (0.71)	—

Figures

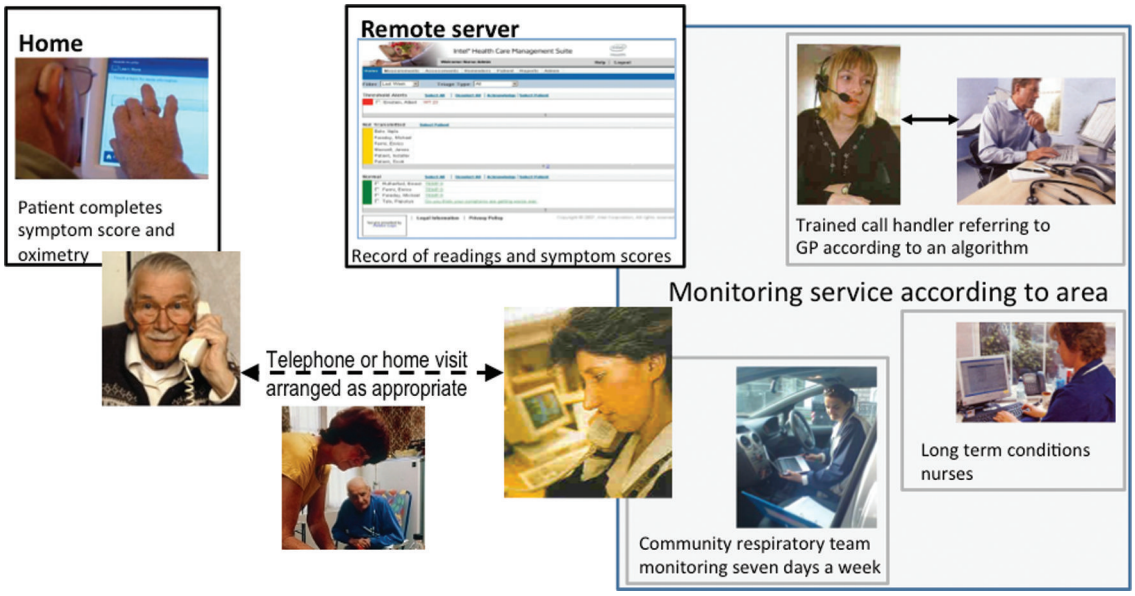

Fig 1 The Lothian COPD monitoring system.[27] Reproduced with permission from reference 27

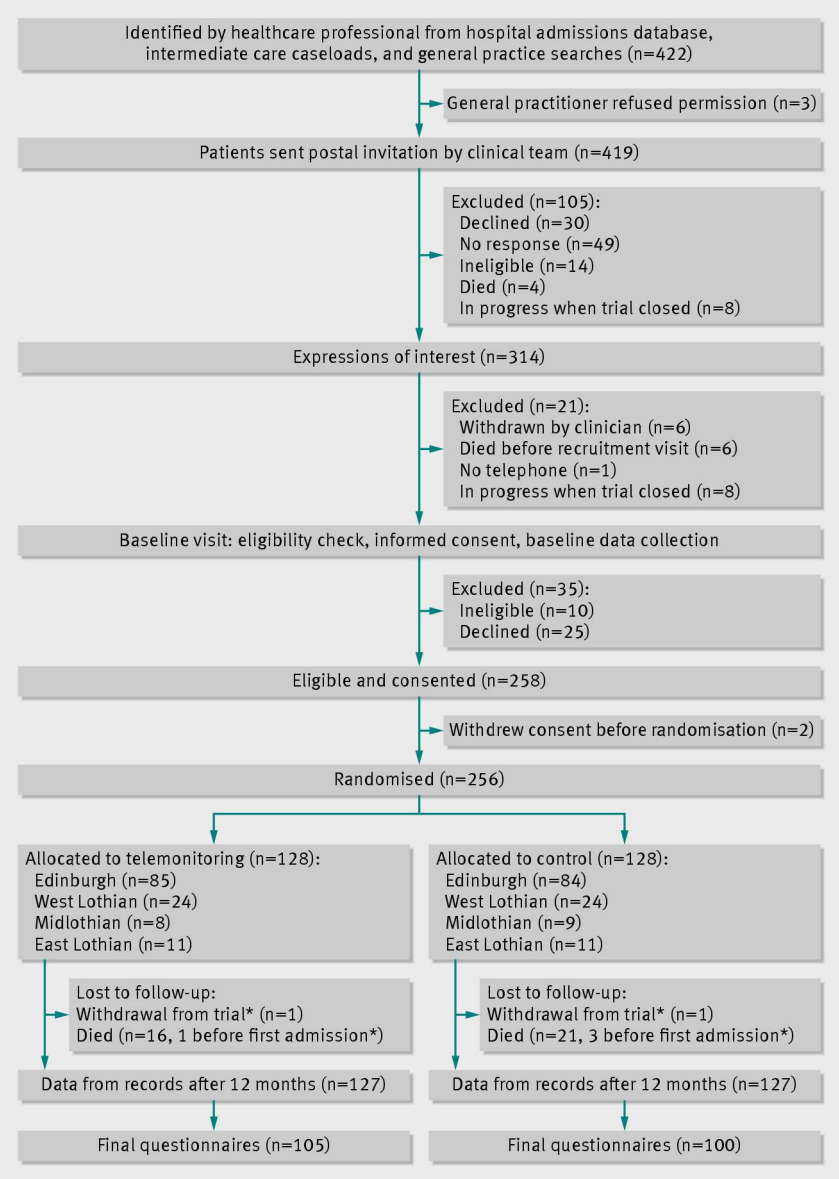

Fig 2 Flow of participants through the trial. *Intention to treat analysis censored patients who died or withdrew before a COPD admission

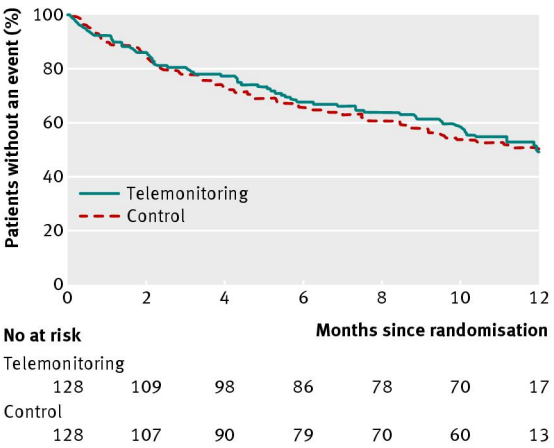

Fig 3 Kaplan-Meier curves showing time to first admission with an exacerbation of COPD

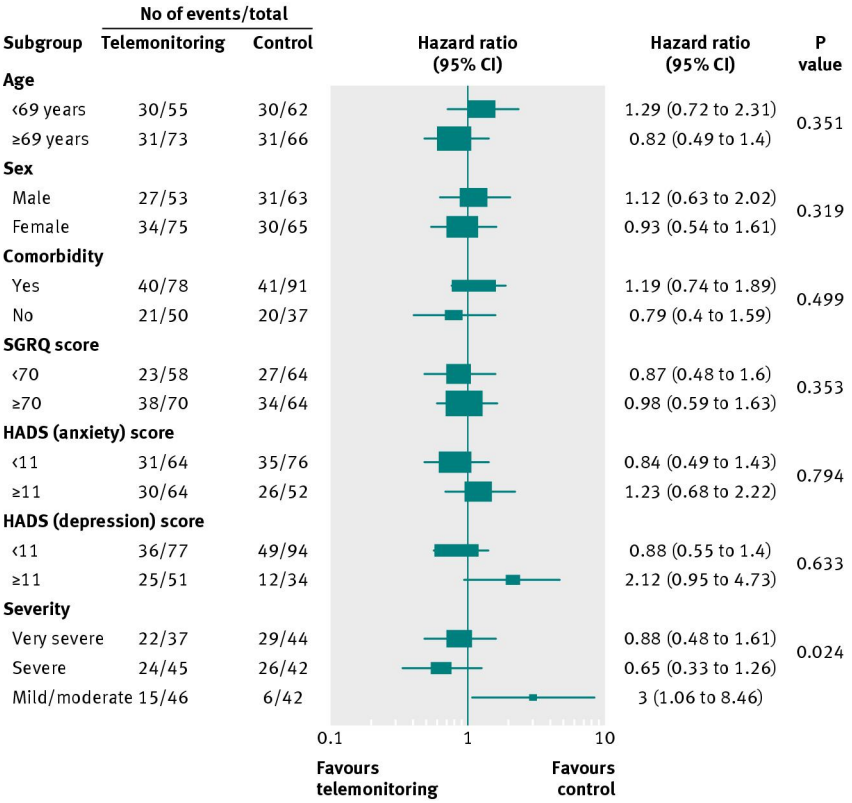

Fig 4 Subgroup analyses on primary outcome