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Chronic obstructive pulmonary disease (COPD): The impact of a telemetric COPD monitoring service

Submission date 07/12/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/01/2009	**Overall study status** Completed	
Last Edited 27/09/2018	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Hilary Pinnock

Contact details
Centre for Population Health Sciences: GP Section
University of Edinburgh
20 West Richmond Street
Edinburgh
United Kingdom
EH8 9DX
+44 (0)131 650 8102
hilary.pinnock@ed.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ARPG/07/3

Study information

Scientific Title
Chronic obstructive pulmonary disease (COPD): The impact of a telemetric COPD monitoring service - a randomised controlled trial with nested qualitative study

Acronym
TELESCOT (TELEmetric supported Self-monitoring of long-term COndiTions) - COPD

Study objectives
Aims:
To investigate the clinical effectiveness, and social and service impact of introducing telemetry-aided, supervised, self-monitoring for chronic obstructive pulmonary disease (COPD) in primary care.

Research Questions: Randomised Controlled Trial
In people with moderate to severe COPD, does tele-supported self-monitoring compared to usual care:
1. Reduce the time to re-admission, and the number and length of hospital admissions and exacerbations?
2. Improve disease-specific quality of life
3. Reduce anxiety and depression?
4. Improve patient knowledge and self-efficacy?
5. Engage patients in self-care and improve compliance?
6. Represent a cost-effective use of NHS resources?

Qualitative Study:
1. What are the experiences of people with COPD and opinions of this service including impact on behaviour, mood, positive and negative experiences and change in relationship with their healthcare provider?
2. What are healthcare providers' experiences and opinions of this service?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lothian Research Ethics Committee, approved on 18/11/2008 (ref: 08/S1101/60)

Study design
Single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease

Interventions
This is a one year researcher-blinded randomised controlled trial.

Intervention group
Patients in the intervention group will be given a modified "tablet" touch screen computer with video capability which is linked by broadband to a secure N3 connection to the internet. Shortly after the tele-monitoring equipment has been installed in their homes, patients allocated to the intervention group will be visited at home by the clinical team responsible for care to instruct them in its use. They will be given a written management plan and an emergency supply of antibiotics and steroids will be requested from the patients' own GP.

Daily (normally mornings) the patient will use the telemonitoring system to record symptoms and use of medication using a touch screen questionnaire and monitor peak flow and oxygen saturation using linked validated instruments. This information will be sent by the secure internet connection to an NHS server which is accessible via a high level password to the specialist respiratory clinicians involved in the care of the patients. The specialist respiratory team will routinely survey the on-line data every day and remind patients if they have not sent information or contact them if questionnaire responses and physiological parameters fall outside the expected range. Following discussion with the patient and repeat of physiological measurements (if required) appropriate clinical management will be instituted.

Control group:
Patients allocated to the control group will receive the same written management plan and will be instructed in its use. An emergency supply of antibiotics and steroids will be arranged with the patients' own GP. Specialist respiratory nurses/physiotherapists will provide comparable care for the control patients as for the intervention group, accessed though via the standard routes of communication, the only difference being that control group patients will not use the tele-monitoring system.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The time until first hospital admission with a primary diagnosis of an exacerbation of COPD up to one year post-randomisation.

An exacerbation is a sustained worsening of the patient's symptoms from his or her usual stable state that is beyond normal day-to-day variations, and is acute in onset. Commonly reported symptoms are worsening breathlessness, cough, increased sputum production and change in sputum colour. The change in these symptoms often necessitates a change in medication.

An exacerbation is defined as being the 'primary diagnosis' if the presenting symptoms are consistent with, and the patient is treated for an acute exacerbation of COPD, and if no other disease was treated as a priority.

Secondary outcome measures

1. Exacerbations and admissions
1.1. The time until first hospital admission with a primary diagnosis of an exacerbation of COPD or all-cause deaths up to one year post-randomisation
1.2. The difference in mean number of bed-days for emergency admissions with a primary diagnosis of COPD during one calendar year
1.3. The number of hospital admissions with a primary diagnosis of COPD during one calendar year
1.4. The number and duration of admissions in which COPD is listed in the discharge letter as a factor in the admission (i.e., not necessarily the primary diagnosis) during one calendar year
1.5. The number of exacerbations (defined as a sustained worsening of the patient's symptoms necessitating a change in medication) during one calendar year
1.6. Proportion of deaths at one year. Cause of death will be taken from the primary and/or secondary care clinical records.

2. Quality of life
2.1. St George's Respiratory Questionnaire (SGRQ) at one year. The SGRQ is a validated and widely used instrument which measures health impairment (symptoms, activities and impacts) in patients with COPD on a scale: 100 (greatest impairment) to 0, is responsive to change, with a minimum important difference (MID) of 4.
2.2. Proportion of patients with an improvement of 4 or more units in the SGRQ at one year.

3. Anxiety and depression
3.1. Hospital Anxiety and Depression Scale (HADS) at one year. The HADS is a validated questionnaire with independent scales for anxiety and for depression (scores >=11 indicate significant anxiety [or depression]; scores <=7 are normal)

4. Patient knowledge and self-efficacy
4.1. Self-Efficacy for Managing Chronic Disease 6-item scale (SECD6) at one year. The SECD6 assesses confidence in ability to self-manage symptoms and impact on life on a scale of 1 (low self-efficacy) to 10 (high). It has been used in a range of long-term conditions.
4.2. Lung Information Needs Questionnaire (LINQ) at one year. The LINQ measures the information needs of people with COPD on a scale of 0 (low needs) to 25 (high). Scores correlate with the healthcare services accessed.

5. Engagement with process
5.1. Medication Adherence Report Scale (MARS) at one year. MARS-5 is a 5-item reduction of the validated MARS scale which has good reliability and validity in populations with respiratory conditions, and other chronic diseases. It assesses adherence to medication on a 5-point scale: higher scores indicating higher levels of adherence.
5.2. Compliance with monitoring and self-management will be assessed using the electronic record of symptoms and the action taken (or not) during one calendar year

6. Cost-effectiveness
6.1. Cost per Quality Adjusted Life-Years (QALYs) at one year. QALYs are derived from responses to the Euroqol EQ-5D.
6.2. Use of healthcare resources during one calendar year will be extracted from the patients' primary and secondary care records."

Overall study start date
01/01/2009

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Both males and females, no age limits
2. Patients registered with Lothian general practices admitted with an exacerbation of COPD as the primary diagnosis to one of the three acute hospitals in Lothian in the previous year

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Patients with other significant lung disease
2. Unable to consent
3. Unable to use the technology (e.g., inability to use the technology or complete the questionnaires)
4. Other more significant medical/social reasons at the GPs discretion

Date of first enrolment
01/01/2009

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Centre for Population Health Sciences: GP Section
Edinburgh
United Kingdom
EH8 9DX

Sponsor information

Organisation
University of Edinburgh (UK)

Sponsor details
c/o Dr Elspeth Currie
Edinburgh Clinical Trials Unit
Queen's Medical Research Institute
47 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4TJ
+44 (0)131 242 9446
ECTU@ed.ac.uk

Sponsor type
University/education

Website
http://www.ed.ac.uk

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, NHS Applied Research Programme Grant (UK) (ref: ARPG/07/3)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2009		Yes	No
Results article	results	01/12/2012		Yes	No
Results article	results	17/10/2013		Yes	No
Results article	results	05/07/2014		Yes	No
Results article	results	21/09/2018		Yes	No