ISRCTN89287773 https://doi.org/10.1186/ISRCTN89287773

Effectiveness and cost effectiveness of a telemedicine hospital at home intervention

Submission date
31/01/2012

Recruitment status
No longer recruiting

Registration date
05/04/2012

Overall study status
Completed

Last Edited
21/12/2017

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a collection of lung diseases that cause breathing difficulties. A COPD exacerbation is a sudden worsening of COPD symptoms that typically lasts for several days and often requires emergency treatment. We need to identify patients whose condition worsens following discharge from hospital in order to trigger early effective treatment and avoid unnecessary re-admissions to hospital. Telemedicine is the use of remote technologies for patient diagnosis and treatment. Studies of Hospital at Home (HAH) services have found that clinical assessment can be carried out safely in the home. It is not known whether patients at an early stage of an exacerbation can be identified and linked with HAH services to prevent admission while safely delivering appropriate care. The aim of this study is to determine whether a telemedicine-triggered hospital at home intervention is effective and cost effective at preventing re-admission to hospital.

Who can participate?
Patients aged 40-100 being discharged from University Hospital Aintree following an exacerbation of COPD.

What does the study involve?
Participants will be randomly allocated to receive either standard care or standard care plus telemedicine. Our telemedicine technology will allow us to monitor patients non-invasively in their own homes for the 3 months following discharge. This technology will pick up any signs of deterioration and then trigger a hospital at home service assessment. Depending on the patient' s condition and needs following this assessment they will either be admitted, treated at home or receive ongoing monitoring. We will compare this intervention with current standard care and study the effects on hospital readmissions as well as a wide range of other outcomes that are important to patients including quality of life. We will also look at the impact of the technology on the patients experience, their family and the healthcare professionals working with them. Participants in both groups will be contacted at 6 weeks and reviewed at 3 months by the study doctor and will have a contact number for advice about the study (and telemedicine device in the intervention group) at other times.

What are the possible benefits and risks of participating?
For participants who have been allocated to the standard care plus telemedicine arm, we would expect that the benefits to them would include an early review in their own homes with a view to treating a possible exacerbation early, thus preventing the need for re-admission to hospital. We do not expect any major risks to patients as we will be using an experienced HAH team who are well established within the hospital trust.

Where is the study run from?
Aintree Chest Centre (UK).

When is study starting and how long is it expected to run for?
March 2012 to September 2012.

Who is funding the study?
This pilot study has no formal funding, but is being supported by Air Products and Docobo.

Who is the main contact?
Dr R Angus

Contact information

Type(s)
Scientific

Contact name
Dr Robert Angus

Contact details
Aintree Chest Centre
University Hospital Aintree NHS Foundation Trust
Longmoor Lane
Liverpool
United Kingdom
L9 7AL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Effectiveness and cost effectiveness of a telemedicine at home intervention to prevent readmissions in chronic obstructive pulmonary disease: a randomised, parallel group, standard practice controlled pilot study

Study objectives

The importance of COPD to the NHS has been acknowledged by the publishing of An Outcomes Strategy for Chronic Obstructive Pulmonary Disease (COPD) and Asthma in England in 2011.

Chronic obstructive pulmonary disease (COPD) affects around three million people in the UK. It causes considerable morbidity and around 30,000 deaths each year. Exacerbations of COPD are common and often require emergency treatment. They have major adverse impacts on health, quality of life and are one of the commonest reasons for admission to hospital in the UK. This is recognised as being a major burden on individual patients and their families. National audits have consistently found that readmission following discharge is also common with around 30% of patients needing re-hospitalisation within 3 months of discharge and deaths among this group are not uncommon.

The annual direct cost of COPD care to the NHS is about £800 million with inpatient care representing over half this cost making COPD one of the most expensive conditions treated by the NHS. There is an additional financial impact on the wider economy with around 24 million working days lost every year.

Preventing readmissions of patients being discharged from hospital following an exacerbation is important for the health and quality of life of the individual patient and for reducing costs to the NHS and UK economy. Strategies that would allow the early identification of a patient who is deteriorating post discharge are needed if early effective treatment is to be triggered and preventable worsening and unnecessary readmissions are to be avoided. The Outcomes Strategy for Chronic Obstructive Pulmonary Disease (COPD) and Asthma in England in particular identifies the role of "proactive care and management" as a key principle.

Telemedicine - use of remote technologies for patient diagnosis and treatment - has been widely studied and successfully used in chronic disease management. A number of studies have explored the use of telemedicine in COPD and these have found that remote monitoring is acceptable, feasible and that automated video questions and physical monitoring can be used to alert care teams to changes in a patient's condition and thus trigger an intervention.

Trials of Hospital at Home (HAH) have demonstrated that clinical assessment can be carried out safely in the home, that HAH is popular among patients and around 30% of patients admitted to hospital could be cared for by HAH with similar health outcomes. HAH is recommended in NICE and British Thoracic Society guidelines.

Most HAH teams provide early supported discharge although some prevent admissions by intercepting patients in the emergency department. What is not known is whether patients at an early stage of an exacerbation can be identified and linked with HAH services to prevent admission while safely delivering appropriate care. Given that HAH successfully manages 90% of cases referred, the potential for reducing admission is high.

A key issue is how HAH could be linked to patients in a timely way and daily telemedicine could provide an answer. Patients recently discharged from hospital are at high risk of readmission (around 30 and 45% in the first 3 and 12 months respectively) and are a logical group to target with admission prevention and HAH. Given the bulk of readmissions occur in the first 3 months a

telemedicine and HAH intervention, over this period, offers the prospect of targeting care efficiently and cost effectively.

We estimate that a 3 month telemedicine and HAH intervention if incorporated into usual NHS care would cost £650 per patient. We would expect 30 out of 100 patients to exacerbate and of these we estimate a minimum of 10 readmissions could be prevented.

Over the last 15 years a number of trials have reported on the potential of telemedicine in the management of COPD. As telecommunications technology has evolved this has developed from the use of the telephone with automated calling, to video calling and now interactive internet based technology where patients can respond by answering questions and uploading personal physiological data. Generally telemedicine approaches were acceptable to patients and were able to alert on a change in clinical state that is then relayed to clinicians in an automated fashion. These trials are reviewed in a number of systematic reviews (1-3). In a recent report from Wales primary care contacts were reduced and there was a trend towards reduced emergency attendances and admissions (4). The English national whole system demonstrator for telemedicine has completed it included COPD
Patients. Preliminary reports in the BMJ (5) and at the King's Fund Telemedicine conference in March 2011(6) suggesting that this benefits patients with improved outcomes with an impact on healthcare utilisation, the full results are expected imminently. We were among the first to explore in a pilot fashion whether telemedicine reviews could substitute for nurse visits in COPD exacerbations including assessment of the issues raised for staff and patients (7). Several additional trials are underway in UK one examining does home telemedicine reduce healthcare use in recurrent hospital attendees with COPD and another to see if reduces the burden on nurse teams after admission (8,9). The challenge is how to harness this potential in a cost effective way for the benefit of patients.

The intervention of Hospital at Home (HAH) for COPD has also been developed and validated in randomised controlled trials, during the last 15 years, including locally where we were the first team in England to report on the success of this approach (10). Schemes vary in offering admission avoidance by intercepting patients in the Accident and Emergency Departments and or early supported discharge reducing length of stay. Others offer admission avoidance in the community in known COPD patients the team attending at the request of the GP (11). Approaching thirty percent of admissions are suitable for HAH care and in those eligible for this ninety percent of exacerbations resolve while under this care. This approach is recommended as standard in the NICE and British
Thoracic Society evidence based guidelines (12,13). In studies, most patients reported they preferred the home care option and this extension and availability after admission is also likely to be welcomed as a gain for patients.

The high incidence of readmissions in the first 3 months after admission with COPD is a major challenge for the NHS; given the real time monitoring and alert possible using telemedicine we postulate this combined with a response from a HAH team, if required, would reduce these admissions. Especially as studies to date confirm that telemedicine does identify the development of an exacerbation in its early phase so HAH is likely to be efficacious. Given the strength of the available evidence for telemedicine in this role and the efficacy of HAH in COPD exacerbations we suggest that this hypothesis should be tested.

The study is necessarily of an open design and so particular effort will be made to minimise risks of bias such as by providing participants in both arms with a carefully worded participant information sheet, collecting hard outcome data (e.g. hospital admissions) and blinding trial staff involved with collecting outcome data where feasible. In particular care will be given to

ensure people in the standard care arm will have a personal action plan for exacerbations and will reminded how to access urgent care.

We believe the findings would have external validity beyond the local trial setting since patients with COPD have similar characteristics across the UK and if found to be effective and cost effective the intervention could be replicated elsewhere. As we indicate the trial findings would allow for assessment of the practicalities of introducing this intervention on a much larger scale for a proposed multicentre randomised, standard practice controlled trial.

The ultimate and principal research objective is to determine whether a telemedicine triggered hospital at home intervention is effective and cost effective at preventing readmissions of patients being discharged from hospital following an exacerbation compared to current standard practice. The pilot is to confirm the operational feasibility of the protocol as a means monitoring from the healthcare provider perspective and functionality from the patient viewpoint.

If feasibility is confirmed we propose subsequently to determine the cost effectiveness of the intervention using an economic analysis performed from an NHS and Personal Social Services perspective which will help inform policy and decision makers. In addition we will assess the impact and acceptability of the technology on patients, their lay carers and the hospital at home team. In order to do this we will employ quantitative and qualitative psychological methods such as Interpretative Phenomenological Analysis and Thematic Analysis as well as a number of quantitative scores.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pilot randomised single-centre standard practice controlled trial with two parallel treatment arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Prevention

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

Our proposed research will study innovative telemedicine technology which will allow us to monitor patients non-invasively in their own homes for the 3 months following discharge. This technology will pick up any signs of deterioration and then trigger a hospital at home service assessment. Depending on the individual patient's condition and needs following this assessment they will be admitted, treated at home or receive ongoing monitoring.

We will compare this intervention with current standard care and study effects on hospital readmissions as well as a wide range of other outcomes that are important to patients including quality of life. We will also look at the impact of the technology on the patients experience, their family and the healthcare professionals working with them.

Data recorded by this device will be transmitted to a central monitoring facility and trigger an alert when changes suggestive of an exacerbation are detected (specifically increased symptoms and deteriorating physiological parameters including pulse and respiratory rate, oxygen saturations or raised temperature). The alert will lead to review of the patient using criteria similar to those used by our current hospital at home service and depending on the outcome of this review receive ongoing monitoring, step up in treatment or hospital admission. Participants in both groups will be contacted at 6 weeks and reviewed at 3 months by the trial doctor for data collection and will have a contact number for advice about the trial (and telemedicine device in the intervention group) at other times.

Standard Care:
Participants randomised into the standard care arm will receive two invitations to clinic, at 6 weeks and 3 months following inclusion into the study. At these visits the following assessments will be made
1. Extended MRC dyspnoea score
2. Quality of life, measured by the COPD Assessment Test
3. Days off work due to COPD symptoms
4. Anxiety and depression assessed using the Hospital Anxiety and Depression scale, Becker's depression inventory and Becker's hopelessness score
5. Number of unscheduled visits to primary care due to worsening COPD symptoms
6. Number of unscheduled secondary care visits, hospital admissions due to worsening COPD symptoms

Standard Care plus Intervention:
Participants randomised into the standard care plus telemedicine arm will also be invited to clinic visits at the same time intervals to assess all of the above. In addition to this, they will be provided with a telemedicine device which will monitor their vital signs on a daily basis including
1. Transcutaneous oxygen saturations
2. Heart rate
3. Temperature
4. Respiratory rate (daily) and spirometry (weekly), will also be measured as part of feasibility testing, but are not currently included as part of the triggers for intervention

Participants will be asked to take the measurements at the same time daily, and will be taken 20 minutes after the participant is sitting at rest, using their oxygen (long term oxygen and not short burst or ambulatory if prescribed), has taken inhalation treatment

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Feasibility of the protocol: Our intention is to perform a much larger study following this pilot study with defined outcome measures. For the purposes of this pilot study these outcome measures will be assessed as far as is practicable, with the added intention of assessing feasibility of the study as well acceptability of the intervention to participants and/or their carer's.

Secondary outcome measures
We will determine the clinical effectiveness of the intervention using criteria that are important to people with COPD and the NHS and specifically the effects within three months of discharge on:

Number of patients admitted to hospital within 3 months of discharge following an admission for a COPD exacerbation
1. Number of patients admitted to hospital
2. Number of patients admitted to hospital within 3 months of discharge following an admission for a COPD exacerbation
3. Duration of hospital admissions (days per admission and total days within 3 months)
4. Number of patients treated for COPD exacerbations as defined by a step up from their usual maintenance treatment
5. Breathlessness using extended MRC dyspnoea score (administered at 6 weeks and 3 months)
6. Quality of life as measured by the COPD Assessment Test (administered at 6 weeks and 3 months)
7. Days off work due to COPD symptoms (number/participant/month)
8. Anxiety and depression assessed using the Hospital Anxiety and Depression scale, Becker's depression inventory, Becker's hopelessness score (administered at 6 weeks and 3 months)
9. Rate of unscheduled primary care consultations initiated by the patient because of worsening COPD symptoms (number/participant/month)
10. Rate of unscheduled secondary care attendances initiated because of worsening COPD symptoms (mean number of emergency department visits, hospital admissions, and intensive care unit admissions per participant/month)
11. Concordance with the telemedicine and hospital at home interventions assessed using equipment usage logs and hospital at home records
12. Health outcome, as determined by the EQ-5D
13. Patient satisfaction using a semi structured questionnaire

Assessed at 6 weeks and 3 months of discharge following a hospital admission for a COPD exacerbation.

Overall study start date
01/03/2012

Completion date
05/09/2012

Eligibility

Key inclusion criteria
Trial participants will be recruited from University Hospital Aintree, at the point of their intended discharge following standard care during their initial admission prior to participation in the trial.
Selection criteria will be broadly inclusive to maximise external validity. Participants must have:
1. A confirmed diagnosis of COPD
2. Be at the point of discharge from hospital following an exacerbation of COPD, excluding patients who require NIV acutely during the admission
3. Patients discharged with support from the HAH team will also be included as this is currently standard practice within the trust
4. Have and are able to use a telephone
5. Are able to use the telemedicine device and peripherals at entry
6. The age range will be between 40-100yrs of both gender

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Participation in this trial after a previous admission
2. Current participation in another clinical trial
3. Patients who require NIV acutely during the admission or chronically
4. A diagnosis of pneumonia on the current admission
5. Serious uncontrolled co-morbidity and situations where the intervention would clearly be inappropriate such as where end of life care is being provided
5. Pregnancy

Date of first enrolment
01/03/2012

Date of final enrolment
05/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Aintree Chest Centre
Liverpool
United Kingdom
L9 7AL

Sponsor information

Organisation
Aintree University NHS Foundation Trust (UK)

Sponsor details
R&D Department
c/o Michelle Mossa
Clinical Sciences Building
Longmoor Lane
Liverpool
England
United Kingdom
L9 7AL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02h67vt10

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Aintree (UK)

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