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ADAPT (After DischArge Pulmonary Telehealth): home telemonitoring follow-up for chronic obstructive pulmonary disease (COPD) patients post hospital discharge

Submission date 01/10/2013	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol
Registration date 07/11/2013	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 23/01/2019	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a common cause of illness and death, with sufferers being extensive users of the healthcare system. Studies have suggested that telemonitoring (Tm) can deliver clinical benefits to patients living with chronic conditions including COPD. However, what has not been clearly established for best clinical benefit is:
1. Which should be the target patient population?
2. Which measurements are most appropriate and useful? (e.g., spirometry, pulse oximetry, temperature, symptom management questions and quality of life questions)
3. The added value of video consultation.
4. The optimal duration for comprehensive Tm on an ongoing basis.
5. How could Tm be better utilised to reflect an individual patient's health status at any given time?
This study aims to address these issues.

Who can participate?
The study aims to recruit 200 patients over the age of 18 who have been discharged from any of the four district general hospitals in the Hywel Dda University Health Board in Wales (Bronglais, Glangwili, Prince Philip and Withybush) following admission for an acute exacerbation (worsening) of COPD (AECOPD). In addition, 200 historical controls who have been admitted following an AECOPD will be recruited from any of the four hospitals.

What does the study involve?
Upon discharge to within 7 days of discharge from hospital or within 7 days of stopping oral steroids or antibiotics in the community, patients are provided with a telemonitoring package that may include video conferencing, together with a thermometer and a pulse oximeter. Each day the patient will answer their symptom management questions, record their temperature and pulse oximetry readings and upload this data according to their agreed management plan before accessing a video or telephone consultation with a healthcare member of staff. The

intervention (provided service) represents three levels of intensity telemonitoring with specific duration for each level:
High Level Tm: daily tele-consultation (preferably via video consultation or telephone if not possible), pulse oximetry and daily symptom management questions for 10 working days after discharge.
Moderate Level Tm: daily pulse oximetry and symptom management questions for up to 12 weeks after discharge.
Low Level Tm: optional symptom management questions and behaviour prompts via text messages or website links for up to 12 months after discharge.
Uniquely, patients can be transferred between these levels (both up and down) according to Tm results and clinical discretion. The controls both prospective and historical will not receive any intervention (i.e., Tm), but their medical notes will be used to establish if there has been a reduction in the number of readmissions for COPD exacerbations.

What are the possible benefits and risks of participating?
The aim will be to deliver a more efficient and effective service for patients. It will be emphasised to patients that the Tm is not a replacement for their usual service delivery, rather that is in combination with standard support. Furthermore, all patients will be treated according to the clinical discretion of their primary care doctors, specialist nurses and hospital specialists. There should be no risks in participating, the interventions provided are intended to supplement rather than replace existing clinical supervision.

Where is the study run from?
The study will be run from the Hywel Dda University Health Board in Wales the intervention patients will be recruited from any of the four district general hospitals. The historical controls will be also be recruited from any of the four district general hospitals within the Health Board.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will begin in late 2013, with the aim of recruiting all patients over a 12-month period. Recruits to the study will then be followed up for 12 months post recruitment. The study will run until December 2016.

Who is funding the study?
European Commission

Who is the main contact?
Dr Keir Lewis
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Study website
http://ec.europa.eu/information_society/apps/projects/factsheet/index.cfm?project_ref=325215

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11/WMW01/XX

Study information

Scientific Title
Does flexible home telemonitoring (Tm) after hospital discharges for chronic obstructive pulmonary disease patients reduce hospital re-admission? A clustered, interventional trial

Acronym
ADAPT

Study objectives
It is hypothesised that the introduction of a short-term intensive telemonitoring (Tm) programme followed by a less intensive 'step-down' approach to Tm for patients discharged from hospital after an acute exacerbation reduces subsequent hospital re-admission.

The null hypothesis is that there will be no difference in admission rates between those receiving Tm and those not receiving Tm.

On 13/02/2015 the following changes were made to the trial record:
1. The scientific title was changed from 'Does home telemonitoring (Tm) follow-up after hospital discharge for chronic obstructive pulmonary disease patients reduce hospital re-admission? A clustered observational trial' to 'Does flexible home telemonitoring (Tm) after hospital discharges for chronic obstructive pulmonary disease patients reduce hospital re-admission? A clustered, interventional trial'
2.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dyfed Powys (now Wales REC 7), 16/12/2013, ref: 13/WA/0380

Study design
Clustered observational longitudinal cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

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
For the 'intervention' arm, 200 patients will receive the ability to interact with the Chronic Disease Management Team via the Tm devices following discharge from hospital for an acute exacerbation of their COPD. The Tm is composed of three stages - gold, silver and bronze:
1. High Level Tm (gold): daily tele-consultation (preferably via video consultation or telephone if not possible), pulse oximetry and daily (six) symptom management questions for 10 working days after discharge.
2. Moderate Level Tm (silver): daily pulse oximetry and six symptom management questions for up to 12 weeks after discharge.
3. Low Level Tm (bronze): optional six symptom management questions and behaviour prompts via text messages or website links for up to 12 months after discharge.
Uniquely, patients can be transferred between these levels (both up and down) according to Tm results and clinical discretion.

The Chronic Disease Management Team will have the ability, particularly during the high level Tm stage, to suggest how they may alleviate symptoms/manage their condition better, as the patient and the team will be in direct contact daily using the video conference (or telephone if that is not possible for any reason). An alert email/text is sent to the team if any of the following occur:
1. Pulse rate <50 or >120 bpm
2. Oxygen saturations fall by 6% or more from their discharge baseline
3. Two from six questions are out of range ('worse' or 'more than usual') for two consecutive days

The six symptom questions are:
1. How do you feel today? Better, Usual, Worse
2. Is your breathing: Better, Usual, Worse?
3. Is the amount of your sputum: Better, Usual, Worse?
4. Is your sputum colour: Clear/white, Yellow, Dark Green or Brown?
5. Are you using your reliever inhalers/nebuliser or oxygen: less than usual, same as usual, more

than usual
6. Are you taking any extra antibiotics or steroids at the moment for a chest infection? Yes, No

The controls both prospective and historical will not receive any 'intervention' i.e. Tm, but their medical notes etc will be used to establish if there has been a reduction in the primary outcome, the number of (re)admissions for COPD exacerbations between the Intervention and Comparator Groups after 1 month. The comparator group will also be used to assess the secondary outcome measures.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 13/02/2015:
Number of (re)admissions for COPD exacerbations within 1 month between the intervention and the comparator group (i.e. the historical controls).

Previous primary outcome measures:
Number of (re)admissions for COPD exacerbations within 1 month between the intervention and the comparator groups (i.e. the prospective and historical controls).

Secondary outcome measures
Assessed 12 months after recruitment

Clinical outcomes:
1. Number of admissions (any admission during 12 months)
2. Number of bed days (days of hospitalization)
3. Number of Primary Care professional contacts
4. Number of visits to Emergency Department
5. Number of outpatient visits (consultant or specialist nurse)
6. Other healthcare contacts specific for the region healthcare organization (eg. community specialist nurse, district nurse, etc)
7. Duration of use of the telemedicine device

Organisational impact:
1. Effects on work processes
2. Effect on structural outcomes
3. Staff perception

Economic outcome - the mean/median costs per person.

Patient perception - acceptability of the use of Tm by patients in the intervention group

Overall study start date
01/12/2013

Completion date
01/12/2016

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Current inclusion criteria as of 13/02/2015:
1. Hospitalisation or parental treatment for exacerbation of COPD according to the Global Strategy for Diagnosis, Management, and Prevention of COPD (Reference: 2013 GOLD guidelines).
2. Clinical diagnosis of COPD with at least a 10 pack year smoking history and Forced Expiratory Volume 1 second (FEV1)/Forced Vital Capacity (FVC) less than 70% (ratio of 0.7) and FEV1 less than 80% predicted, recorded within the last 2 years.
3. Optimised on inhalers and other drugs used for COPD according to usual care.
4. Capability to use the Tm devices provided (by the patient or his/her carer, including cognitively able to participate).
5. Aged more than 18 years

Previous inclusion criteria:
1. Hospitalisation for exacerbation of COPD according to the Global Strategy for Diagnosis, Management, and Prevention of COPD (Reference: 2011 GOLD guidelines).
2. Working diagnosis of COPD with at least a 10 pack-year smoking history.
3. Forced Expiratory Volume (FEV)/Forced Vital Capacity (FVC) less than 80% and FEV1 less than 70%
4. Optimised on inhalers
5. Capability to use the telemonitoring devices provided (by the patient or his/her carer, including cognitively able to participate)
6. Men and women over the age of 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
600: 200 patients in the intervention arm; 200 prospective controls; 200 historical controls

Key exclusion criteria
1. Those unwilling or unable to provide written consent
2. Discharged to a locality not covered by the outreach Tm team/hospital (e.g., different geographical area served by another hospital/health institution

3. Discharged to a locality with no mobile phone signal or telephone landline
4. Those unable or unwilling to use Tm after teaching, but prior to installation
5. Clinician's discretion

Date of first enrolment
01/01/2014

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Hywel Dda University Health Board
Llanelli
United Kingdom
SA14 8QF

Sponsor information

Organisation
Hywel Dda University Health Board (UK)

Sponsor details
Research and Development Department
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Sponsor type
Hospital/treatment centre

Website
http://www.wales.nhs.uk/sitesplus/862/home

ROR
https://ror.org/012gye839

Funder(s)

Funder type
Government

Funder Name
European Commission - The Information and Communication Technologies Policy Support Programme Project reference: 325215

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No