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A new model for continuous care of chronic patients - eCare and eLearning for patients with chronic obstructive pulmonary disease (COPD)

Submission date	Recruitment status	[_] Prospectively registered
14/11/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/12/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/12/2012	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

07/WMW01/53

Study information

Scientific Title

Acronym
Better Breathing

Study objectives
Are home electronic monitoring and electronic learning resources feasible and safe for patients with moderate to severe chronic obstructive pulmonary disease (COPD)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Carmarthenshire LREC gave approval on the 29th October 2007

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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 (COPD)

Interventions
Patients will be randomised into two groups, to either receive standard care or to receive six months telehealth support (doc@HOME), which is an integrated solution for the remote health management of patients with long term conditions and consists of a robust, handheld data collection unit which connects through a standard telephone line at the patient's home to a secure server. doc@HOME is designed to ensure that care follows the patient providing access from anywhere at anytime. Patients will be able to:
1. Complete a system integrated patient tailored questionnaire regarding respiratory status and

upload daily
2. Automated daily uploading of physiological measurements obtained from a pulse oximeter and digital thermometer
3. Receive feedback through the system in the form of text/email-like messages between the patient and clinician in response to uploads that can either be automated or targeted according to the review of information received

All patients will be required to fill in a series of questionnaires (St George's Respiratory Questionnaire, the Hospital Anxiey and Depression Score questionnaire and the ED-5Q questionnaire) to assess health status and quality of life at five timepoints: baseline, 1 month, 6 months, 7 months and 12 months. Together, these take about 30 minutes to complete. These will be delivered in face-to-face interviews by a member of the Chronic Disease Management Team.

The first six months of the study will be the active intervention in which half of the sample will receive the telehealth support, after which there will be six months of passive intervention in order to assess changes in general health status and quality of life.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Are home electronic monitoring and electronic learning resources feasible and safe for patients with moderate to severe Chronic Obstructive Pulmonary Disease (COPD)? Measured at baseline, 1 month and 6 months only.

Secondary outcome measures
1. Does home telemedicine reduce respiratory hospital admissions?
2. Does home telemedicine reduce community specialist team visits?
3. Does home telemedicine improve quality of life and mood?
4. Is home telemedicine cost-effective?

Measured at all timepoints throughout the trial.

Overall study start date
01/11/2007

Completion date
01/03/2009

Eligibility

Key inclusion criteria
Participants (no gender/age specification) will be recruited for the study from the Prince Phillip and West Wales General Hospital Pulmonary Rehabilitation Scheme. The standard inclusion criteria to be accepted through the scheme for pulmonary rehabilitation is patients who:
1. Feel limited by their chest
2. Have a primary physician

3. Spirometric diagnosis of COPD
4. Are on maximal respiratory medications
5. Have no unstable cardiac disease
6. Have no cognitive impairments

In addition, for this project, participants must:
7. Be willing and able to provide informed consent
8. Have a standard telephone line installed in their homes
9. Be willing to have equipment installed in their homes
10. Have attended at least 50% of pulmonary rehabilitation (PR) sessions (aiming for equal baselines)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. No other confounding medical condition to the use of the equipment, e.g. unable to see clearly or touch the screen
2. Not in a nursing or residential institution
3. Participation in any investigational drug trial within one month prior to recruitment
4. Mental condition rendering the subject unable to understand the nature, scope and possible consequences of the study

Date of first enrolment
01/11/2007

Date of final enrolment
01/03/2009

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre

Respiratory Unit
Llanelli
United Kingdom
SA15 3LQ

Sponsor information

Organisation
Informing Healthcare (UK)

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Sponsor type
Government

Website
http://www.wales.nhs.uk/ihc

ROR
https://ror.org/04a496k07

Funder(s)

Funder type
Government

Funder Name
European Community eTEN programme

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	01/02/2010		Yes	No