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Home telemonitoring for patients with chronic obstructive pulmonary disease (COPD)

Submission date	Recruitment status	[_] Prospectively registered
16/11/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/01/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/01/2019	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
N/A

Study information

Scientific Title
Does home telemonitoring reduce healthcare use in recurrent hospital attenders with chronic obstructive pulmonary disease (COPD)? A pilot randomised trial

Study objectives
To see if telemonitor deployment results in fewer admissions to hospital for chronic obstructive pulmonary disease (COPD).

Secondary outcomes:
1. To test the null hypotheses that there is no difference in primary care contacts, emergency room attendances, length of hospital admissions, Chronic Disease Management Team (CDMT) phone calls/visits, quality of life (computerised adaptive testing [CAT], EuroQol instrument [EQ5D]) scores during the 12 months 'telemedicine plus standard care' versus 12 months 'standard care alone'.
2. To record telemedicine usage/concordance during the 12-month monitoring period
3. To estimate cost-effectiveness of telemedicine using changes in EQ5D, CAT scores and healthcare contacts

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dyfed Powys Local Research Ethics Committee pending approval approval pending as of 02/11 /2009

Study design
Randomised controlled cross-over trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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 (COPD)

Interventions

From hospital databases, we will identify 240 patients who have had more than two admissions to any of Prince Philip, West Wales General, Withybush and Bronglais Hospitals within the last 2 years.

Medications will be optimised if not already done. 120 will be randomised to receive telemonitors (Tm's) for 1 year whilst the other 120 receive standard care. After 1 year, the Tm's will be swapped into the homes of the second group (120) in a crossover trial for a further year of monitoring.

Once daily the patients would complete a set of questions relating to COPD symptoms and record their oxygen levels, pulse rate and temperature. The Tm automatically sends the information via a (free) telephone line to a secure internet site. The results are reviewed daily by the home COPD specialist team and if there is any signs of worsening of their condition they would intervene with a phone call followed by a visit and treatment escalation, if appropriate. We hope that earlier intervention may prevent further deterioration, requiring hospital admission or multiple GP visits. The monitors are also set up to generate an email alert to the nurses if any questions or recordings indicate a significant deterioration. All participants are aware that the Tm is not a replacement for their usual actions but to be used as an early warning system and they should seek direct help live in a severe emergency.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The number of hospital admissions

Secondary outcome measures
1. Quality of life measures (EQ-5D and CA-COPD questionnaires) at baseline and every 6 months for 2 years
2. Healthcare contacts - GP visits, outpatient visits and home contacts by the community COPD nurses over the 2 years of the study
3. A cost evaluation will also be undertaken after the 2 years

Overall study start date
04/01/2010

Completion date
03/01/2012

Eligibility

Key inclusion criteria
1. 240 still living subjects with a primary diagnosis of COPD will identified from hospital admissions database
2. Two or more admissions to any of the following hospitals in the last 2 years - Prince Philip; West Wales General; Withybush; Bronglais
3. Diagnosis and reason for admission corroborated by a member of the research team
4. We will include COPD of any severity of airflow obstruction, who have been admitted to

hospital two or more times in the last 2 years
5. Participants must be at least 40 years old, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
240 - 120 in each of the two arms of the study

Key exclusion criteria
1. Inability or refusal to sign informed consent
2. Less than 40 years of age
3. Life expectancy less than 2 years or cognitive/physical impairment that would preclude home telemonitoring use

Date of first enrolment
04/01/2010

Date of final enrolment
03/01/2012

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Prince Philip Hospital
Llanelli
United Kingdom
SA14 8QF

Sponsor information

Organisation
Hywel Dda Health Board (UK)

Sponsor details
c/o Mr Chris Tattersall
Withybush Hospital
Fishguard Road
Haverfordwest
Wales
United Kingdom
SA61 2PZ

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/012gye839

Funder(s)

Funder type
Government

Funder Name
Welsh Assembly Government (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2010	17/01/2019	Yes	No
Results article	results	01/02/2010	17/01/2019	Yes	No