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Tele-Health for Early Stage Chronic Obstructive Pulmonary Disease: a pilot study

Submission date	Recruitment status	[_] Prospectively registered
22/09/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/11/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/03/2017	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Gail Mountain

Contact details
Regent Court
30 Regent Street
Sheffield
United Kingdom
S1 4DA
-
g.a.mountain@sheffield.ac.uk

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Pilot study in preparation for a pragmatic randomised controlled trial of tele-health for early stage chronic obstructive pulmonary disease

Study objectives
1. Tele-health monitoring will reduce the proportion of patients who require hospital admission to manage their Chronic Obstructive Pulmonary Disease (COPD) for the duration of, and for six months following discharge from the Tele-health-supported Community COPD Service when compared with those who received the standard Community COPD Service
2. Tele-health monitoring will improve the quality of life for patients for the duration of, and for six months following discharge from the standard Community COPD Service as measured by a change from baseline in the St Georges Respiratory Questionnaire compared to the usual care group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the South Yorkshire Research Ethics Committee on the 29th of 2010, ref: 10/H1310/48

Study design
Pilot single-centre single-blind two-arm randomised controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease (COPD)

Interventions
Patients will be randomised to one two groups:
1. Telehealth supported COPD Service:
1.1. Three home visits with COPD specialist clinicians (nurse or physiotherapist)
1.1.1. within 24 hours of hospital discharge
1.1.2. within 48 hours of hospital discharge
1.1.3. week 8 after hospital discharge
1.2. Daily use of telemonitoring equipment by patient for eight weeks post hospital discharge

2. Standard COPD Service:
2.1. Five home visits and one telephone consultation with COPD specialist clinicians (nurse or physiotherapist)
2.1.1. within 24 hours of hospital discharge
2.1.2. within 48 hours of hospital discharge
2.1.3. 4 days after hospital discharge
2.1.4. 14 days after hospital discharge
2.1.5. 6 weeks after hospital discharge (telephone consultation)
2.1.6. week 8 after hospital discharge

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. The health service primary outcome will be the proportion of patients who are admitted to hospital with COPD as their primary or secondary cause of admission either during or six months following discharge from the Tele-health supported or standard Community COPD Service. This will be assessed through analysis of patient-completed self-reporting diaries and hospital either during or six months following the Tele-health supported or standard Community COPD Service and analysis of hospital admission/visit data
2. The patient-centred primary outcome will be the patients St. Georges Respiratory Questionnaire score upon admission to either the Tele-health supported or standard Community COPD Service, eight weeks later on discharge and six months later. This scale is a validated and widely-used instrument which measures health impairment in patients with COPD on a scale of 0 to 100 (greatest impairment). This scale is responsive to change with a minimum important difference (MID) of 4

Key secondary outcome(s))
1. Proportion of patients requiring unscheduled health care support to manage their COPD (including A&E, GP or community nurse visits) either during or six months following the standard Community COPD Service to be collected through patient-completed self-reporting diaries for the standard service and using the technology for the Tele-health supported service; and analysis of hospital, GP and community nursing visit data
2. Cost effectiveness of intervention
3. Improved self-management of their COPD by the patient to be assessed through analysis of the St. Georges Respiratory Questionnaire and a self-completed bespoke patient satisfaction questionnaire
4. Satisfaction with technology as part of their Tele-health supported Community COPD Service to be assessed through analysis of a self-completed bespoke patient satisfaction questionnaire

Completion date
31/01/2011

Eligibility

Key inclusion criteria
1. Open to male and female adult participants (> age 16)
2. Being discharged from the local NHS Foundation Trust and diagnosed with COPD
3. Between 1 and 3 previous admissions (including the current admission) in the previous 12 months according to the hospital discharge abstract from the current date of discharge where COPD is the primary or secondary documented reason for hospitalisation
4. Patient opts to be included in the caseload of the Community COPD Service
5. Willing to use Tele-health technology as part of their discharge plan
6. Able to communicate in English and read English (a requirement of the technology)
7. Have a telephone landline and a viable telecommunications network with no more than three internal telephone extensions

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
All

Key exclusion criteria
1. Prior/current involvement in another tele-health initiative
2. Cognitive impairment to the extent that it impedes ability to participate
3. Other significant impairments which will restrict ability to participate
4. No telephone landline
5. Unwilling to use Tele-health technology
6. Existence of co-morbidities which require on-going intervention from other community nursing services
7. More than three hospital admissions within twelve months of the date of discharge for which COPD is the primary diagnosis
8. Patient unable or unwilling to provide written or oral informed consent

Date of first enrolment
01/11/2010

Date of final enrolment
31/01/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Regent Court
Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation
Barnsley Health and Social Care Research Alliance (UK)

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Collaboration for Leadership in Applied Health Research and Care, South Yorkshire (CLAHRC SY)

Results and Publications

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	06/08/2014		Yes	No
Results article	results	22/03/2017		Yes	No
Protocol article	protocol	07/01/2011		Yes	No