

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

Submission date 22/09/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/11/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/03/2017	Condition category Respiratory	<input type="checkbox"/> Individual participant data

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/11/2010

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

Age group

Adult

Sex

Both

Target number of participants

60

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

England

United Kingdom

Study participating centre

Regent Court
Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation

Barnsley Health and Social Care Research Alliance (UK)

Sponsor details

Gawber Road
Barnsley
England
United Kingdom
S75 2EP

Sponsor type

Hospital/treatment centre

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

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