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Randomised controlled trial of nurse-led breathlessness intervention to improve the management of breathlessness for patients with Chronic Obstructive Pulmonary Disease (COPD)

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 08/04/2014	**Condition category** Respiratory	[ ] Individual participant data [ ] Record updated in last year

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
N0274135623

Study information

Scientific Title

Study objectives
To evaluate the effectiveness of a non-pharmacological nurse intervention through a breathlessness service to improve the management of breathlessness for patients with COPD

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Respiratory: Chronic obstructive pulmonary disease (COPD)

Interventions
Men and women with a confirmed diagnosis of COPD, who are physically able to access and attend the clinic on a regular basis will be randomised to attend either the nurse run breathlessness clinic or continue with routine care from a respiratory specialist nurse. The intervention will consist of goal setting, a range of strategies to manage breathing control, psychosocial support, and relaxation techniques.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Dyspnoea and emotional function as measured by the results of self reported Chronic Respiratory Questionnaire (CRQ-SR). This measures dyspnoea, fatigue, emotional function and mastery.
2. Functional exercise capacity as measured by the six-minute shuttle walk.
3. Borg scores and Oxygen saturation will also be recorded.

Secondary outcome measures
Additional GP and hospital attendance and hospital admissions.

Overall study start date
01/04/2004

Completion date
01/10/2006

Eligibility

Key inclusion criteria
Patients with a confirmed diagnosis of Chronic Obstructive Pulmonary Disease whose therapy has been optimised and breathlessness remains a predominating symptom.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/2004

Date of final enrolment
01/10/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
West Suffolk Hospitals NHS Trust
Bury St Edmunds
United Kingdom
IP33 2QZ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
West Suffolk Hospitals NHS Trust (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