

A randomised prospective controlled study to assess the effects of a respiratory case management model on hospital readmission rates in patients with moderate to severe chronic obstructive pulmonary disease

Submission date 13/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 27/09/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 14/06/2016	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

Study information

Scientific Title

A randomised prospective controlled study to assess the effects of a respiratory case management model on hospital readmission rates in patients with moderate to severe chronic obstructive pulmonary disease

Acronym

EXHALE (Exercise, Home support and Lung Education)

Study objectives

Whether intensive education, support and individualised exercise programme can reduce hospital admissions in patients with moderate to severe Chronic Obstructive Pulmonary Disease (COPD).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Sefton Research and Ethics Committee, September 2004. Ref: 04/Q1501/75

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Chronic Obstructive Pulmonary Disease

Interventions

Case management model of care: weekly home visits and small group exercise sessions for eight weeks. Monthly visits thereafter, with weekly, then fortnightly phone calls. Dedicated telephone support seven days a week for 12 months.

Control group have usual care.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Number of hospital admissions for COPD at 12 months

Key secondary outcome(s)

1. Quality of life/health status
2. Exercise capacity, lung function, and treatment over a one year period
3. Total number and length of hospital admissions for any cause

4. Number of General Practitioner visits, accident and emergency department visits over the 12 month follow up

Completion date

30/09/2006

Eligibility

Key inclusion criteria

1. Patients with moderate to severe COPD confirmed on spirometry
2. Aged 40 years or more who have had one or more admission to hospital in last 12 months
3. Must be current or ex-smokers
4. Must have home telephone

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients with previous diagnosis of asthma
2. Significant/unstable cardiac dysfunction
3. Underlying malignancy, dementia or major psychiatric illness
4. Participation in pulmonary rehabilitation in last 12 months

Date of first enrolment

01/10/2004

Date of final enrolment

30/09/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University Hospital Aintree
Liverpool

United Kingdom
L9 7AL

Sponsor information

Organisation

University Hospital Aintree (UK)

ROR

<https://ror.org/008j59125>

Funder(s)

Funder type

Government

Funder Name

South Sefton Primary Care Trust (in collaboration with Liverpool and Knowsley Primary Care Trusts) (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration