ISRCTN33946398 https://doi.org/10.1186/ISRCTN33946398

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

Registration date
27/09/2006

Overall study status
Completed

Last Edited
14/06/2016

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
N/A

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 Pumonary Disease (COPD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sefton Research and Ethics Committee, September 2004. Ref: 04/Q1501/75

Study design
Randomised controlled 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

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 measure
Number of hospital admissions for COPD at 12 months

Secondary outcome measures
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

Overall study start date
01/10/2004

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

Age group
Adult

Sex
Both

Target number of participants
270

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 rehabillitation in last 12 months

Date of first enrolment
01/10/2004

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Aintree
Liverpool
United Kingdom
L9 7AL

Sponsor information

Organisation
University Hospital Aintree (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

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

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