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A randomised 2x2 trial of community versus hospital rehabilitation, followed by telephone or conventional follow up; impact on quality of life, exercise capacity and use of health care resources

Submission date 25/04/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/04/2003	**Overall study status** Completed	
Last Edited 04/05/2010	**Condition category** Respiratory	

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
HTA 01/15/10

Study information

Scientific Title

Study objectives
Pulmonary rehabilitation is a program of supervised exercises and education to improve the function and quality of life of patients with chronic obstructive pulmonary disease (COPD) (chronic lung disease, predominantly caused by smoking). To date, this treatment has usually been carried out in hospital, where research has already shown it to be effective. Programs typically last for 6 weeks, but improvements persist much longer. For maximum benefit patients must be assisted to change their lifestyles. It is possible that the importance attached to being treated in hospital is more likely to convince patients to change their lifestyles. Alternatively, those treated in a community setting may identify the treatment more with day to day life and hence be more likely to make ongoing changes. This study randomises patients to receive their rehabilitation program in either hospital or community setting to see if one is superior to the other. This will be evaluated over 18 months to see how the effect persists, with measures of purely physical function (exercise), quality of life and use of healthcare status being evaluated. In addition, half of the patients will receive telephone support to see if this can cost effectively enhance the persistence of treatment effect.

More details can be found at http://www.hta.ac.uk/1316

Please note that, as of 24 January 2008, the start and end date of this trial were updated from 1 July 2002 and 30 June 2006 to 1 November 2002 and 31 July 2007, respectively.

Please note that as of 04/05/10 this record was extensively updated. All updates can be found in the relevant field with the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised 2x2 factorial trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Other

Study type(s)
Treatment

Participant information sheet

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

Interventions
Participants were randomised to one of four groups:
1. Hospital rehabilitation with no telephone follow-up
2. Hospital rehabilitation with telephone follow-up
3. Community rehabilitation with no telephone follow-up
4. Community rehabilitation with telephone follow-up

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Added 04/05/10:
Shuttle walking test (ESWT), assessed post-rehabilitation and at 18 months

Secondary outcome measures
Added 04/05/10:
Health-related quality of life, assessed by Chronic Respiratory Questionnaire (CRQ), Short form-36 (SF-36) and EuroQol (EQ-5D)

Overall study start date
01/11/2002

Completion date
31/07/2007

Eligibility

Key inclusion criteria
Added 04/05/10:
1. Diagnosis of COPD as defined by British Thoracic Society guidelines
2. Medical Research Council (MRC) grade 3 dyspnoea or worse despite optimal care
3. Clinically stable 4 weeks prior to commencing programme
4. Written informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
Added 04/05/10: 240

Key exclusion criteria
Added 04/05/10:
1. Lack of informed consent
2. Unwilling/lack of motivation to make lifestyle changes
3. Inability to hear and understand educational talks and exercise instructions (hearing aids and interpreters may be used if appropriate)
4. Prognosis under 2 years from any disease
5. Long term oxygen therapy or any requirement for oxygen therapy on exercise
6. Unstable or uncontrolled cardiac disease
7. Musculoskeletal problems precluding exercise training

Date of first enrolment
01/11/2002

Date of final enrolment
31/07/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dept of Respiratory Medicine
Sheffield
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Sponsor information

Organisation
Department of Health (UK)

Sponsor details

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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2010		Yes	No