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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Added 04/05/10:

Shuttle walking test (ESWT), assessed post-rehabilitation and at 18 months

Key secondary outcome(s))

Added 04/05/10:

Health-related quality of life, assessed by Chronic Respiratory Questionnaire (CRQ), Short form-36 (SF-36) and EuroQol (EQ-5D)

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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

United Kingdom

England

Study participating centre
Dept of Respiratory Medicine
Sheffield
United Kingdom
S10 2JF

Sponsor information

Organisation

Department of Health (UK)

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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