

# 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

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/05/2010	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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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

### Primary study design

Interventional

### Study design

Randomised 2x2 factorial trial

### 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?
<a href="#">Results article</a>	results	01/02/2010		Yes	No