

# 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

**Contact name**  
Dr Roderick Allan Lawson

**Contact details**  
Dept of Respiratory Medicine  
Royal Hallamshire Hospital  
Glossop Road  
Sheffield  
United Kingdom  
S10 2JF  
+44 0 114 271 2958  
rod.lawson@sth.nhs.uk

## 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

United Kingdom

S10 2JF

**Sponsor information****Organisation**

Department of Health (UK)

**Sponsor details**

Quarry House  
Quarry Hill  
Leeds  
United Kingdom  
LS2 7UE  
+44 (0)1132 545 843  
Sheila.Greener@doh.gsi.gov.uk

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