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# A study of the effectiveness of individual components of a pulmonary rehabilitation programme when compared with the combined programme

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 23/01/2004 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 23/01/2004 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 18/01/2010 | 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
RRCC148LG PROCTER

# Study information

### Scientific Title

### Study objectives
Two questions are being asked in this study. They are: What is the absolute and relative contribution to the reported outcomes of pulmonary rehabilitation of two of it's components: physical training and group cognitive behavioural therapy? Is the combined programme of pulmonary rehabilitation more clinically and cost effective than either of its two components delivered independently?

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Not Specified

### Participant information sheet

### Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease (COPD)

### Interventions
1. Pulmonary Rehabilitation (combined intervention): The rehabilitation programme in this study will consist of a combination of a physical training programme, cognitive-behavioural programme and standard care. These components are described.
2. Physical training component: This approach involves a six week programme of twice weekly 2 hour sessions of aerobic exercise individually based on 80% of the participants' peak oxygen uptake as determined by the shuttle-walking test. The physical training will be carried out by a single trainer following standardised methods and using the same equipment in order to ensure that an equal level of training is provided to the whole sample. Additionally, participants will be

provided with an individualised home exercise routine with a diary card to indicate completion.
3. Group cognitive behavioural therapy: the cognitive-behavioural approach aims to address issues relating to the impact of COPD on the individual and their life; facilitate adjustment to it and develop a range of appropriate physiological coping mechanisms. It requires active client participation, learning, discussion and practice of technique both within and between sessions. The sessions will be held once a week for 1.5 hours for six weeks. SD will lead the group. The maximum number of people recommended to attend would be 8-10 and partners and carers would be welcome.
4. Standard care control group: COPD management would be provided according to British Thoracic Society guidelines and would be comparable to the care participants would receive were this study not being carried out.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Outcome variables:
1. Physical Assessment Details: height and weight will be recorded and BMI will be calculated. A shuttle-walk test will be carried out. Forced expiratory volume and Forced vital capacity will be carried out.
2. Health status: The Chronic Respiratory Disease Questionnaire will be used.
3. Anxiety and Depression: HADS will be used.
4. Self-efficacy: The COPD Self-Efficacy Scale.
5. Resource Utilisation: Direct, indirect, personal and transfer resource utilisation will be assessed using the Health Service Utilisation and expenditure measurement.
Control variables: Demographic details: household composition specifically to include number of dependent children, number of habitable rooms per household, current or most recent occupation of head of household, marital status (where possible questions will match those used by the Office of National Statistics) collected on admission to the study only.
Disease characteristics: age at diagnosis, duration of disease, medication taken, use of domicillary oxygen and concurrent medical condition collected on admission to the study only.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/01/2001

### Completion date
01/01/2004

## Eligibility

### Key inclusion criteria
Patients with chronic obstructive pulmonary disease (COPD) recruited from general practice with diagnosis confirmed by spirometry

### Participant type(s)

Patient

**Age group**
Not Specified

**Sex**
Not Specified

**Target number of participants**
Not provided at time of registration

**Key exclusion criteria**
Does not match inclusion criteria

**Date of first enrolment**
01/01/2001

**Date of final enrolment**
01/01/2004

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**University of Northumbria at Newcastle**
Newcastle upon Tyne
United Kingdom
NE7 7XA

# Sponsor information

**Organisation**
NHS R&D Regional Programme Register - Department of Health (UK)

**Sponsor details**
The Department of Health
Richmond House
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**Sponsor type**
Government

**Website**
http://www.doh.gov.uk

# Funder(s)

**Funder type**
Government

**Funder Name**
NHS Executive Northern and Yorkshire (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 | 01/01/2004 | | Yes | No |