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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
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
18/01/2010

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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

Study type(s)
Not Specified

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(s)
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.

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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)

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (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				

Results article	01/01/2004	Yes	No