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A Self-management Programme of Activity, Coping and Education for Chronic Obstructive Pulmonary Disease (COPD): is it a feasible alternative to conventional rehabilitation?

Submission date
27/03/2012

Recruitment status
No longer recruiting

Registration date
22/05/2012

Overall study status
Completed

Last Edited
04/10/2022

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Recent evidence has shown pulmonary rehabilitation (classes containing exercise and advice) for patients with chronic obstructive pulmonary disease (COPD) to be of benefit. However, only 3% of individuals with COPD have access to such a service. It may be more appropriate for patients to have access to a manual which covers issues such as drug and symptom management, exercise and nutrition at home. This would give help and advice concerning managing their own condition without having to travel to the hospital. This study is needed in order to inform the current delivery of the rehabilitation service, optimise patient care and aid in the development of new COPD rehabilitation programmes. The aim of the study is to to develop a novel, truly independent self-management rehabilitation programme specifically for patients with COPD and to evaluate the effectiveness of self-management rehabilitation programme compared to conventional out-patient rehabilitation

Who can participate?
Patients referred to pulmonary rehabilitation with an established diagnosis of COPD with an MRC breathlessness grade between 2 and 5.

What does the study involve?
320 participants will be randomly allocated to either receiving conventional outpatient pulmonary rehabilitation or the home-based self-management programme. For those assigned to the hospital based rehabilitation programme, they will complete the normal 7 week programme of exercise and educational advice by attending classes twice weekly. Participants will undergo a standard assessment, consisting of lung function tests, exercise capacity (walking tests) and completing some questionnaires about their health status. Participants will be assessed before commencing the hospital programme, immediately after the programme is completed and then 6 months after the hospital programme, as is routine. For those assigned to the self-management group, participants will undergo the same assessments at the same time points as the hospital group, however, they will introduced to a manual for people with lung

disease. The manual will outline how participants can manage their condition and include information on drug and symptom management, exercise and nutrition. Included will be some home-based exercises for participants to carry out daily. Participants will receive 2 phone calls to review their progression with the manual. This group will not participate in the exercise and educational sessions at the hospital.

What are the possible benefits and risks of participating?
We hope that the research will aid participants' understanding of their disease, its consequences, exercise and rehabilitation and inform both present and future pulmonary rehabilitation programmes therefore benefiting patients with COPD. For those placed in the self-management group, they will not participate in the routine 7 weeks of rehabilitation at the hospital. We do not yet know if the self-management manual is as effective as the hospital-based rehabilitation, however, if the self-management manual has proved to be ineffective for any patients, they will be offered the conventional rehabilitation at the end of the study.

Where is the study run from?
Pulmonary Rehabilitation Department, Glenfield Hospital, University Hospitals of Leicester NHS Trust (UK)

When is the study starting and how long is it expected to run for?
The study started in 2007 and is expected to be completed mid-2013

Who is funding the study?
Pulmonary Rehabilitation Research Group - University Hospitals of Leicester NHS Trust (UK)

Who is the main contact?
Prof Sally Singh
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

10196

Study information

Scientific Title
A Self-management Programme of Activity, Coping and Education for Chronic Obstructive Pulmonary Disease (COPD): is it a feasible alternative to conventional rehabilitation? A randomised study

Acronym
SPACE for COPD

Study objectives
The Self-management Programme of Activity, Coping and Education (SPACE) will be as effective at increasing quality of life (as measured by the Chronic Respiratory Quesionnaire-Dyspnoea domain) as conventional Pulmonary Rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicester, Northamptonshire and Rutland Research Ethics Committee, 15/02/2007, ref: 07/Q2501/6

Study design
Randomised single-blind single-centre interventional study

Primary study design
Interventional

Study type(s)
Quality of life

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

Interventions
Self-management intervention:
A Self-management Programme of Activity, Coping and Education (SPACE) for COPD. Participants in this group will receive a 171-page A4 workbook comprising sections on disease education, stress management strategies, breathing control advice and techniques to improve exercise capacity and levels of domestic physical activity. It also includes an individual action plan designed to help cope with exacerbations. Motivational telephone calls will be made at 2 and 4 weeks to encourage participants to complete the manual and pursue an active lifestyle. It is anticipated that participants will have worked through the manual in approximately seven weeks.

Pulmonary Rehabilitation intervention:
Participants in this group will attend classes (consisiting of exercise and education) at the hospital, twice weekly for 7 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Quality of life as determined by the Chronic Respiratory Questionnaire (self-reported) - Dyspnoea domain, measured at baseline, after the intervention at 7 weeks and 6 months later

Key secondary outcome(s))
Measured at the initial assessment, and at 7 weeks and 6 months after this assessment:
1. Chronic Respiratory Quesionnaire (Self-reported) - fatigue, emotion and mastery domains
2. Pulmonary Rehabilitation Adapted Index of Self-Efficacy (PRAISE)
3. Hospital Anxiety and Depression Scale (HADS)
4. Exercise tolerance (Incremental and Endurance Shuttle Walk Tests)
5. Daily physical activity (measured by wearing SenseWear accelerometers for 5 days)

Completion date
30/06/2013

Eligibility

Key inclusion criteria
1. Adults with an establised diagnosis of Chronic Obstructive Pulmonary Disease [ratio of the forced expiratory volume in the first one second to the forced vital capacity of the lungs (FEV1 /FVC ratio <70%)]
2. Medical Research Council (MRC) dyspnoea grade of 2-5

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with significant neurological, locomotive, cardiac or psychological conditions which would exclude them from exercising
2. Those unwilling to participate
3. Who have participated in Pulmonary Rehabilitation in the previous 12 months

Date of first enrolment
15/02/2007

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Glenfield Hospital
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Pulmonary Rehabilitation Research Group at University Hospitals of Leicester NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/01/2018		Yes	No
Results article		26/10/2021	04/10/2022	Yes	No