

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/05/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/10/2022	Condition category Respiratory	<input type="checkbox"/> 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 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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 Questionnaire-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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 (consisting of exercise and education) at the hospital, twice weekly for 7 weeks.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

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

Secondary outcome measures

Measured at the initial assessment, and at 7 weeks and 6 months after this assessment:

1. Chronic Respiratory Questionnaire (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)

Overall study start date

15/02/2007

Completion date

30/06/2013

Eligibility

Key inclusion criteria

1. Adults with an established 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

Age group

Adult

Sex

Both

Target number of participants

320

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

England

United Kingdom

Study participating centre

Glenfield Hospital

Leicester

United Kingdom

LE3 9QP

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust (UK)

Sponsor details

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Gwendolen House

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Leicester
England
United Kingdom
LE5 4PY

Sponsor type

Hospital/treatment centre

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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