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A study for the delivery of standardised self management (SPACE Self management Programme of Activity, Coping and Education) at the time of discharge after an acute exacerbation of COPD - is it effective?

Submission date
26/03/2013

Recruitment status
No longer recruiting

Registration date
26/03/2013

Overall study status
Completed

Last Edited
06/04/2017

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
A recent report suggested that individuals discharged from hospital after an exacerbation (or flare-up) of their Chronic Obstructive Pulmonary Disease (COPD) often feel isolated and have little information about how to manage the disease. In collaboration with healthcare professionals and individuals with COPD, we have developed a comprehensive manual (A Self Management Programme of Activity, Coping and Education [SPACE]) to help people with COPD to understand and manage their lung condition effectively. The manual is divided into four sections (in total 170 pages) and has advice and information on managing breathlessness, staying active, recognising the symptoms of exacerbations, and using medications appropriately. In this study we would like to evaluate the use of the manual upon discharge from hospital. The study aims to evaluate the impact of the manual for individuals with COPD in regards to readmission rates, quality of life and exercise capacity. The SPACE manual will be compared to usual care. Overall, the study is to establish the value of the SPACE manual at the point of discharge for an admission of COPD.

Who can participate?
Patients who have Chronic Obstructive Pulmonary Disease (COPD) who have been admitted to hospital with an exacerbation of their COPD. Patients who are willing, with an MRC dyspnoea grade of 2-5.

What does the study involve?
There are two groups in the study; half of those who agree to take part receive the SPACE manual and the other half receive usual care. This is done randomly, i.e. like tossing a coin. For those allocated to receive SPACE, participants are introduced to the manual while they are still in hospital, and sections that would be most useful to them are highlighted. When they are discharged home from hospital, they receive a phone call within 72 hours and at 2, 4, 6, 8, and 10

weeks to monitor their progress and provide further support and advice. For those allocated to receive usual care, participants receive usual care upon discharge from hospital. All participants are required to perform an assessment at the start of the study which includes walking tests and completing some questionnaires to find out how their COPD affects them in their daily life. All participants are reassessed 3 months later, using the same assessment.

What are the possible benefits and risks of participating?
The information from this study may help to treat future patients with COPD. If participants are allocated to the SPACE manual group they receive a comprehensive information manual about their lung disease and how they might manage it, which they can keep. In both groups of patients repeated questionnaires, lung function measures and walking tests are performed to monitor participants' recovery. The disadvantages and risks are the same for both groups of patients in the study and are the same as for patients who are not taking part in the study. No disadvantages or risks have been identified.

Where is the study run from?
University Hospitals Coventry and Warwickshire (UK)

When is the study starting and how long is it expected to run for?
January 2013 to January 2014

Who is funding the study?
The British Lung Foundation (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13469

Study information

Scientific Title
A randomised controlled study for the delivery of standardised self management (SPACE Self management Programme of Activity, Coping and Education) at the time of discharge after an acute exacerbation of COPD - is it effective?

Acronym
SPACE at Discharge for COPD

Study objectives
The aim of this project is to provide evidence to support the delivery of a structured self-management programme for patients with an exacerbation (and hospitalised) of chronic obstructive pulmonary disease (COPD). Currently there is no evidence-based self-management strategy available in the UK, over and above exacerbation management advice. Over the last 4 years we have developed a self-management manual, SPACE for COPD (Self Management Programme of Activity, Coping & Education for Chronic Obstructive Pulmonary Disease). It is a structured programme of exercise, education and psychosocial support for individuals with COPD. The hypothesis driving this research project is that a discharge self-management strategy is effective at improving health status and physical activity for patients with COPD which would indirectly, favourably influence readmissions, realising greater health benefits compared to usual care.

The trialists will undertake a randomised controlled trial of the intervention. This will be achieved in a pragmatic trial of self management at discharge (SPACE for COPD) vs usual care to assess the impact of the manual on health status, physical activity and other important outcomes.

The primary objective of this study is to establish the value of the space manual at the point of discharge for an admission of COPD.

Secondary aims are:
1. To examine the impact of SPACE for COPD upon readmission rates, in individuals with COPD 3 months after discharge
2. To examine the impact of SPACE for COPD upon quality of life in individuals with COPD 3 months after discharge
3. To examine the impact of SPACE for COPD upon exercise capacity 3 months after discharge
4. To describe the acceptability and appropriateness of self-management manual, SPACE for individuals with COPD who were allocated to the treatment group

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands Solihull, 23/07/2012, ref: 12/WM/0106

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Topic: Respiratory; chronic obstructive pulmonary disease

Interventions
SPACE for COPD versus Usual Care

A Self-Management Programme of Activity, Coping and Education for patients with Chronic Obstructive Pulmonary Disease (COPD). SPACE consists of a manual developed by various healthcare professionals, patients and carers, is underpinned by the health belief model embracing self-efficacy and approved by the Plain English Campaign. It promotes behaviour change through education, developing self-management skills and motivational interviewing techniques, with a focus of increasing physical activity.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Hospital readmissions; Timepoint(s): 3 months

Secondary outcome measures
1. Bristol COPD Knowledge Questionnaire; Timepoint(s): baseline and 3 months
2. Chronic Respiratory Questionnaire; Timepoint(s): baseline and 3 months
3. EUROQOL; Timepoint(s): baseline and 3 months
4. Exercise Capacity - Incremental and Endurance Shuttle Walk Tests; Timepoint(s): baseline and 3 months
5. Physical Activity (SenseWear); Timepoint(s): baseline and 3 months
6. Pulmonary Rehabilitation Adapted Index of Self-Efficacy (PRAISE); Timepoint(s): baseline and 3 months

Overall study start date
07/01/2013

Completion date
07/01/2014

Eligibility

Key inclusion criteria
1. Patients with an established diagnosis of an exacerbation of COPD and MRC 2-5
2. Willing to take part
3. Male & Female; Lower Age Limit 50 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 86; UK Sample Size: 86

Key exclusion criteria
1. Inability to participate in interventions designed to improve physical capacity, e.g. neurological, severe cardiac, locomotive, or psychiatric disability
2. Unwilling to participate
3. Participation in other research projects
4. Unable to read English
5. Interventions

Date of first enrolment
07/01/2013

Date of final enrolment
07/01/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

PRI Suite
Coventry
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Sponsor information

Organisation
Coventry University Hospital (UK)

Sponsor details
Clinical Sciences Research Institute
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Sponsor type
Hospital/treatment centre

Website
http://www.uhcw.nhs.uk

ROR
https://ror.org/025821s54

Funder(s)

Funder type
Charity

Funder Name
British Lung Foundation (UK)

Alternative Name(s)
BLF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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	02/06/2016		Yes	No