ISRCTN35501175 https://doi.org/10.1186/ISRCTN35501175

A Self-management Programme of Activity Coping and Education for Chronic Obstructive Pulmonary Disease: is it effective in primary care?

Submission date
25/08/2009

Recruitment status
No longer recruiting

Registration date
08/04/2010

Overall study status
Completed

Last Edited
10/11/2016

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

Contact name
Prof Sally Singh

Contact details
Department of Pulmonary Rehabilitation
Glenfield Hospital
Leicester
United Kingdom
LE3 9QP
+44 (0)116 250 2350
sally.singh@uhl-tr.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial to evaluate the effectiveness of a Self-management Programme of Activity Coping and Education for Chronic Obstructive Pulmonary Disease delivered in primary care

Acronym
SPACE for COPD

Study objectives
The hypothesis is that a structured education and self-management programme for patients with chronic obstructive pulmonary disease (COPD) will promote independence and improve their quality of life and physical function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Parallel-group randomised clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Chronic obstructive pulmonary disease

Interventions
Participants in the intervention 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 5 weeks, 3 and 5 months 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 eight weeks.

The control group arm will be monitored in primary care according to the practice framework. Changes in medication during the study period will be recorded. Participants in this group will receive telephone contact to check for GP and hospital contacts and to arrange follow-up visits.

Outcome measures will be collected at the initial assessment, and eight weeks and six months after this assessment to determine the short and medium term effects for both study groups.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Health status determined by Chronic Respiratory Disease Self-Reported Questionnaire - dyspnoea component, measured at the initial assessment, and at 8 weeks and 6 months after this assessment

Secondary outcome measures
Measured at the initial assessment, and at 8 weeks and 6 months after this assessment:
1. Domestic physical activity
2. Exercise capacity
3. Mental wellbeing
4. Self-efficacy
5. Health utilisation
6. Task completion
7. Adherence
8. Patient knowledge
9. Exacerbation rates

Overall study start date
30/09/2009

Completion date
30/09/2012

Eligibility

Key inclusion criteria
Patients (no age limit, either sex) with an established diagnosis of COPD according to international guidelines and Medical Research Council (MRC) dyspnoea scale 2 - 5.

Participant type(s)
Patient

Age group

All

Sex
Both

Target number of participants
192

Key exclusion criteria
1. Inability to participate in interventions designed to improve physical capacity, e.g., neurological, locomotive or psychiatric disability
2. Unwillingness to participate
3. Participation in other research projects
4. Inability to read English
5. Participation in rehabilitation in the last 12 months
6. Patients must have been clinically stable for four weeks

Date of first enrolment
30/09/2009

Date of final enrolment
30/09/2012

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
c/o Carolyn Maloney
Gwendolen House
Gwendolen Road

Leicester
England
United Kingdom
LE5 4PY

Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Collaboration in Applied Health Research and Care for Leicestershire, Northamptonshire and Rutland (CLAHRC-LNR)

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	01/12/2014		Yes	No
Other publications	economic evaluation	01/02/2016		Yes	No