

# A self-management programme of activity coping and education - SPACE FOR COPD - in primary care: a pragmatic trial

<b>Submission date</b> 17/11/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/02/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/03/2023	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Chronic obstructive pulmonary disease (COPD) is the name used to refer to a number of progressive devastating and debilitating lung diseases, which includes chronic bronchitis, emphysema and chronic obstructive airways disease. People that have COPD typically feel breathless after physical activity, have a persistent cough with phlegm and suffer frequently from chest infections. There is no cure for the condition, but making lifestyle changes and taking medications can alleviate symptoms. New skills such as how to exercise, how to manage their stress and how to manage their breathing are important to learn. SPACE FOR COPD is a manual which aims to teach people these skills, and to provide them with information about their condition and how best to manage it. A previous research study showed that there were clear benefits to using the manual in the short term, and some of these gains were maintained after 6 months. In this study, however, the treatment period was brief, with only an initial consultation of 30-45 minutes. The added benefit of more sustained ongoing support should be tested. It is now important to investigate whether these improvements can be better maintained in the longer term, and also if the manual can be given to patients as part of routine clinical care, rather than as part of a research study.

### Who can participate?

Adults diagnosed with COPD

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in group 1 are given the SPACE FOR COPD manual in group settings in the community. Those in group 2 are given their usual care and do not receive the SPACE FOR COPD manual. We assess participants at the start of the study, after 6 months and after 9 months to investigate both the short-term and longer-term effects of the self-management manual.

### What are the possible benefits and risks of participating?

The benefits of participating within this study involve gaining a better understanding of COPD and how patients can improve their symptoms. Information gathered from the patients will aid

and inform both current and future research, and aim to provide better care for patients living with COPD. There are no anticipated risks of participating in the research project.

Where is the study run from?  
Glenfield Hospital (UK)

When is the study starting and how long is it expected to run for?  
January 2015 to September 2017

Who is funding the study?  
1. Collaboration for Leadership in Applied Health Research and Care East Midlands (UK)  
2. Academic Health Science Network East Midlands (UK)

Who is the main contact?  
Sally Singh  
Sally.Singh@uhl-tr.nhs.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Sally Singh

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
A self-management programme of activity coping and education - SPACE FOR COPD - in primary care: a prospective, pragmatic, single-centre, single-blinded randomised controlled trial

**Acronym**

N/A

**Study objectives**

SPACE for COPD delivered by a trained facilitator in groups will significantly improve breathlessness compared to usual care.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee South Central - Hampshire B, 21/10/2014, IRAS: 152408, REC ref: 14/SC/1169

**Study design**

Single-centre single-blinded randomised controlled trial, sub-study of semi-structured qualitative interviews with the HCPs that delivered the intervention

**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**

Chronic obstructive pulmonary disease (COPD), self management

**Interventions**

Those randomised to the SPACE group will be given the SPACE manual and will receive six group sessions in the community delivered by trained healthcare professionals going through various topics related towards goal setting. Those randomised to usual care will have no change in their care and will not receive the SPACE FOR COPD manual.

**Intervention Type**

Behavioural

**Primary outcome measure**

COPD Assessment Test (CAT) at baseline, 6 months and 9 months

**Secondary outcome measures**

1. The Chronic Respiratory Questionnaire Self Report (CRQ-SR) at baseline, 6, 9 months for both groups
2. The Patient Activation Measure (PAM) at baseline, 6, 9 months for both groups
3. The Hospital Anxiety and Depression Scale (HADS) at baseline, 6, 9 months for both groups
4. The Bristol COPD Knowledge Questionnaire (BCKQ) at baseline, 6, 9 months for both groups
5. Exercise performance (The Incremental Shuttle Walk Test and Endurance Shuttle Walking Test) at baseline, 6, 9 months for the interventional group, at 9 months only for the usual care group
6. The EQ-5D throughout the study
7. Healthcare utilisation throughout the study
8. Smoking status throughout the study
9. Physical activity via the SenseWear Armband (SAB) at baseline, 6, 9 months for both groups

**Overall study start date**

01/01/2015

**Completion date**

30/09/2017

## Eligibility

**Key inclusion criteria**

Established diagnosis of COPD

**Participant type(s)**

Patient

**Age group**

All

**Sex**

Both

**Target number of participants**

193

**Key exclusion criteria**

1. Unable to participate in exercises component of rehabilitation, e.g. neurological, locomotive or psychiatric disability
2. Unable to read English to the level of an 8 year old
3. Unwilling to take part
4. Has received or participated in the Pulmonary Rehabilitation or received the SPACE manual within the last 12 months

**Date of first enrolment**

01/01/2015

**Date of final enrolment**

02/11/2016

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

### Glenfield Hospital

Grobby Road

Leicester

United Kingdom

LE3 9QP

# Sponsor information

## Organisation

Leicester General Hospital (UK)

## Sponsor details

c/o Carolyn Maloney

Research and Development Office

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## Sponsor type

Hospital/treatment centre

## ROR

<https://ror.org/02zg49d29>

# Funder(s)

## Funder type

Government

**Funder Name**

Collaboration for Leadership in Applied Health Research and Care East Midlands (UK)

**Funder Name**

Academic Health Science Network East Midlands (UK)

## Results and Publications

**Publication and dissemination plan**

The trialists aim to publish the protocol and results of the trial. They also aim to publish a qualitative paper from this study also looking at Health Care Professionals' experiences and thoughts on delivering the SPACE manual in group settings.

**Intention to publish date**

30/06/2018

**Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>		23/10/2018	23/10/2018	No	No
<a href="#">Protocol article</a>		10/07/2017	07/03/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No