ISRCTN17942821 https://doi.org/10.1186/ISRCTN17942821

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

**Submission date**
17/11/2014

**Recruitment status**
No longer recruiting

**Registration date**
11/02/2015

**Overall study status**
Completed

**Last Edited**
20/10/2026

**Condition category**
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

### Contact details
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP
-
Sally.Singh@uhl-tr.nhs.uk

# Additional identifiers

# 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

### Primary study design
Interventional

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

### Study type(s)
Treatment

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

### Key secondary outcome(s)
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

### Completion date
30/09/2017

## Eligibility

### Key inclusion criteria

Established diagnosis of COPD

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
All

### Sex
All

### Total final enrolment
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
United Kingdom

England

### Study participating centre
**Glenfield Hospital**
Groby Road
Leicester
England
LE3 9QP

## Sponsor information

**Organisation**
Leicester General Hospital (UK)

**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

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not expected to be made available

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 17/10/2022 | 20/10/2026 | Yes | No |
| Protocol article | | 10/07/2017 | 07/03/2023 | Yes | No |
| Basic results | | 23/10/2018 | 23/10/2018 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |