

Evaluating a group-based maintenance self-management intervention for patients with COPD

Submission date 03/05/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/08/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/07/2024	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Chronic obstructive pulmonary disease describes a group of lung conditions that make it difficult to empty air out of the lungs because the airways are narrowed. Patients suffer from shortness of breath and tend to avoid activities which make them breathless, causing muscles to waste and weaken. An added problem is that patients often have repeated chest infections, some requiring hospital admission. This is detrimental for the patient and costly for the health service.

Pulmonary Rehabilitation is a package of supervised exercise and education which is known to improve physical and mental well-being, as well as preventing hospital admissions in patients with COPD. However the benefits of rehabilitation do not last and patients talk about a feeling of 'abandonment' at the end of the programme. The aim of this research is to test a new maintenance (on-going support) programme for patients with COPD.

Who can participate?

COPD patients aged over 18 who have completed pulmonary rehabilitation in the past 4 weeks.

What does the study involve?

In this study, we will divide people into 2 groups at the end of rehabilitation. One group will receive best usual care including referral to a community exercise programme if wanted. The second group will receive best usual care plus the new maintenance programme. In this programme, patients will work through a booklet and attend group sessions for 12-months to gain support from patients and staff. All patients will do several tests over 12-months to measure physical and mental well-being. We will also interview patients and staff about their experiences of the programme.

What are the possible benefits and risks of participating?

If successful, the new maintenance programme has the potential to preserve and enhance the benefits of rehabilitation for the patient. This may reduce hospital admissions, saving the health service money.

This study was developed in response to patient feedback and with the support of patient representatives. The findings of the study will be announced at conferences, in publications and at patient groups.

Where is the study run from?

1. Glenfield General Hospital, UK
2. Harefield Hospital, UK

When is the study starting and how long is it expected to run for?
August 2019 to September 2023

Who is funding the study?

National Institute for Health Research (NIHR)

Who is the main contact?

1. Mr Khaled Alqahtani (public),
kada5@leicester.ac.uk
2. Dr Linzy Houchen-Wolloff (scientific),
linzy.houchen@uhl-tr.nhs.uk

Contact information

Type(s)

Public

Contact name

Mr Khaled Alqahtani

ORCID ID

<https://orcid.org/0000-0001-5235-8467>

Contact details

Centre for Exercise and Rehabilitation Science
NIHR Leicester Biomedical Research Centre "Respiratory"
Glenfield Hospital
Grobby Road
Leicester
United Kingdom
LE3 9QP
01162582762
kada5@leicester.ac.uk

Type(s)

Scientific

Contact name

Dr Linzy Houchen-Wolloff

ORCID ID

<https://orcid.org/0000-0003-4940-8835>

Contact details

Centre for Exercise and Rehabilitation Science
NIHR Leicester Biomedical Research Centre "Respiratory
Glenfield Hospital
Grobby Road
Leicester
United Kingdom
LE3 9QP
01162582762
linzy.houchen@uhl-tr.nhs.uk

Type(s)

Scientific

Contact name

Prof Sally Singh

ORCID ID

<https://orcid.org/0000-0002-9834-0366>

Contact details

Centre for Exercise and Rehabilitation Science (CERS)
NIHR Leicester Biomedical Research Centre (BRC)-Respiratory
Glenfield Hospital
Grobby Road
Leicester
United Kingdom
LE3 9QP
0116 258 3388
sally.singh@uhl-tr.nhs.uk

Type(s)

Scientific

Contact name

Dr William Man

Contact details

Royal Brompton and Harefield NHS Foundation Trust
Harefield Hospital
Hill End Road
Harefield
United Kingdom
UB9 6JH
020 3733 4165
W.Man@rbht.nhs.uk

Type(s)

Scientific

Contact name

Dr Claire Nolan

ORCID ID

<https://orcid.org/0000-0001-9067-599X>

Contact details

Mary Seacole Building
Brunel University London
Kingston Lane
Uxbridge
United Kingdom
UB8 3PN
020 3733 4165
Claire.nolan@brunel.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

109551; CPMS: 42162

Study information

Scientific Title

SPACE FOR COPD© delivered as a maintenance programme on Pulmonary Rehabilitation discharge: a randomised controlled trial evaluating the long-term effects on exercise tolerance and mental wellbeing

Acronym

SPACE maintenance

Study objectives

Those completing the maintenance programme after Pulmonary Rehabilitation (PR) will have sustained improvements in endurance walking time at 12 months, compared to those receiving usual care alone, following PR.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/10/2019, Leicester Central REC, (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)207 104 8234; NRESCCommittee.EastMidlands-LeicesterCentral@nhs.net), ref: 19/EM/0267

Study design

Prospective multicentre randomized controlled trial with blinded quantitative outcomes

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease

Interventions

Current interventions as of 10/06/2021:

Eligible and willing participants will be consented and then randomised to either usual care or the SPACE FOR COPD maintenance programme. Randomisation will be 1:1 into the two groups, and will be done using a concealed allocation web-based programme (sealedenvelope.com). Randomisation codes will be blocked per site, so that there are even numbers of intervention and control patients at each site, delivered in a timely appropriate manner (i.e. enough intervention participants recruited consecutively to one site to enable a group session to run). Those randomised to the intervention will be introduced to the SPACE FOR COPD® manual at their first group session. The SPACE FOR COPD® manual is divided into four stages and has 176 pages, providing an exercise programme and covering several education topics, with goal-setting text, case studies, and activities to encourage problem solving and support behaviour change. The text is interspersed with photographs, diagrams and 'top tips' boxes. There is a single A4 sheet action plan with a sputum colour chart to manage exacerbations. For the purposes of this trial, another single page insert will be devised to facilitate longer-term goal setting. The content has been approved by the Plain English Campaign and received the Crystal Mark for clarity of British English (appropriate for an eight year old to read). The manual will be introduced by Health Care Professionals (HCP), who have expertise in the management of COPD, the SPACE FOR COPD® programme and skills in motivational interviewing. HCPs will advise patients on how to use the manual and follow it independently at home. Participants will be expected to complete an exercise diary at home. Once at home, patients will have the opportunity to contact their HCP with questions via telephone. There will be follow-up maintenance group sessions (5-10 participants per group), at the recruiting centres or online based on a previously successful format. The aims of these group sessions are to discuss progress, address barriers, to increase motivation to maintain/ enhance healthy lifestyle behaviours and to encourage social support and not re-provide rehabilitation. Using motivational interviewing (MI) techniques, the sessions would involve the clinician facilitating the patients to identify barriers and facilitators to maintaining exercise, express empathy, support self-efficacy and roll with resistance. The teams at Leicester and London have worked together on previous projects and London are familiar with the SPACE FOR COPD programme. These groups will occur 4 times over 12-months, divided as follow:

- At month 1 (introduction/ group responsibilities/ goal setting),
- At months 4 (exacerbation management/ goal setting),
- At month 7 (mood management and goal setting) and
- At month 10 (question and answer/ keeping going).

Each session will last for 2 hours at the recruiting centre or online. Patients will be sent reminders about group sessions by their preferred method (e.g. text, email, or letter).

There will also be an embedded qualitative component of the trial. All eligible participants will be offered the chance to take part in the trial at the end of their Pulmonary Rehabilitation

programme. Qualitative interviews will be performed in willing subjects (described later), at 12-months (or earlier if there is attrition to the programme).

Previous interventions:

Eligible and willing participants will be consented and then randomised to either usual care or the SPACE FOR COPD maintenance programme. Randomisation will be 1:1 into the two groups, and will be done using a concealed allocation web-based programme (sealedenvelope.com). Randomisation codes will be blocked per site, so that there are even numbers of intervention and control patients at each site, delivered in a timely appropriate manner (i.e. enough intervention participants recruited consecutively to one site to enable a group session to run). Those randomised to the intervention will be introduced to the SPACE FOR COPD® manual at their first group session. The SPACE FOR COPD® manual is divided into four stages and has 176 pages, providing an exercise programme and covering several education topics, with goal-setting text, case studies, and activities to encourage problem solving and support behaviour change. The text is interspersed with photographs, diagrams and 'top tips' boxes. There is a single A4 sheet action plan with a sputum colour chart to manage exacerbations. For the purposes of this trial, another single page insert will be devised to facilitate longer-term goal setting. The content has been approved by the Plain English Campaign and received the Crystal Mark for clarity of British English (appropriate for an eight year old to read). The manual will be introduced by Health Care Professionals (HCP), who have expertise in the management of COPD, the SPACE FOR COPD® programme and skills in motivational interviewing. HCPs will advise patients on how to use the manual and follow it independently at home. Participants will be expected to complete an exercise diary at home. Once at home, patients will have the opportunity to contact their HCP with questions via telephone. There will be follow-up maintenance group sessions (5-10 participants per group), at the recruiting centres based on a previously successful format. The aims of these group sessions are to discuss progress, address barriers, to increase motivation to maintain/ enhance healthy lifestyle behaviours and to encourage social support and not re-provide rehabilitation. Using motivational interviewing (MI) techniques, the sessions would involve the clinician facilitating the patients to identify barriers and facilitators to maintaining exercise, express empathy, support self-efficacy and roll with resistance. The teams at Leicester and London have worked together on previous projects and London are familiar with the SPACE FOR COPD programme. These groups will occur 4 times over 12-months, divided as follow:

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- At months 4 (exacerbation management/ goal setting),
- At month 7 (mood management and goal setting) and
- At month 10 (question and answer/ keeping going).

Each session will last for 2 hours at the recruiting centre and refreshments will be provided. Patients will be sent reminders about group sessions by their preferred method (e.g. text, email, or letter).

There will also be an embedded qualitative component of the trial. All eligible participants will be offered the chance to take part in the trial at the end of their Pulmonary Rehabilitation programme. Qualitative interviews will be performed in willing subjects (described later), at 12-months (or earlier if there is attrition to the programme).

Intervention Type

Behavioural

Primary outcome(s)

Endurance walking distance at 12 months in those who have completed the maintenance programme compared to usual care (measured by Endurance Shuttle Walking Test).

Key secondary outcome(s)

At 12-months:

1. Maximum walking distance measured using incremental Shuttle Walking Test distance
2. Quality of life measured using EQ-5D
3. Anxiety and depression measured using the Hospital Anxiety and Depression Scale
4. Physical activity measured over 7 days using accelerometer devices (e.g. steps, calories, and MET levels).
5. Symptoms (breathlessness, fatigue, sputum production, cough, sleep, chest tightness) measured using the Chronic Respiratory Disease Questionnaire
6. Patient activation (knowledge, skills and confidence to manage COPD) measured using the Patient Activation Measure (PAM-13) questionnaire
7. Forced Expiratory Volume in 1 second (FEV1) measured using a spirometer.
8. Adherence to the SPACE FOR COPD maintenance programme in terms of sessions attended, completion of the programme and exercise diary entries.
9. Data for future health economic analysis in both groups; including hospital admissions, health care contacts, medication use and mortality collected from patient self-report.

Qualitative outcomes:

10. To understand the patient experience of SPACE FOR COPD; to identify facilitators and barriers of the package to maintain health and well-being.
11. To work with staff, managers and commissioners involved in the delivery of SPACE FOR COPD as a maintenance option to explore how, if successful, this programme could be rolled-out more widely.

Completion date

30/09/2023

Eligibility

Key inclusion criteria

1. 18 years and older
2. Completed PR within the last 4 weeks
3. Clinical diagnosis of COPD
4. Able to read and write English to the age of an eight-year-old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

116

Key exclusion criteria

1. Significant disability which limits the daily physical activity

Date of first enrolment

18/10/2019

Date of final enrolment

31/05/2021

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Glenfield General Hospital

Groby Road

Leicester

United Kingdom

LE3 9QP

Study participating centre

Harefield Hospital

Hill End Road

Harefield

United Kingdom

UB9 6JH

Sponsor information

Organisation

University Hospitals of Leicester

ROR

<https://ror.org/02fha3693>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from (Linzy Houchen-Wolloff, Linzy.Houchen@uhl-tr.nhs.uk, anonymised quantitative and qualitative data, after all publications are completed).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		25/04/2022	10/08/2022	Yes	No
Abstract results		19/05/2024	24/07/2024	No	No
Basic results		24/07/2024	25/07/2024	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes