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

Submission date
03/05/2019

Recruitment status
No longer recruiting

Registration date
12/08/2019

Overall study status
Completed

Last Edited
25/07/2024

Condition category
Respiratory

[X] 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 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

Study website
https://www.leicestershospitals.nhs.uk/aboutus/departments-services/pulmonary-rehabilitation/research-and-development/current-studies/

Contact information

Type(s)
Public

Contact name
Mr Khaled Alqahtani

ORCID ID
http://orcid.org/0000-0001-5235-8467

Contact details
Centre for Exercise and Rehabilitation Science
NIHR Leicester Biomedical Research Centre â€“ Respiratory
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP
01162582762
kada5@leicester.ac.uk

Type(s)
Scientific

Contact name
Dr Linzy Houchen-Wolloff

ORCID ID
http://orcid.org/0000-0003-4940-8835

Contact details
Centre for Exercise and Rehabilitation Science
NIHR Leicester Biomedical Research Centre â€“ Respiratory
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP
01162582762
linzy.houchen@uhl-tr.nhs.uk

Type(s)
Scientific

Contact name
Prof Sally Singh

ORCID ID
http://orcid.org/0000-0002-9834-0366

Contact details
Centre for Exercise and Rehabilitation Science (CERS)
NIHR Leicester Biomedical Research Centre (BRC)-Respiratory
Glenfield Hospital
Groby 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
http://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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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; NRESCommittee.EastMidlands-LeicesterCentral@nhs.net), ref: 19/EM/0267

Study design
Prospective multicentre randomized controlled trial with blinded quantitative outcomes

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
https://www.leicestershospitals.nhs.uk/aboutus/departments-services/pulmonary-rehabilitation/research-and-development/current-studies/

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

Secondary outcome measures
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.

Overall study start date
01/10/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
116

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
England

United Kingdom

Study participating centre
Glenfield General Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP

Study participating centre
Harefield Hopsital
Hill End Road

Harefield
United Kingdom
UB9 6JH

Sponsor information

Organisation
University Hospitals of Leicester

Sponsor details
University Hospitals of Leicester NHS Trust
Research & Innovation Office
Leicester General Hospital
Gwendolen Road
Leicester
England
United Kingdom
LE5 4PW
01162584199
David.Hetmanski@uhl-tr.nhs.uk

Sponsor type
University/education

Website
https://www.leicestershospitals.nhs.uk/contact/

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

Publication and dissemination plan
In order to have a well-structured dissemination plan, we have adopted the Scientist Knowledge Translation Plan. It guides researchers through the stages of developing a dissemination strategy including clarifying 'key messages' identifying ways to transmit those messages and designing an evaluation plan. See here for details: http://ktdrr.org/training/webcasts/webcast5/webcast_ktplan_101013r.pdf
Audiences for this trial are commissioning organisations (such as CCGs, STPs and NHS England), HCPs providing rehabilitation, patients and the public, external statutory organisations (such as the Department of Health, NICE, CLAHRCs), and Academia. They will be involved throughout the research process to better shape the outcomes and have it easily translated to the community at the end of the trial. The delivery of the trial outcomes will be communicated via face-to-face. Moreover, it will include, but not limited to, development of links with key organisations, use of electronic media, and publications including full and plain English summary reports.

Intention to publish date
01/03/2024

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
HRA research summary			28/06/2023	No	No
Abstract results		19/05/2024	24/07/2024	No	No
Basic results		24/07/2024	25/07/2024	No	No