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Improving completion of pulmonary rehabilitation with PR-buddies (IMPROVE)

Submission date
20/12/2022

Recruitment status
No longer recruiting

Registration date
23/01/2023

Overall study status
Completed

Last Edited
22/03/2024

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
More than a million people in the UK are affected by chronic obstructive pulmonary disease (COPD). Pulmonary rehabilitation (PR) is the best treatment for the symptoms and impact of COPD, it improves the quality of life and exercise capacity. PR classes include exercise and information on how to manage symptoms. The impact of PR is restricted by poor rates of uptake and completion. Only 4 out of 10 people with COPD, referred for PR, complete the classes. Volunteers who have completed PR will be trained to support COPD patients who have been referred for PR. The volunteers will be called ‘PR-buddies’. In previous research, we found that PR-buddies/Lay Health Workers (LHWs) can be successfully recruited and trained to support COPD patients referred for PR. PR-buddies were enthusiastic, committed volunteers, and patients welcomed their support. LHWs are effective in a range of health issues but they have not been used much in the NHS. We want to know if trained PR-buddies are effective and acceptable in improving the rates of uptake and completion of PR.

Who can participate?
Adult patients with COPD deemed fit to participate can volunteer to participate as a PR-buddy. Adult patients who have been referred to a PR service can receive support from PR-buddies as part of the trial.

What does this study involve?
This study will use a 'train the trainer' model. The research team will recruit and train staff from PR teams across the UK in how to set-up and run a PR-buddy service. The PR-staff will then recruit and train patients from their service who have recently completed PR and who volunteer to become PR-buddies. The training will include how to identify the barriers to attending PR and the use of behaviour change techniques to overcome these barriers and find effective ways to help people to attend PR. The PR-buddies will support patients who are newly referred for PR. The main outcome of the IMPROVE Trial is whether PR-buddies increase the rates of uptake and completion of PR compared with PR centres that do not have a PR-buddy service.

What are the possible benefits and risks of participating?
If they are allocated a PR-buddy, then the main benefit for the patient is that they will receive support from them to help them overcome obstacles for attending PR and make it easier and

more useful for them. We hope that the patients and the PR-buddies find the trial to be enjoyable. We think that there are no major risks associated with this trial. There is a slight risk that the patient may not get along well with the PR-buddy or the PR-buddy may find it difficult to work with some of the patients.

Where is the study run from?
The lead site for this study is Guy's and St Thomas' NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2021 to December 2023

Who is funding the study?
National Institute of Health and Care Research (NIHR) (UK)

Who is the main contact?
Toby Morgan (Trial Manager), toby.morgan@kcl.ac.uk

Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
308114

Protocol serial number
NIHR130999, CPMS 53971, IRAS 308114

Study information

Scientific Title
Improving life quality in chronic obstructive pulmonary disease (COPD) by increasing uptake and completion of pulmonary rehabilitation with lay health workers: a cluster randomised controlled trial

Acronym
IMPROVE

Study objectives
The combined uptake and completion rate of pulmonary rehabilitation by patients with chronic obstructive pulmonary disease will be improved from a mean of 40% to a mean of at least 56% by providing support to these patients from patients who have previously completed pulmonary rehabilitation and have been trained by pulmonary rehabilitation teams in the use of behaviour change techniques to overcome obstacles to uptake and completion of pulmonary rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/10/2022, North West - Preston Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44(0)207 104 8019; preston.rec@hra.nhs.uk), ref: 22/NW/0330

Study design
Randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease

Interventions
-

Intervention Type
Other

Primary outcome(s)
Uptake rate and completion of pulmonary rehabilitation, completion defined as attendance of 70% or more of the planned classes, measured using patient records at month 33

Key secondary outcome(s))
1. Recruit and retain 38 pulmonary rehabilitation centres measured using study records at month 13 (for recruitment) and at month 26 (for retention)
2. Assess recruitment and retention of patient participants measured using study records between months 25 and 31
3. Rates of improvement in:
3.1. Exercise capacity and symptoms measured using:
3.1.1. The COPD assessment test (CAT) at baseline, 3 and 6 months post-assessment
3.1.2. The 6-minute walking distance test and incremental shuttle walk test prior to and after the end of pulmonary rehabilitation
3.2. Quality of life measured using the Euroqol EQ-5D-5L questionnaire at baseline, 3 and 6 months post-assessment
3.3. Well-being measured using the Hospital anxiety and depression survey (HADS) at baseline, 3 and 6 months post-assessment

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Category A - Inclusion criteria of participating pulmonary rehabilitation sites:
1. > 200 pulmonary rehabilitation referrals per year to allow for at least 35 (17.5%) participants to be recruited over six months.
2. Conduct routine baseline and final pulmonary rehabilitation session data including uptake and completion rates, quality of life assessment (COPD Assessment Test-CAT or Chronic Respiratory Questionnaire -CRQ-SAS), exercise tests (Six Minute Walking Distance - 6MWD or Intermittent Shuttle Walk Test - ISWT), and well-being assessment (General Anxiety Disorder Assessment 7 – GAD7) and (Patient Health Questionnaire 9 -PHQ9 or Hospital Anxiety and Depression Scale HADS).
3. Completion rate < = 55% determined by count based on appropriate referrals received. Referrals of non-COPD chest problems and patients with significant other disabilities that prevent participation should not be included in the completion rate denominator. The decision to limit inclusion to sites with a completion rate of 55% or less relates to the priority given to service inequalities and the need for the NHS to have a threshold for the introduction of the intervention. Including all sites may diminish the opportunity to show a difference in those services in greatest need.
4. Agree to randomisation to intervention or usual care
5. Agree to include all eligible patients in the invitation to be randomised for the PRB

intervention or usual care.
6. Agree to release three pulmonary rehabilitation staff for training (not simultaneously) over 2 days with an additional half-day remote training
7. Agree that two pulmonary rehabilitation staff will undertake intervention delivery
8. Agree on the third pulmonary rehabilitation staff member to have a backup role in event of a colleague becoming ill or leaving the service during recruitment and LHW training.
9. At least two of three participating staff members to be a registered healthcare professional (HCP)
10. If the third member is a non-HCP then should be at least Band 4 NHS pay scale
11. All team members to have at least one year's experience in pulmonary rehabilitation

Category B - Inclusion criteria of intervention site participating team members:
1. Aged 18 years or over
2. Be employed member of staff within the pulmonary rehabilitation service at the intervention site whether NHS or non-NHS service
3. Willing to undertake 2½ days of training to train, recruit, manage and support PRBs
4. Willing to manage and support PRBs over a nine-month period
5. Willing to take part in research activities including keeping accurate records

Category C - Inclusion criteria of pulmonary rehabilitation buddy volunteers:
1. Aged 18 years or over
2. COPD diagnosis and pulmonary rehabilitation completion within the previous year
3. Volunteer for the role
4. Willing to undertake training and be supervised by the pulmonary rehabilitation team
5. Willing to support at least 6 pulmonary rehabilitation patients over 9 months
6. Able to travel independently
7. Agree to use encrypted smartphones (after training) for recording conversations with supported patients

Category D - Inclusion criteria of participating patients:
1. Aged 18 years or over.
2. COPD diagnosis
3. Referred to pulmonary rehabilitation service
4. Medical Research Council (MRC) breathlessness score > 2
5. Consent to be randomised to intervention or usual care arm of the trial
6. Consent to receive telephone contact by PRB and to meet when appropriate
7. Consent to give personal details to the research team
8. Consent to give research team information on attendance and routinely collected data

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Category A - Exclusion criteria of participating pulmonary rehabilitation sites:
1. Unable to join trial until after June 2023
2. Unable to identify at least three members of staff for the trial willing to consent to participation
3. Local trust R&D office unwilling to support the trial

Category B - Exclusion criteria of pulmonary rehabilitation site participating staff:
1. Will not be employed in their post for the duration of the trial at the site in question

Category C - Exclusion criteria of pulmonary rehabilitation buddy volunteers
1. Unable to participate for the duration of the trial at the site in question
2. Unable to travel independently to meet referred patients
3. Unable or unwilling to use a smart mobile phone
4. Unable to give valid consent
5. Failed DBS check

Category D - Exclusion criteria of participating patients
1. Poorly controlled angina on minimal exertion
2. Myocardial infarction in 6 weeks prior to commencement of the programme
3. Breathlessness as a result of cardiac disease.
4. Uncontrolled hypertension
5. Any medical problem that severely restricts exercise or compliance with the programme e.g. severe arthritis or dementia
6. Unable to give valid consent
7. Unable to join until after month 20 of the trial

Date of first enrolment
13/02/2023

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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 data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		19/03/2024	22/03/2024	Yes	No

HRA research summary			28/06/2023	No	No
Protocol file	version 1.3	04/01/2023	23/01/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes