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Improving utilisation of pulmonary rehabilitation

Submission date
29/01/2018

Recruitment status
No longer recruiting

Registration date
20/03/2018

Overall study status
Completed

Last Edited
23/04/2025

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
An estimated 1.2 million people in the UK live with diagnosed Chronic Obstructive Pulmonary Disease (COPD), which causes breathlessness, difficulty with daily activities, frequent infections and admissions to hospital. Pulmonary rehabilitation (PR) is a programme of supervised exercise and education that helps people to control their symptoms, improve their quality of life and avoid being admitted to hospital. However, many patients who could benefit from attending PR do not get a place on a programme because they do not know about it or healthcare professionals (HCPs) do not refer them. Of those who are referred only two-thirds take up their place. There is no clear evidence about the best ways to increase referral or uptake. The aim of this study is to identify what helps or hinders PR referral and uptake, to improve patients' experience of the COPD pathway, and to develop a 'toolkit' of materials and recommendations for HCPs to use in primary care to increase referral and uptake.

Who can participate?
Patients aged 18 or over with COPD, physiotherapists and nurses who manage/run PR classes, GPs and nurses in primary care who care for people with COPD, and commissioners (respiratory clinical leads), all in the East of England

What does the study involve?
Patients attend interviews and focus groups to explore their experiences of the pulmonary rehabilitation pathway, its demands on their capabilities, their experience of PR referral and the reasons they did or did not choose to attend. GPs and nurses complete an online survey and attend interviews and focus groups to explore their experience of PR referral and uptake and the COPD care pathway. Physiotherapists complete an online survey and attend focus groups to explore their ideas for improving PR referral and uptake, and attend interviews to collect their experiences of the COPD care pathway. Commissioners are interviewed for their perspectives on improving referral and uptake and their views of the COPD care pathway. Patients and HCPs are also invited to join a toolkit user development group to take part in developing the toolkit jointly with the research team. When development is complete, the toolkit is tested by nurses in primary care to see if it is acceptable and usable in a real life setting, during annual COPD reviews with patients.

What are the possible benefits and risks of participating?
There is no guarantee that participants will benefit personally from taking part but possible long-term benefits of the study are that it will help more patients to attend PR. There is no risk of harm because there are no drugs or medical procedures involved. Patients are able to stop and rest if they feel tired during any of the activities and are welcome to have a family member, carer or friend with them.

Where is the study run from?
The study is taking place in healthcare organizations across the East of England (UK)

When is the study starting and how long is it expected to run for?
April 2016 to December 2020 (updated 16/12/2019, previously: December 2018)

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Frances Early

Contact information

Type(s)
Scientific

Contact name
Dr Frances Early

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

33565

Study information

Scientific Title
Improving the utilisation of pulmonary rehabilitation through development of a toolkit for use by referring clinicians and enhancing the inclusivity of the pulmonary rehabilitation pathway

Study objectives
The aim of this study is to increase the number of eligible patients taking up PR through increasing referrals, increasing take-up of referrals and improving patients' experiences of the COPD pathway.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Cambridge Central Research Ethics Committee, 19/04/2017, ref: 17/EE/0136

Study design
Non-randomised; Both; Design type: Process of Care, Psychological & Behavioural, Management of Care, Qualitative

Primary study design
Interventional

Secondary study design
Non randomised study

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)

Interventions
The aim of the project is to increase the number of people who are referred to pulmonary rehabilitation (PR) and who take up a referral. The study is a mixed methods design and comprises two work packages.

Work package 1 (WP1) uses Inclusive Design methods to identify the demands made of patients as they travel through the COPD care pathway (which includes referral to PR) and how those demands match patients’ capabilities. The work package will identify ways in which the care

pathway excludes patients and ways in which the pathway design could be modified to enable inclusive access to PR for as many eligible patients as possible.

Work package 2 (WP2) will focus on the referral process in primary care and will work with healthcare professionals(HCPs) and patients to identify how referral and uptake to PR can be supported and barriers overcome. Methods include an online survey, focus groups and interviews. This learning, together with outputs from WP1, will then be incorporated into a web-based toolkit which will be developed collaboratively with healthcare professionals and patients and will be for use by nurses and patients in primary care settings.

Work Package 1:
Inclusive Design theory provides the theoretical basis for this work package, mapping COPD primary care pathway, proposing and validating recommendations. Activities are as follows:
1. Semi-structured interviews to map COPD primary care pathway. Each participant will take part in one activity (30 to 60 minutes).
1.1. 6 interviews with HCPs (including GPs, practice nurses, or physiotherapists) in Cambridgeshire and Peterborough NHS Foundation Trust (CPFT) and PROVIDE Community Interest Company (PR service provider in Cambridge)
1.2. 1-2 interviews with PR service manager in CPFT and PROVIDE
1.3. 1-2 interviews with commissioner in CPFT.
1.4. 5 to 7 interviews with patients who have accepted a PR offer and attended PR.
1.5. 3 to 5 interviews with patients who have declined an offer of PR. Patients will be drawn from 2 general practices in CPFT.
1.6. 3 to 5 interviews with patients who have not been referred to PR. Patients will be drawn from general practices in CPFT.
2. Second interviews to validate recommendations. Each participant will take part in one activity (30 minutes).
2.1. 2-4 interviews with HCPs (including GPs, practice nurses, or physiotherapists) in CPFT and PROVIDE
2.2. Email 5-10 HCPs to seek comments.
3. Focus group to validate recommendations. Each participant will take part in one activity (30 to 60 minutes).
3.1. 2 focus group of 1 physiotherapist and 8-10 patients who attend the Breathe Easy Support Group

Work Package 2:
Normalisation Process Theory (NPT) and Burden of Treatment (BoT) theory provide the theoretical basis for this work package, framing data collection and toolkit design. Activities are as follows:
1. Online survey. Each participant will complete the online survey (10 to 20 minutes).
1.1. Online survey distributed to all GP practices across the East of England (within area covered by CRN Eastern).
1.2. Online survey distributed to all PR providers in the East of England.
1.3. In addition, the PR survey will be circulated to approximately 900 PR providers who have participated in the national COPD audit programme
2. Qualitative research. Each participant will take part in one activity (30 to 60 minutes).
2.1. 1 focus group of PR providers in the East of England.
2.2. Purposive sampling to select 4 PR services within the CRN Eastern area based on utilisation of commissioned places in 2014/15 (two highest and two lowest):
2.2.1. 4 focus groups (1 within each PR service) of patients who have accepted a PR offer and attended PR.
2.2.2. 4 to 8 interviews with patients who have declined an offer of PR. Patients will be drawn

from general practices that refer to the 4 PR services.
2.2.3. 4 to 8 interviews with patients who have not been referred to PR. Patients will be drawn from general practices that refer to the 4 PR services.
2.2.4. 4 focus groups or 15-20 interviews (depending on practicalities) with practice nurses and / or GPs from practices that refer to the 4 PR services.
2.2.5. 4 interviews with commissioners from the CCGs that commission the 4 PR services.
2.3. Purposive sampling in two areas with significant BME populations to identify patients of South Asian heritage:
2.3.1. 2 focus groups (one in each area) of patients who have accepted a PR offer and attended PR.
2.3.2. 1 to 4 interviews with patients who have declined an offer of PR. Patients will be drawn from general practices in the two areas.
2.3.3. 1 to 4 interviews with patients who have not been referred to PR. Patients will be drawn from general practices in the two areas.
2.3.4. 2 interviews with physiotherapists who lead PR in each area.
2.3.5. 2 interviews with HCPs who refer to PR services in each area.
3. Toolkit development. Participants will be involved throughout the development process (6 months).
3.1. A user group will be established comprising 5 HCPs and 5 patients recruited from research participants, interested volunteers from PPI events and British Lung Foundation networks.
3.2. The study team and user group will review the needs and tools identified through the survey, qualitative research and a prior systematic literature review. They will prioritise the findings using a consensus method adapted from nominal group technique to consider and vote on priorities. The group will define assessment criteria for usability and acceptability testing.
3.3. An iterative design process (explore, create, evaluate) will be used to move from concept to building the toolkit, including acceptability and usability testing. Participants may take part remotely online or by attending user feedback sessions. Agile development methods will allow early web pages to be developed by the study team and built in the live location immediately to develop concepts and stimulate ideas. Early and subsequent versions of the toolkit will be continuously explored, created, evaluated and fed back upon with the user group, alongside continuous web development in short time cycles over 6 months. The usability and acceptability assessment criteria will determine the feedback requested. With each round of feedback, those criteria will be open to further refinement as users explore and identify their practical needs.
3.4. The toolkit will be built on a WordPress platform and hosted on University of Cambridge web servers. It will be designed to interface with systems and processes in general practice in ways to be identified during the research, e.g. linked to SystmOne, integrated into annual review.
3.5. Practice nurses in 5 general practices will then be trained to use the toolkit for 4 weeks to gather feedback on its use in clinical settings and conduct exploratory efficacy testing. Nurse feedback will reflect assessment criteria as above, including user experience, perceived understanding of PR/referral criteria, technical issues, nurse time to implement the toolkit. It will be collected via a short questionnaire to be completed following toolkit use with each patient and an interview at the end of the 4 week period. Each patient will be asked to complete a short evaluation questionnaire to assess the impact on the patient experience. This will be returned directly to the study team by stamped addressed envelope. We will also collected usage metrics from the system and data on referral numbers and uptake compared to baseline.

Intervention Type
Other

Primary outcome measure

Work Package 1
1. Patients' experiences of accessing pulmonary rehabilitation are measured using interviews and focus groups.
2. Care pathway elements that create barriers (mapping primary care pathways) are assessed using patient and HCP interviews and focus groups

Work Package 2
1. HCP and patients' perspectives on barriers to PR referral and update are assessed using online surveys and qualitative research (focus group or interviews), user groups, feedback sessions
2. Components for a toolkit to increase for PR referral and update are suggested using online surveys and qualitative research (focus group or interviews), user groups, feedback sessions
3. Acceptability and usability of a toolkit for HCPs and patients are assessed using online surveys and qualitative research (focus group or interviews), user groups, feedback sessions

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/04/2016

Completion date
31/12/2020

Eligibility

Key inclusion criteria
Work Package 1:
1. People resident in the East of England, aged 18 or over, with a diagnosis of COPD, stable disease, eligible for PR as defined by the guideline recommendations and able to read/write English
2. Within Cambridgeshire and Peterborough – healthcare professionals who refer to PR programmes, physiotherapists who provide PR, PR service managers and the CCG strategy manager

Work Package 2:
1. Patients resident in the East of England, age 18 or over, diagnosis of COPD, stable disease and eligible for PR as defined by guideline recommendations and able to read/write English. Patients of South Asian heritage will be eligible even if they do not have the ability to read or write in English but can communicate, read and write in Hindi or Urdu. Regarding patients who have accepted a PR offer, only those for whom this is the first offer they have accepted will be eligible
2. HCPs who refer to PR programmes in the CRN Eastern area and PR providers in the East of England PR Network
3. Commissioners (respiratory clinical leads) from selected CCGs

Participant type(s)
Mixed

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
Planned Sample Size: 631; UK Sample Size: 631

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/06/2017

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North East London NHS Foundation Trust
Tantallon House
Goodmayes Hospital Site
Barley Lane
Ilford
United Kingdom
IG3 8XJ

Study participating centre
BOC Clinical Services (West Norfolk PR Service)
The Priestley Centre
10 Priestley Road
The Surrey Research Park
Guildford
United Kingdom
GU2 7XY

Study participating centre
South Essex Partnership University NHS Foundation Trust
The Lodge, Runwell Hospital

Runwell Chase
Runwell
Wickford
United Kingdom
SS11 7XX

Study participating centre
Colchester Hospital University NHS Foundation Trust
Colchester District General Hospital
Turner Road
Colchester
United Kingdom
CO4 5JL

Study participating centre
James Paget University Hospitals NHS Foundation Trust
Lowestoft Road
Gorleston
Great Yarmouth
United Kingdom
NR31 6LA

Study participating centre
Ipswich Hospitals NHS Trust
Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre
Luton and Dunstable University Hospital NHS Foundation Trust
Lewsey Road
Luton
United Kingdom
LU4 0DZ

Study participating centre
Southend University Hospital NHS Foundation Trust
Prittlewell Chase

Westcliff-on-Sea
United Kingdom
SS0 0RY

Study participating centre
Papworth Hospital NHS Foundation Trust
Papworth Everard
Cambridge
United Kingdom
CB23 3RE

Study participating centre
Central London Community Healthcare NHS Trust
7th floor
64 Victoria Street
London
United Kingdom
SW1E 6QP

Study participating centre
Hertfordshire Community NHS Trust
14 Tewin Road
Welwyn Garden City
United Kingdom
AL7 1BW

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
Cambridgeshire Community Services NHS Trust
UNIT 3
Meadow Lane
St. Ives
United Kingdom
PE27 4LG

Study participating centre
Peterborough and Stamford Hospitals NHS Foundation Trust
Edith Cavell Hospital
Bretton Gate
Bretton
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
Norfolk Community Health and Care NHS Trust
Elliot House
130 Ber Street
Norwich
United Kingdom
NR1 3FR

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trust
Elizabeth House, Fulbourn Hospital
Cambridge Road
Fulbourn
Cambridge
United Kingdom
CB21 5EF

Study participating centre
Anglian Community Enterprise
Community Interest Company
Anglian Community PR Service
659-662 The Crescent
Colchester Business Park
Colchester
United Kingdom
CO4 9YQ

Study participating centre
Bedford Hospital NHS Trust
South Wing
Kempston Road

Bedford
United Kingdom
MK42 9DJ

Study participating centre
Provide Community Interest Company
COPD Team
Broomfield Hospital
Court Road
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
NHS Norwich CCG
Norwich City Hall
St. Peters Street
Norwich
United Kingdom
NR2 1NH

Study participating centre
NHS Cambridgeshire and Peterborough CCG
Lockton House
Clarendon Road
Cambridge
United Kingdom
CB2 8FH

Study participating centre
NHS Bedfordshire CCG
Capability House
Wrest Park
Silsoe
Bedford
United Kingdom
MK45 4HR

Study participating centre
NHS North East Essex CCG
Aspen House

Stephenson Road
Severalls Business Park
Colchester
United Kingdom
CO4 9QR

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

Sponsor details
Addenbrookes Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04v54gj93

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

WP1:
Planned publication of 3 papers in a high-impact peer reviewed journal:
1. The study protocol: Improving uptake of pulmonary rehabilitation in Eastern of England: an Inclusive Design/ mixed-methods study protocol
2. Findings from qualitative research (Improve uptake and attendance of pulmonary rehab service)
3. Qualitative research methodology (The Role of Inclusive Design in Improving People's' Access to pulmonary rehab)
Intent to publish between November 2017 and August 2018

WP2:
Planned publication of 4 papers in a high-impact peer reviewed journal:
1. Qualitative research methodology (mapping theory to research design)
2. Findings from online survey
3. Findings from qualitative research
4. Outputs from toolkit development
Intent to publish between September 2018 and December 2019.

Intention to publish date

30/06/2020

Individual participant data (IPD) sharing plan

Data collected during WP1 will be entered onto secure computers in the Engineering Design Centre (EDC) at the University of Cambridge and will only be accessible to the study team. Paper documents will be stored in a locked cupboard in the EDC and only be accessible by the study team. Data collected during WP2 will be entered onto secure NHS computers for the purposes of data analysis and only accessible to the study team. Paper documents will be stored in a locked filing cabinet on NHS premises only accessible by the study team. Only study team members will have access to the final dataset.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol for Work Package 2	21/01/2019		Yes	No
Protocol article	protocol for Work Package 1	01/04/2018	16/12/2019	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	A systems approach to developing user requirements for increased pulmonary rehabilitation uptake by COPD patients	16/07/2024	23/04/2025	Yes	No