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Pragmatic evaluation of a quality improvement programme for people living with modifiable high-risk chronic obstructive pulmonary disease

Submission date
08/10/2021

Recruitment status
No longer recruiting

Registration date
13/10/2021

Overall study status
Ongoing

Last Edited
08/05/2025

Condition category
Respiratory

[X] 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

Chronic obstructive pulmonary disease (COPD) represents a major challenge to public health due to its increasing incidence and it is currently the third leading cause of death worldwide. The main symptoms of COPD are breathlessness, wheeze and chronic cough, for which patients receive medicinal and non-medicinal treatment. However, both underdiagnosis and misdiagnosis are problematic, with an estimated 60-70% of true COPD cases being undiagnosed, and symptoms commonly being incorrectly diagnosed as cardiac-related. COPD has a gradual onset over a number of years and most COPD cases are identified during an exacerbation or after significant loss of lung function. Timely diagnosis of COPD remains limited, due to various factors including patients not recognising or adapting to their symptoms. Similarly, sub-optimal treatment is also a barrier to patients receiving appropriate care, with about two-thirds of patients in large database studies not being prescribed maintenance therapy. Research from large population-based studies of patients in primary and secondary care have shown that patients with late diagnosis and suboptimal treatment of COPD have a greater future risk of exacerbations, faster worsening of lung function, greater risk of cardiovascular (relating to the heart and blood vessels) events, greater risk of death, and larger healthcare costs.

Patients with COPD often experience exacerbations (or flare-ups), when their symptoms worsen to the point where additional treatment is required. Exacerbations have a negative impact on quality of life, accelerate disease progression and can result in hospital admissions and death. A significant proportion of COPD patients with frequent exacerbations remain undertreated according to health quality standards in primary care. Reviewing electronic medical records (EMR) data could identify patients with modifiable, high-risk COPD, such as those experiencing frequent previous exacerbations and prescribed sub-optimal medication according to current guidelines. Patients with modifiable, high-risk COPD have scope to benefit from further clinical assessment and provision of appropriate medication and other treatments.

This study will assess the impact of a primary care quality improvement programme aiming to reduce COPD exacerbations and major adverse cardiac or respiratory events (MACREs) for modifiable high-risk COPD patients. The intervention is based on current guidelines and will support practices to identify suitable patients, assess the severity of disease and prescribe appropriate management and treatment. Comparing the effectiveness of the intervention

against usual care within a UK primary care setting will address current evidence gaps regarding the potential patient health benefits of earlier diagnosis and optimised management of modifiable high-risk patients.

Who can participate?
GP practices in England with a sufficient number of patients aged 40 years or older with COPD

What does the study involve?
This study aims to recruit 168 GP practices and collect anonymous data for about 2016 patients from their electronic medical records. Half of the participating practices are randomly allocated to receive a quality improvement intervention, aiming to identify patients at risk of COPD exacerbations whose current treatment may be optimised. The other half of the participating practices continue their usual clinical patient care. The study does not require patients to attend their GP practice outside of their normal care. Each practice takes part in the study for about three years and anonymous patient data is extracted from their electronic medical records. All data will be stored in an ethically approved database (Optimum Patient Care Research Database, https://opcrd.co.uk) and provided to the study team at the end of the study.

What are the possible benefits and risks of participating?
Practices in the intervention arm of the trial will be supported to offer guideline-recommended care to their patients with existing and newly identified COPD, including optimising treatment. Assuming treatment optimisation reduces future exacerbation risk, practices may see lower consultation rates amongst their COPD patients and lower medication costs due to patients having more stable symptom profiles. Fewer exacerbations would also protect against rapid decline in lung function, therefore minimising the proportion of COPD patients with severe, complex disease. Practices will be supported to identify potential undiagnosed COPD patients, thus improving diagnosis of hidden COPD. These patients can then receive appropriate treatment to improve their health.
Optimising treatment for already-diagnosed and newly identified modifiable high-risk COPD patients is expected to reduce future exacerbation risk and rate of lung function decline, and improve quality of life. In addition, patients will be referred to non-pharmacological treatment as appropriate, such as smoking cessation and pulmonary rehabilitation.
GP practices that were randomised to the control arm will receive the quality improvement programme at the end of the study.

Where is the study run from?
Observational and Pragmatic Research International Ltd (UK)

When is the study starting and how long is it expected to run for?
October 2021 to October 2026

Who is funding the study?
1. AstraZeneca (UK)
2. Optimum Patient Care Global Limited (UK)

Who is the main contact?
Andy Dickens
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Study website
https://opri.org.uk/PREVAIL/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
295908

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
OPRIUK-2003, IRAS 295908, CPMS 48750

Study information

Scientific Title
A 3-year cluster randomised controlled trial of the impact of a quality improvement and clinical decision support package versus usual care for patients with modifiable high-risk chronic obstructive pulmonary disease with or without a current diagnosis.

Acronym
PREVAIL

Study objectives
Can a quality improvement programme improve the treatment and clinical outcomes in people with Chronic Obstructive Pulmonary Disease (COPD)?

Patients whose COPD treatment and management could be optimised, or whose COPD is not recognised and diagnosed, suffer exacerbations of the disease, ongoing symptoms and reduced health-related quality of life. Clinical guidelines note the importance of diagnosing COPD and optimising treatment for those at high risk of future exacerbations. The study will focus on

patients who have a high risk of future exacerbations and potential for increased COPD medication, referred to as modifiable ‘high-risk’ COPD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/11/2021, East Midlands - Derby Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 207 104 8276; derby.rec@hra.nhs.uk), ref: 21/EM /0252

Study design
Multi-centre cluster randomized trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease (COPD)

Interventions
Enrolled practices will be randomised in a 1:1 ratio (using permuted blocks of different sizes) to either the intervention or control arm of the trial. Practices in the control arm will continue their usual patient care during the trial, and will receive the intervention at the end of the study period.

Practices in the intervention arm will participate in a COPD quality improvement package, supporting healthcare professionals in primary care to diagnose, assess, and optimise the management of their patients with modifiable high-risk COPD, through the promotion of guideline-based care. Modifiable high-risk patients are those whose medical history of COPD exacerbations (flare-ups of disease), or history of smoking and respiratory symptoms and infections for those who do not have a COPD diagnosis, put them at a higher risk of exacerbations and cardiac or respiratory illness in the future. We describe this as a ‘modifiable’ risk because, with appropriate management, the risk may be modified and reduced.

The intervention consists of four main components: i) identification of patients with modifiable high-risk COPD, ii) assessment of disease/quantification of future risk, iii) pharmacological/non-pharmacological treatment, iv) clinical follow up. Each practice will receive support and resources to deliver the intervention, including: clinical support to undertake clinic assessments,

a spirometry service for patient lung function testing, patient questionnaires exploring respiratory symptoms and health and, individualised patient quality improvement reports based on guidelines.

As a cluster randomised trial of a quality improvement intervention, patients will not be required to attend any research study visits; any consultations will be part of quality improvement activities undertaken by practices as part of guideline-recommended care and treatment. Participating practices in both the intervention and control arms will be required to contribute anonymised and de-identified data (i.e. data which does not identify any patients) to the Optimum Patient Care Research Database (OPCRD) as part of the quality improvement programme. The study is anticipated to start in 2021 and finish in 2026, with each practice spending approximately 3 years in the study.

Intervention Type
Other

Primary outcome measure
1. The annual rate of moderate or severe exacerbations is measured using electronic medical records data (prescription of oral corticosteroids and/or antibiotics, or hospital visits/admissions following a respiratory event), at baseline, 12, 24 and 30 months. All outcome data will be analysed retrospectively at the end of the trial.
2. The annual rate of major cardiac or respiratory events is measured using electronic medical records data (new diagnosis/hospitalisation for heart failure, coronary artery revascularization, myocardial infarction, stroke, cardiac/respiratory death, respiratory hospitalisation), at baseline, 12, 24 and 30 months. All outcome data will be analysed retrospectively at the end of the trial.

Secondary outcome measures
Total annual systemic corticosteroid exposure is measured using electronic medical records data (average annual dose of prednisolone taken via any systemic route), at baseline, 12, 24 and 30 months. All outcome data will be analysed retrospectively at the end of the trial.

Overall study start date
01/10/2021

Completion date
01/10/2026

Eligibility

Key inclusion criteria
Criteria for participants (primary care practices):
1. Primary care (GP) practice in England
2. Has a minimum of 12 modifiable “high-risk” COPD patients

Modifiable high-risk patients suitable for quality improvement programme:
Diagnosed COPD at baseline, i.e., “already-diagnosed”:
1. Diagnosed with COPD at trial baseline
2. Aged 40 years or older at trial baseline
3. In baseline period: two or more moderate, or one or more severe, exacerbations in the 24 months preceding randomization, including at least one exacerbation in the last 12 months
4. Therapy at baseline: no therapy, on a short-acting bronchodilator (SABA, SAMA or SABA-

SAMA), on monotherapy with a long-acting β2 agonist (LABA), long-acting muscarinic antagonist (LAMA) or inhaled corticosteroid (ICS), or on dual therapy with LAMA-LABA or ICS-LABA

Undiagnosed patients with potential modifiable high-risk COPD:
1. No diagnosis of COPD at trial baseline
2. Aged 40 years or older by trial baseline
3. Current smoker, or ex-smoker with a significant smoking history (10+ years smoking duration or 10+ pack-years)
4. In baseline period: two or more moderate, or one or more severe exacerbations of potential COPD in the 24 months preceding randomization, including at least one exacerbation in the last 12 months
5. Therapy at baseline: no therapy, on a short-acting bronchodilator (SABA, SAMA or SABA-SAMA), on monotherapy with a long-acting β2 agonist (LABA), long-acting muscarinic antagonist (LAMA) or inhaled corticosteroid (ICS), or on dual therapy with LAMA-LABA or ICS-LABA

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
A total of 168 GP practices will be recruited into the trial. Estimated number of patients (analysis sample) to be included in the trial is 2,016 patients (approximately 12 patients per practice).

Key exclusion criteria
Criteria for participants (primary care practices):
1. Practices that are in the process of, or planning to change the electronic medical records system (also called GP clinical system) or practice ownership within the study period
2. Practices engaged in active research studies or COPD related Quality Improvement Programs which might impact the ability to implement the quality improvement programme (intervention)

Modifiable high-risk patients (diagnosed and undiagnosed COPD) not suitable for quality improvement programme:
1. Patients with a 'consent refusal' code in electronic medical records indicating opt-out for the usage of their data for research
2. Women who are pregnant at randomization or who become pregnant
3. Patients with a current asthma diagnosis and evidence of an asthma consultation in the last 24 months (applies to undiagnosed COPD only)

Date of first enrolment
07/03/2022

Date of final enrolment
31/10/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Observational and Pragmatic Research International Ltd
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Sponsor information

Organisation
Observational & Pragmatic Research Institute

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Sponsor type
Research organisation

Website
https://opri.sg/

ROR
https://ror.org/02gq3ch54

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Optimum Patient Care

Alternative Name(s)
Optimum Patient Care Ltd, Optimum Patient Care Limited, OPC

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publications in high impact peer-reviewed journals and oral presentations at relevant respiratory conferences.

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made available due to restrictions on the use of the Optimum Patient Care Research Database (study data source), as outlined within the legally binding data-sharing agreement with the study

sponsor. Individual requests for dataset access may be made available for approved researchers on specific requests to the steering committee and with the written approval for data sharing by the ADEPT committee (governing body of OPCRD).

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Protocol article		25/04/2025	01/05/2025	Yes	No