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# Does ensuring people go home from hospital on the right inhalers after an exacerbation of chronic obstructive pulmonary disease reduce the risk of being re-admitted to hospital?

**Submission date**
01/09/2022

**Recruitment status**
No longer recruiting

**Registration date**
08/09/2022

**Overall study status**
Completed

**Last Edited**
19/07/2024

**Condition category**
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is the name for a group of lung conditions that cause breathing difficulties. This study tests if optimising the inhaled medicines of people living with COPD who have been admitted to hospital with a chest infection called an 'exacerbation', helps reduce the risk of death and readmission to hospital over the following 3 months. This is a preliminary study called a 'feasibility study' that will tell us if a full-size study to answer the question is possible.

Who can participate?
Patients aged 18 years and over who have been admitted to hospital with an exacerbation of COPD

What does the study involve?
Participants' clinicians will use a new tool to see if they are on the right inhalers. If not, they will suggest making a switch. Participants will then be phoned at 30 and 90 days to see how they got on with the new inhalers(s) if inhalers were switched, and to see if they were re-admitted to hospital. Some participants and some clinicians too will undergo more in-depth interviews about inhaler switching in this way.

What are the possible benefits and risks of participating?
The benefit to taking part is that there will be a closer look at the inhalers people are using. If there is a switch, the new inhaler(s) may not suit the person so well.

Where is the study run from?
The study is being run from the Royal Free Hospital in London, with people also invited to take part in Birmingham and Newcastle (all in the UK).

When is the study starting and how long is it expected to run for?
February 2022 to July 2023

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

Who is the main contact?
Ms Anne-Marie Preston, anne-marie.preston@nhs.net

# Contact information

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Principal investigator

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# Additional identifiers

### Integrated Research Application System (IRAS)
309854

### Central Portfolio Management System (CPMS)
52972

# Study information

### Scientific Title
Optimised inhalers to reduce chronic obstructive pulmonary disease exacerbation re-admissions and mortality: a feasibility study

### Acronym
OPTIHALE

### Study objectives
This study will test the hypothesis that re-admissions and mortality after a hospitalised chronic obstructive pulmonary disease (COPD) exacerbation can be reduced by optimising both inhaled drug prescription and device prior to discharge. This is a feasibility study.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 01/07/2022, Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham HRA1 Meeting Room, NG1 6FS, UK; +44 (0)207 104 8010; blackcountry.rec@hra.nhs.uk), ref: 22/WM/0125

### Primary study design
Observational

### Study design
Feasibility study

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Exacerbations of chronic obstructive pulmonary disease (COPD)

### Interventions
Participants' clinicians will use a new tool to see if they are on the right inhalers. If not, they will suggest making a switch. Participants will then be phoned at 30 and 90 days to see how they got on with the new inhalers(s) if inhalers were switched, and to see if they were re-admitted to hospital. Some participants and some clinicians too will undergo more in-depth interviews about inhaler switching in this way.

### Intervention Type
Other

### Primary outcome(s)
The primary aim of this study is to establish the feasibility of a future definitive trial; as such the feasibility outcomes are to measure:
1. The proportion of patients prescribed incorrect inhaled medicine, according to NICE guidance, assessed by review of the prescription chart and admission documentation prior to discharge
2. The proportion of patients with critical inhaler device errors, assessed by direct observation of technique prior to discharge
3. The proportion of patients with insufficient peak inspiratory flow rate for their current device, assessed using the In-Check device prior to discharge
4. The proportion of patients willing to have inhalers changed where a change is indicated, assessed by asking the patient prior to discharge
5. Of those eligible for an inhaler change, the proportion of patients in which the change is made and if not why not, by assessing the discharge prescription and interview with clinicians at the point of discharge
6. Of those who had an inhaler change, the continuation of that change in the community assessed by patient interview at 30 and 90 days
7. Patient perception of inhaled medication assessed using the Feeling of Satisfaction with Inhaler (FSI-10) questionnaire prior to discharge and at 30- and 90 days
8. Loss to follow-up at 30 and 90 days
9. Challenges in data collection assessed by interviews with clinicians using the tool throughout the study period
10. The time taken to collect the data and deliver the inhaler selection tool, assessed by timing use of the tool at the point of use
11. The first language distribution of patients with COPD at the three sites, to understand the need for translation of trial materials, assessed by interviews with patients prior to discharge

### Key secondary outcome(s)
In addition, to inform the power calculation for a definitive study, the researchers will assess:
1. The mortality rate at 30 and 90 days, by review of electronic patient records
2. The all-cause re-admission rate at 30 and 90 days, by patient interview

3. The acceptability of the intervention is assessed using qualitative interviews. Then, based on input from trial participants and clinicians, the researchers will further refine and develop the inhaler selection tool. These interviews will be conducted after discharge.

### Completion date
31/07/2023

## Eligibility

### Key inclusion criteria

1. In hospital with an exacerbation of COPD
2. Age 18 years or over
3. Able to provide informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Key exclusion criteria
Discharge home with palliative care

### Date of first enrolment
03/10/2022

### Date of final enrolment
30/04/2023

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Royal Free Hospital**
Pond Street
London
United Kingdom
NW3 2QG

### Study participating centre
**Queen Elizabeth Hospital**
Edgbaston

Birmingham
United Kingdom
B15 2GW

**Study participating centre**
**The Royal Victoria Infirmary**
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
TS1 4LP

# Sponsor information

**Organisation**
Royal Free London NHS Foundation Trust

**ROR**
https://ror.org/04rtdp853

# 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? |
|---|---|---|---|---|---|
| Results article | | 04/03/2024 | 19/07/2024 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |