

# Supported rescue packs (medications and instructions) post-discharge in chronic obstructive pulmonary disease

<b>Submission date</b> 22/02/2024	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/07/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/07/2025	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Chronic obstructive pulmonary disease (COPD) is a chronic lung disease affecting approximately 10% of the adult population globally. COPD is recognised to be an important area of focus, as part of one of the healthcare challenges defined by the Office of Life Sciences. Patients with COPD often experience exacerbations which are triggered episodes leading to disease worsening. Exacerbations are associated with increased morbidity and a risk of mortality.

Severe exacerbations, where patients are hospitalised, are of particular concern to patients, carers and healthcare givers. The National Institute for Health and Care Excellence (NICE) recommends that hospital clinicians looking after patients with COPD should provide rescue packs (a course of prednisolone and antibiotics) and a basic management plan to patients on discharge. It is recognised that there is a high-risk 90-day period to patients with COPD following discharge from hospital, where there is a 43% risk of readmission and a 12% risk of mortality; however repeated national audit data has shown that, despite NICE recommendations this high risk of readmission and mortality has not changed.

We will conduct a multicentre randomised clinical trial of 1400 patients in 30 acute NHS trusts. This will test the hypothesis that a self-supported rescue pack management plan consisting of rescue packs + written self-management plan + twice weekly telephone/text symptom alert assessments in the high-risk 90-day period is better than standard care in reducing 90-day readmission by 20%. If successful, this intervention would be rapidly implementable, improve patient clinical outcomes and have a cost saving of approximately £350 million per annum.

### Who can participate?

Adults aged 40 years and over, to be discharged from hospital with exacerbation of COPD

### What does the study involve?

Patients who consent will be randomly assigned to one of two groups, akin to flipping a coin:

1. Intervention Group: Receives a rescue pack and biweekly automated calls for 90 days, monitoring their health. Calls, lasting over 2 minutes, occur from 10am to 6.30pm Monday to

Thursday. If unanswered, up to five callbacks will be made, or a message left.

2. Comparison Group: Receives standard care, without a rescue pack, and no automated calls.

Study Schedule:

- Screening: Eligibility confirmed upon discharge, with consent obtained. Basic medical information collected, optionally including nasal samples.
- Baseline (Day 0): Random assignment, routine investigation results collected, and questionnaires on quality of life and COPD impact completed. Optional stool and nasal samples taken.
- Days 30, 90, 180: Participants interviewed regarding healthcare utilization and medication usage. Questionnaires repeated over the phone. Optionally, stool and nasal samples collected.
- One Year/End of Study: Follow-up call to assess healthcare utilization and adverse events.

What are the possible benefits and risks of participating?

Taking part in the study may help participants better manage your COPD through closer monitoring. We also hope that the knowledge gained from the study will improve our understanding of COPD and the provision of rescue packs, which may help to inform future treatment for COPD patients. Specifically, we will generate evidence on whether use of rescue packs with phone support is something that reduces the likelihood of being re-admitted to hospital. We will also understand more about the potential risks of rescue packs, such as the development of antibiotic-resistant bacteria.

Participants may experience side effects from taking the antibiotics and steroids in a rescue pack, if they need to take them. These can include:

Antibiotics: side effects would depend on which antibiotic has been selected, but more common side-effects might include

- Nausea or vomiting
- Bloating and indigestion
- Diarrhoea
- Thrush
- Rash

Steroids: short term use of corticosteroids is not associated with long term risks, however, but short courses can cause:

- Indigestion or heartburn
- Increased appetite
- Difficulty sleeping (insomnia)
- Changes in mood and behaviour, such as feeling irritable or anxious
- An increased risk of infections – especially chickenpox, shingles, and measles
- High blood sugar (hyperglycemia or diabetes).

Where is the study run from?

King's College London (UK)

Guy's and St Thomas' NHS Foundation Trust (UK)

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

January 2024 to December 2027

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?

rapid-rescue@kcl.ac.uk

# Contact information

## Type(s)

Scientific, Principal investigator

## Contact name

Prof Mona Bafadhel

## ORCID ID

<https://orcid.org/0000-0002-9993-2478>

## Contact details

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## Type(s)

Scientific, Principal investigator

## Contact name

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## Type(s)

Public

## Contact name

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

331831

### **ClinicalTrials.gov (NCT)**

NCT06347536

### **Protocol serial number**

IRAS 331831, NIHR156698, CPMS 63008

## **Study information**

### **Scientific Title**

Supported rescue packs post-discharge in chronic obstructive pulmonary disease: An open-label multicenter randomised controlled trial

### **Acronym**

RAPID

### **Study objectives**

Provision of a rescue pack of antibiotics and corticosteroids, together with written (and translated) education on their use and twice-weekly telephone (or text) based support for when to use rescue packs, can reduce all-cause hospital re-admission in the 90-day high-risk period following discharge from hospital after an exacerbation of COPD.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 03/07/2024, South Central - Oxford B Research Ethics Committee (Health Research Authority, 2 Redman Place Stratford E20 1JQ, Stratford, E20 1JQ, United Kingdom; +44 207 104 8134; oxfordb.rec@hra.nhs.uk), ref: 24/SC/0186

### **Study design**

Open-label multicenter randomized controlled trial

### **Primary study design**

Interventional

## **Study type(s)**

Quality of life, Treatment

## **Health condition(s) or problem(s) studied**

Chronic obstructive pulmonary disease (COPD)

## **Interventions**

Patients allocated to the intervention arm will receive:

1. A rescue pack (prednisolone and antibiotics for 5-7 days). The prescription will conform to local prescribing guidelines for antibiotic and systemic corticosteroids for exacerbations of COPD.
2. A written rescue pack management plan.
3. Twice-weekly automated telephone symptom reminder calls and/or text messages for 90 days.

Comparator Intervention: Usual care (to be studied and described) – but no provision of a rescue pack at discharge.

The method of randomisation in the trial is stratified randomisation, using blocking within strata defined by Previous exacerbations in the last year and COPD Hospitalisation in the last year. Randomisation implementation: The randomisation sequence will be generated dynamically by the KCTU team via the KCTU web based randomisation system, in accordance with the specification agreed with the CI and Senior Statistician. The Chief Investigator, Senior Statistician and TMG will be blinded to the sequence generation.

## **Intervention Type**

Mixed

## **Primary outcome(s)**

Time to first all-cause readmission within 90 days of discharge measured using patient records

## **Key secondary outcome(s)**

Measured using patient records:

1. Time to and frequency of COPD-related readmissions at 30 and 90 days
2. Days alive and out of hospital at day 90
3. Time to and frequency of all COPD exacerbations at days 30 and 90
4. Cumulative systemic oral corticosteroids use over 90 days
5. Cumulative systemic antibiotic use over 90 days
6. Health care contacts at baseline, days 90 and 180, and 1 year
7. All cause readmission at 30 days
8. All cause-, cardiovascular- and COPD- related mortality at day 90 and over 12 months
9. Quality of life (COPD assessment Test (CAT) score and EQ-5D-5L) at baseline , days 90 and 180, and 1 year
10. Incremental cost-effectiveness ratio (ICER, a ratio of the additional cost divided by the additional effectiveness of SRP compared to UC) at days 90 and 180 and 1 year
11. Qualitative description of usual care
12. Qualitative examination of fidelity to and adaptation of the plan in the intervention arm
13. Adverse events
14. Antimicrobial resistance

## **Completion date**

31/12/2027

## Eligibility

### Key inclusion criteria

1. Adults aged 40 years and over
2. Patient to be discharged from hospital with exacerbation of COPD
3. Able to provide informed consent

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

40 years

### Sex

All

### Key exclusion criteria

Current participant exclusion criteria as of 07/02/2025:

1. Requirement for invasive ventilation during the hospital admission
2. Patients with signs of new consolidation on chest X-ray (if available)
3. Patients who have an expected survival of less than 90 days
4. Discharge to a residential or nursing home
5. Inability to engage with supported self-management
6. No access to telephone
7. Participation in another intervention study
8. Previous participation in the RAPID trial.

Previous participant exclusion criteria as of 28/11/2024 to 07/02/2025:

1. Requirement for invasive ventilation during the hospital admission
2. Patients who have an expected survival of less than 90 days
3. Discharge to a residential or nursing home
4. Inability to engage with supported self-management
5. No access to telephone
6. Participation in another intervention study

Previous participant exclusion criteria:

1. Requirement for invasive ventilation during the hospital admission
2. Patients who have an expected survival of less than 90 days
3. Discharge to a residential or nursing home
4. Inability to engage with supported self-management
5. No access to telephone
6. Participation in another intervention study
7. Individuals discharged from hospital to a non-physical virtual ward

**Date of first enrolment**

23/01/2025

**Date of final enrolment**

31/12/2026

**Locations****Countries of recruitment**

United Kingdom

England

Wales

**Study participating centre****Guy's and St Thomas' Hospitals**

Trust Offices

Guy's Hospital

Great Maze Pond

London

United Kingdom

SE1 9RT

**Study participating centre****Royal Free London NHS Foundation Trust**

Royal Free Hospital

Pond Street

London

United Kingdom

NW3 2QG

**Study participating centre****Blackpool Teaching Hospitals NHS Foundation Trust**

Victoria Hospital

Whinney Heys Road

Blackpool

United Kingdom

FY3 8NR

**Study participating centre**

**University Hospitals Sussex NHS Foundation Trust**  
Worthing Hospital  
Lyndhurst Road  
Worthing  
United Kingdom  
BN11 2DH

**Study participating centre**  
**County Durham and Darlington NHS Foundation Trust**  
Darlington Memorial Hospital  
Hollyhurst Road  
Darlington  
United Kingdom  
DL3 6HX

**Study participating centre**  
**Sherwood Forest Hospitals NHS Foundation Trust**  
Kings Mill Hospital  
Mansfield Road  
Sutton-in-ashfield  
United Kingdom  
NG17 4JL

**Study participating centre**  
**Imperial College Healthcare NHS Trust**  
The Bays  
St Marys Hospital  
South Wharf Road  
London  
United Kingdom  
W2 1BL

**Study participating centre**  
**East Suffolk and North Essex NHS Foundation Trust**  
Colchester Dist General Hospital  
Turner Road  
Colchester  
United Kingdom  
CO4 5JL

**Study participating centre**

**University Hospitals of Morecambe Bay NHS Foundation Trust**

Westmorland General Hospital  
Burton Road  
Kendal  
United Kingdom  
LA9 7RG

**Study participating centre**

**University Hospitals of Leicester NHS Trust**

Leicester Royal Infirmary  
Infirmary Square  
Leicester  
United Kingdom  
LE1 5WW

**Study participating centre**

**Maidstone and Tunbridge Wells NHS Trust**

The Maidstone Hospital  
Hermitage Lane  
Maidstone  
United Kingdom  
ME16 9QQ

**Study participating centre**

**Milton Keynes University Hospital NHS Foundation Trust**

Standing Way  
Eaglestone  
Milton Keynes  
United Kingdom  
MK6 5LD

**Study participating centre**

**Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus**

Nottingham University Hospital  
Derby Road  
Nottingham  
United Kingdom  
NG7 2UH

**Study participating centre**

**Oxford University Hospitals NHS Foundation Trust**

John Radcliffe Hospital  
Headley Way  
Headington  
Oxford  
United Kingdom  
OX3 9DU

**Study participating centre**

**North Tees and Hartlepool NHS Foundation Trust**

Hardwick Road  
Stockton-on-tees  
United Kingdom  
TS19 8PE

**Study participating centre**

**Salisbury NHS Foundation Trust**

Salisbury District Hospital  
Odstock Road  
Salisbury  
United Kingdom  
SP2 8BJ

**Study participating centre**

**Somerset NHS Foundation Trust**

Trust Management  
Lydeard House  
Musgrove Park Hospital  
Taunton  
United Kingdom  
TA1 5DA

**Study participating centre**

**Yeovil Hospital**

Yeovil District Hospital  
Higher Kingston  
Yeovil  
United Kingdom  
BA21 4AT

**Study participating centre**

**Stockport NHS Foundation Trust**

Stepping Hill Hospital  
Poplar Grove  
Stockport  
United Kingdom  
SK2 7JE

**Study participating centre**

**South Tyneside and Sunderland NHS Foundation Trust**

Sunderland Royal Hospital  
Kayll Road  
South Shields  
United Kingdom  
SR4 7TP

**Study participating centre**

**Cardiff & Vale University Health Board**

Llandough  
United Kingdom  
CF64 2XX

**Study participating centre**

**Bradford Teaching Hospitals NHS Foundation Trust**

Bradford Royal Infirmary  
Duckworth Lane  
Bradford  
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BD9 6RJ

**Study participating centre**

**University Hospitals Birmingham NHS Foundation Trust**

Queen Elizabeth Hospital  
Mindelsohn Way  
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**Study participating centre**

**North Bristol University Trust**

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**Study participating centre**  
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**Study participating centre**  
**The Newcastle upon Tyne Hospitals NHS Foundation Trust**  
Freeman Hospital  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**  
**University Hospital Southampton NHS Foundation Trust**  
Southampton General Hospital  
Tremona Road  
Shirley  
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SO16 6YD

**Study participating centre**  
**Northumbria Healthcare NHS Foundation Trust**  
North Tyneside General Hospital  
Rake Lane  
North Shields  
United Kingdom  
NE29 8NH

## **Sponsor information**

**Organisation**

King's College London

**ROR**

<https://ror.org/0220mzb33>

**Organisation**

Guy's and St Thomas' NHS Foundation Trust

**ROR**

<https://ror.org/00j161312>

## **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**

When the study is complete, a data sharing dataset will be created from the raw data by the study analyst, which will not include any other identifiable data and study PIN will be altered so that individuals are not recognisable from the dataset.

The datasets generated during and/or analysed during the current study will be available upon request from Mona Bafadhel and John Hurst ([mona.bafadhel@kcl.ac.uk](mailto:mona.bafadhel@kcl.ac.uk); [j.hurst@ucl.ac.uk](mailto:j.hurst@ucl.ac.uk)).

**IPD sharing plan summary**

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 4.0	05/11/2024	07/02/2025	No	No
<a href="#">Protocol file</a>	version 4.2	04/07/2025	16/07/2025	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes