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

Submission date
22/02/2024

Recruitment status
Recruiting

Registration date
04/07/2024

Overall study status
Ongoing

Last Edited
16/07/2025

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) 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 024 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

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Public

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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
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United Kingdom
BN11 2DH

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

Study participating centre
Sherwood Forest Hospitals NHS Foundation Trust
Kings Mill Hospital
Mansfield Road
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Study participating centre
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St Marys Hospital
South Wharf Road
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United Kingdom
W2 1BL

Study participating centre
East Suffolk and North Essex NHS Foundation Trust
Colchester Dist General Hospital
Turner Road
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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
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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
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SP2 8BJ

Study participating centre
Somerset NHS Foundation Trust
Trust Management
Lydeard House
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TA1 5DA

Study participating centre
Yeovil Hospital
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BA21 4AT

Study participating centre

Stockport NHS Foundation Trust
Stepping Hill Hospital
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SK2 7JE

Study participating centre
South Tyneside and Sunderland NHS Foundation Trust
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Study participating centre
Cardiff & Vale University Health Board
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Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
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Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
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Study participating centre
North Bristol University Trust
Bristol

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Study participating centre
Frimley Health NHS Foundation Trust
Portsmouth Road
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Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
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High Heaton
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Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
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Study participating centre
Northumbria Healthcare NHS Foundation Trust
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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; 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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 4.0	05/11/2024	07/02/2025	No	No
Protocol file	version 4.2	04/07/2025	16/07/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes