

# Early supported discharge with pulmonary rehabilitation following exacerbations of COPD

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<b>Registration date</b> 10/10/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/04/2020	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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. It includes emphysema (damage to the air sacs in the lungs) and chronic bronchitis (long-term inflammation of the airways)

We would like to find out if it is possible to combine a supervised home-based exercise programme with a service which provides medical care for patients in their own homes (known as early supported discharge or hospital at home) after they have been in hospital with a flare-up of chronic obstructive pulmonary disease (COPD). We also would like to find out if patients, family members/carers and healthcare professionals involved in this research feel combining the home-based exercise programme within an early supported discharge service is acceptable.

This is important as pulmonary rehabilitation ((PR): an outpatient-based exercise and education programme delivered by healthcare professionals from different clinical backgrounds) increases the distance a patient can walk and quality of life, and reduces the risk of patients going back into hospital. However very few patients attend outpatient-based PR after a flare-up. One of the reasons for this is because patients find it hard to travel to the outpatient classes after being in hospital

### Who can participate?

COPD patients aged over 40, family members, carers, and hospital staff

### What does the study involve?

We will recruit 80 patients who have been admitted to hospital with a flare-up of COPD. We will randomly allocate half of the patients to receive a home-based exercise programme alongside usual early supported discharge care, with the other half receiving usual early supported discharge care alone. The patients recruited will be assessed before being discharged from hospital. The assessment will include measures of quality of life, activity levels, muscle strength, anxiety and depression, exercise capacity and body composition. These will be re-assessed 4 weeks and 3 months after being discharged. Safety outcomes will be recorded 3 months and 12 months after the patients have been discharged from hospital

What are the possible benefits and risks of participating?

There are no significant risks associated with participating in the proposed research. There may also be no benefits to patients by taking part in this research. However, the information that we gain from this study will help design a future randomised control trial which will aim to help improve the treatment of patients hospitalised with an exacerbation of COPD in the future.

Where is the study run from?

1. Royal Brompton & Harefield NHS Foundation Trust
2. The Hillingdon Hospitals NHS Foundation Trust

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

October 2019 to October 2020

Who is funding the study?

National Institute for Health Research (NIHR), UK

Who is the main contact?

Ruth Barker

r.barker2@rbht.nhs.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

Miss Ruth Barker

**ORCID ID**

<http://orcid.org/0000-0002-7022-0194>

**Contact details**

Harefield Respiratory Research Group

D Floor

Harefield Hospital

Hill End Road

Harefield

United Kingdom

UB9 6JH

+44 (0)1895 823737 Ext 85332

r.barker2@rbht.nhs.uk

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

## **Secondary identifying numbers**

43224

# **Study information**

## **Scientific Title**

Early Supported discharge with Pulmonary REhabilitation following Severe acute exacerbations of COPD – Safety and Outcomes (ESPRESSO)

## **Acronym**

ESPRESSO

## **Study objectives**

The principal research objective is to determine whether a supervised home-based exercise intervention, delivered alongside a hospital at home (HaH) service, for patients hospitalised with a flare-up of COPD is feasible and acceptable

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 18/09/2019, NHS HRA London-Dulwich REC (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH; +44 (0)207 104 8241; NRESCommittee.London-Dulwich@nhs.net), ref: 19/LO/1472

## **Study design**

Randomised; Both; Design type: Treatment, Process of Care, Education or Self-Management, Physical, Rehabilitation, Qualitative

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Home

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

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

Chronic obstructive pulmonary disease

## **Interventions**

This is a mixed-methods feasibility trial including a parallel-group, assessor-blinded prospective randomised controlled trial, with embedded qualitative interviews and focus groups. The principal objective is to determine whether a supervised home-based exercise intervention, delivered alongside a hospital at home service, for patients hospitalised with acute exacerbations of chronic obstructive pulmonary disease (COPD) is feasible and acceptable.

This study design has been selected to address the principal objective of this study by:

1. Determining practicability (measured by feasibility and clinical endpoints)
2. Exploring safety (measured by safety endpoints), and
3. Understanding the acceptability to key stakeholders (measured by qualitative outcomes)

80 patient participants will be recruited when hospitalised for an acute exacerbation of COPD, and randomised 1:1 using minimisation, to receive either usual nursing-focused hospital-at-home care or a home-based exercise intervention integrated within usual nursing-focused hospital-at-home care. Patient participants will be assessed at discharge from hospital, and subsequently re-assessed four weeks and three months post-discharge from hospital.

Safety outcomes will be measured three months and 12 months post-discharge from hospital for patient participants. Patient participants, and their family members and carers, who meet the purposive sampling criteria will be invited to take part in qualitative interviews three months post-discharge from hospital. Interviews will be conducted until data saturation is achieved (approximately 15-20 qualitative interviews). These interviews will be conducted in the home of the interviewees.

Once all the three-month post-hospital discharge follow-up assessments have been conducted as part of the randomised controlled trial, staff members (both researchers and clinicians) who meet the staff participant purposive sampling criteria will be invited via email to take part in focus groups. Each staff participant will take part in one focus groups, which will be conducted at their usual place of work (Harefield Hospital or Hillingdon Hospital). No interim analysis is planned as part of this study. However, the results from this mixed-methods feasibility trial will be used to inform a full-scale randomised controlled trial in the future.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Due to this being a feasibility trial, there are no primary or secondary outcome measures (see below)

## **Secondary outcome measures**

In order to address the principal research objective, there will be measures recorded pertaining to:

1. Feasibility outcomes:

1.1 Number of patients screened for eligibility, proportion of eligible patients randomised, proportion of participants remaining in the trial

at four weeks, three months and 12 months

1.2 Proportion of patients for which assessor blinding is maintained

1.3 Number of HaH visits and type of HaH care provided; proportion implemented by different healthcare professionals; contamination in usual care group

- 1.4 Home-based exercise training uptake and adherence
- 1.5 Proportion referred to outpatient-based PR at discharge and on discharge from HaH service
- 1.6 Uptake and completion of outpatient-based PR

## 2. Clinical outcomes:

Completion rates, missing data, variances, difference and 95% confidence intervals between groups for outcomes listed below:

- 2.1 London Chest Activities of Daily Living questionnaire
- 2.2 Physical activity levels
- 2.3 Short Physical Performance Battery
- 2.4 Muscle strength (lower limb and hand grip)
- 2.5 COPD Assessment Test questionnaire
- 2.6 Euro-Qol 5-Dimensions 5-Levels questionnaire
- 2.7 Hospital Anxiety and Depression Scale
- 2.8 Modified Centre for Epidemiological Studies - Depression Score
- 2.9 Six-minute self-paced step test
- 2.10 Bio-electrical impedance analysis

## 3. Safety outcomes:

- 3.1 Adverse events
- 3.2 Health resource usage
- 3.3 Mortality

## 4. Qualitative outcomes:

- 4.1 Experiences and preferences of people living with COPD, their family members or carers and healthcare professionals throughout the HaH model of care
- 4.2 Barriers and facilitators to participation in a HaH model of care from the perspective of people living with COPD, their family members or carers and healthcare professionals
- 4.3 Areas of unmet need and opportunities for integration with pulmonary rehabilitation during HaH
- 4.4 Core and optional interventions required in the home-based exercise intervention
- 4.5 Acceptability of duration and frequency of interventions required for patients living with COPD in terms of adherence to a home-based exercise training intervention schedule from the perspective of people living with COPD, their family members or carers and healthcare professionals
- 4.6 Acceptability to home-based exercise training integrated within a HaH model of care to people living with COPD, their family members or carers and healthcare professionals

## Overall study start date

01/04/2018

## Completion date

21/10/2021

# Eligibility

## Key inclusion criteria

- 1. Randomised controlled trial inclusion criteria:
  - 1.1 > 40 years of age
  - 1.2 Diagnosis of chronic obstructive pulmonary disease (COPD)

- 1.3 Hospitalisation (inpatient on a medical assessment unit or hospital ward) with a primary diagnosis of an acute exacerbation of COPD
- 1.4 Accepted for Hospital at Home care by Hillingdon Integrated Respiratory Service according to local Standard Operating Procedures (no impaired consciousness – Glasgow Coma Scale < 15; no acute confusion state; pH greater than 7.35kPa; no acute changes on radiograph; no concomitant medical problem requiring in-patient stay such as suspected pulmonary embolus or acute coronary syndrome; and adequate social support)
- 1.5 Able to give valid informed consent
- 2. Patient participant interview purposive sampling criteria:
  - 2.1 Protocol completion:
    - 2.1.1 Completed course of care per protocol
    - 2.1.2 Did not complete course of care per protocol
  - 2.2 Readmission in three months of hospital discharge:
    - 2.2.1 Readmitted
    - 2.2.2 Not readmitted
  - 2.3 Social history:
    - 2.3.1 Lives alone
    - 2.3.2 Does not live alone
  - 2.4 Improvement in COPD Assessment Test (CAT) in three months from hospital discharge:
    - 2.4.1 Change in CAT score of  $\geq -2$  points
    - 2.4.2 Change in CAT score of  $< -2$  points
- 3. Family member and carer interview purposive sampling criteria:  
This is the person nominated by the participant as giving them the most help and support due to their COPD and who is not a health care professional who must be:
  - 3.1 Aged > 18 years of age
  - 3.2 Able to understand and speak English
  - 3.3 Able to give valid informed consent
- 4. Staff focus groups purposive sampling criteria:
  - 4.1 Provider of usual care
  - 4.2 Provider of outpatient-based PR
  - 4.3 Provider of study intervention procedures
  - 4.4 Provider of study assessments

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 80; UK Sample Size: 80

## **Key exclusion criteria**

Randomised controlled trial exclusion criteria:

1. Receiving specialist palliative care with expectation of death within three months as judged by the specialist palliative care service;
2. No fixed abode or contact number;
3. Evidence of an environment that would make delivery of study intervention and/or usual care unsafe;
4. Evidence of acute coronary syndrome, unstable ischaemic heart disease or any condition that would make exercise unsafe.

## **Date of first enrolment**

21/10/2019

## **Date of final enrolment**

21/10/2020

## **Locations**

### **Countries of recruitment**

England

United Kingdom

### **Study participating centre**

**Royal Brompton & Harefield NHS Foundation Trust**

Royal Brompton Hospital

Sydney Street

London

United Kingdom

SW3 6NP

### **Study participating centre**

**The Hillingdon Hospitals NHS Foundation Trust**

Pield Heath Road

Uxbridge

United Kingdom

UB8 3NN

## **Sponsor information**

### **Organisation**

Royal Brompton & Harefield NHS Foundation Trust

### Sponsor details

Royal Brompton Hospital  
Sydney Street  
London  
England  
United Kingdom  
SW3 6NP  
+44 (0)207 3518829  
l.bridgewater@rbht.nhs.uk

### Sponsor type

Hospital/treatment centre

### ROR

<https://ror.org/02218z997>

## Funder(s)

### Funder type

Government

### Funder Name

NIHR Academy; Grant Codes: ICA-CDRF-2017-03-018

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

### Intention to publish date

01/10/2021

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to not having sought consent to share in this manner.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No