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Early supported discharge with pulmonary rehabilitation following exacerbations of COPD

Submission date
30/09/2019

Recruitment status
Suspended

Registration date
10/10/2019

Overall study status
Completed

Last Edited
20/04/2020

Condition category
Respiratory

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
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Contact information

Type(s)
Scientific

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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 > = -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

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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?
HRA research summary			28/06/2023	No	No