ISRCTN11636308 https://doi.org/10.1186/ISRCTN11636308

Testing the feasibility of combined breathlessness exercise rehabilitation for Chronic Obstructive Pulmonary Disease (COPD) and chronic heart failure (the COHERE study)

Submission date 06/09/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/11/2018	**Overall study status** Completed	
Last Edited 24/07/2019	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims

This study is collecting data from a combined breathlessness rehabilitation programme for adults with Chronic Obstructive Pulmonary Disease (COPD) and/or Heart Failure. It is a relatively new idea to combine adults with COPD and/or heart failure into one rehabilitation programme. Traditionally, patients were sent to pulmonary or cardiac rehabilitation. However, many patients present with both COPD and heart failure. Furthermore, both diseases are characterised by breathlessness and it has been suggested a rehabilitation centred around symptoms, in this case, breathlessness, would be a suitable advancement. The aim of this study is to assess how feasible or how practical it is to combine patients with one or both diseases into an exercise programme and assess how feasible it is to recruit patients and collect a range of new health measures for a full trial.

Who can participate?

Patients aged between 40 and 85 with a confirmed diagnosis of COPD and/or heart failure who are enrolled into the combined exercise rehabilitation programme at University Hospitals of Leicester (UHL)

What does the study involve?

All participants are referred to the combined exercise rehabilitation programme as part of their usual care. The exercise rehabilitation programme is a standard clinical programme comprising of strength and aerobic exercises. The rehabilitation programme consists of 12 classes that are typically run twice a week for 6 weeks. This study is not impacting or altering the clinical care rehabilitation programme. Frailty, physical activity, cardio-metabolic risk and symptom burden are assessed before and after the rehabilitation programme, to see how feasible it is to collect these measures. Participants are invited to a focus group discussion upon completion of rehabilitation, to further understand participant's experiences of the combined rehabilitation programme and the study.

What are the possible benefits and risks of participating?
Participants are contributing to valuable research that may impact the future clinical rehabilitation programme. The information from this current study will guide a large trial in the future. Participants are also provided with a feedback report about their health. The risks of participating in this study are low. There is a risk of some discomfort or bruising as a result of the blood sample but all measures will be taken to reduce this risk.

Where is the study run from?
University Hospital Leicester NHS Trust (UK)

When is the study starting and how long is it expected to run for?
December 2017 to March 2019

Who is funding the study?
1. Loughborough University (UK)
2. University Hospital Leicester NHS Trust (UK)

Who is the main contact?
Prof. Sally Singh
sally.singh@uhl-tr.nhs.uk

Contact information

Type(s)
Public

Contact name
Miss Amy Jones

ORCID ID
http://orcid.org/0000-0001-6565-8645

Contact details
National Centre for Sport and Exercise Medicine
Loughborough University
Loughborough
United Kingdom
LE11 3TU
+44 (0)7446705065
a.v.jones@lboro.ac.uk

Type(s)
Scientific

Contact name
Prof Sally Singh

Contact details
Leicester Respiratory Biomedical Research Unit
Leicester
United Kingdom

LE3 9QP
+44 (0)116 250 2350
sally.singh@uhl-tr.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number
227456

ClinicalTrials.gov number

Secondary identifying numbers
IRAS project ID 227456

Study information

Scientific Title
A feasibility trial of combined breathlessness exercise rehabilitation for Chronic Obstructive Pulmonary Disease (COPD) and chronic heart failure (COpd and HEart failure REhabilitation - COHERE)

Acronym
COHERE

Study objectives
This study will examine the feasibility of a combined breathlessness exercise rehabilitation programme for patients with Chronic Obstructive Pulmonary Disease (COPD) and/or heart failure. Feasibility will be assessed by various factors including ease of recruitment, uptake into a combined rehabilitation programme and the feasibility of assessing a suite of outcome measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Leicester South, 09/05/2018, ref: 18/EM/0051

Study design
Single-centre observational cohort feasibility study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease (COPD) and/or chronic heart failure

Interventions
This study will be assessing the feasibility of a combined breathlessness exercise rehabilitation programme for patients with COPD and/or heart failure and how feasible it is to recruit patients and collect novel outcome measures for a full trial. All participants will be referred to this programme as part of their usual care. The exercise rehabilitation programme is a standard clinical programme comprising of strength and aerobic exercises. The rehabilitation programme consists of 12 classes that are typically run twice a week for six weeks.

The outcome measures that will be assessed both before and upon completion of rehabilitation are health-related quality of life (questionnaire based) symptom evaluation (questionnaire based), cardiometabolic risk (venous blood sample, body composition, arterial stiffness), frailty (assessed through a series of small physical tests) and physical activity (assessed with an accelerometer and questionnaire). Lung function and B-Type Natriuretic Peptide (BNP) will be assessed at baseline. Routine measures collected in the clinical programme will also be recorded for research purposes. These include measures of anxiety and depression, exercise capacity and muscular strength.

Intervention Type
Other

Primary outcome measure
Feasibility will be determined using, but not restricted to, the following criteria:
1. The number of participants eligible for inclusion (i.e. meet the inclusion criteria)
2. Suitability of the inclusion criteria
3. Recruitment/response rate (i.e. number and proportion of those eligible who consent to take part)
4. Refusal rate
5. Uptake and completion of the study
6. Willingness of patients to be recruited and the willingness of healthcare professionals to refer to this study and future trials
7. Service provider and multi-disciplinary teams' willingness and ability to deliver the new combined exercise rehabilitation programme
8. The practicality of delivering the intervention in the proposed setting
9. The time needed to collect and analyse the data
10. Test methods for the collection of data as well as data completeness and accuracy (including changes in clinical health outcome measures)
11. The acceptability of the combined exercise rehabilitation programme and the COHERE trial will be assessed through focus groups
12. Compliance to the combined exercise rehabilitation programme and COHERE study. Poor programme compliance will be defined as absence from rehabilitation sessions and poor trial

compliance will be assessed by absence from outcome measure assessments
13. Adherence to the combined exercise rehabilitation programme assessed via a self-report exercise diary, which is usual care
14. The training and resource needs to deliver the intervention and ensure fidelity (ensuring readiness for a future much larger multi-centre trial)

Secondary outcome measures
1. Cardiometabolic risk assessed by fasted venous blood sample and arterial stiffness, assessed before and upon completion of the rehabilitation programme
2. Body composition, waist circumference and blood pressure measured before and after rehabilitation
3. Physical activity and sedentary behaviour assessed using an ActiGraph accelerometer. The device will be given to participants to wear for 7 consecutive days before and after the rehabilitation programme. Participants will also complete the Pro-ACTIVE physical activity questionnaire
4. Symptoms assessedusing the Multidimensional Dyspnea Profile, Dyspnea 12 Questionnaire and PROMIS fatigue questionnaire before and after the rehabilitation programme
5. Health-related quality of life assessed using the Chronic Heart Questionnaire- Self Report, and the EuroQol 5D-5L questionnaire before and after rehabilitation
6. Frailty levels assessed using the Short Physical Performance Battery before and after the rehabilitation programme
7. Lung function assessed using spirometry and B-Type Natriuretic Peptide levels before rehabilitation

Measures that are taken as part of patient's usual care will also be recorded for research purposes. These include:
1. Exercise capacity, measured using the Incremental and Endurance Shuttle Walk Test
2. Muscle strength, measured using the Quadriceps Maximal Voluntary Contraction
3. Breathlessness, measured using the Medical Research Council scale and COPD Assessment Test
4. Mood state, measured using the Hospital and Anxiety Depression Scale
5. Quality of life, measured using the Dartmouth COOPS Charts
These are completed in the clinical visits that occur before the rehabilitation programme and at discharge

Overall study start date
01/12/2017

Completion date
31/08/2020

Eligibility

Key inclusion criteria
1. Be aged between 40 and 85 years
2. Have a physician confirmed diagnosis of COPD and/or heart failure
3. Be referred or due to enrol on the University Hospitals of Leicester (UHL) NHS Trust combined rehabilitation programme
4. Be willing and able to comply with the trial protocol

5. Be able to provide informed consent
6. Meet the ‘UHL Breathlessness Rehabilitation Class Standard Operating Procedure’ criteria for eligible patients

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Be under 40 or over 85 years of age
2. Completed or began a rehabilitation programme less than 6 months ago
3. Have had clinical concerns about them raised by rehabilitation staff/not meet the ‘UHL Breathlessness Rehabilitation Class Standard Operating Procedure'
4. Not have a confirmed diagnosis of COPD and/or heart failure
5. Have completed or began a rehabilitation programme in the last 6 months
6. Have insufficient proficiency in English to comply with the study protocol

Date of first enrolment
09/05/2018

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Glenfield Hospital
Groby Rd
Leicester
United Kingdom
LE3 9QP

Study participating centre

National Centre for Sport and Exercise Medicine
Loughborough University
Loughborough
United Kingdom
LE11 3TU

Sponsor information

Organisation
University Hospital Leicester

Sponsor details
R & I Office, Leicester General Hospital
Gwendolen Road
Leicester
England
United Kingdom
LE5 4PW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
University/education

Funder Name
Loughborough University

Alternative Name(s)
Lboro

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
University Hospital Leicester NHS Trust

Results and Publications

Publication and dissemination plan
It is anticipated that the results from this study will be published in international journals and will be used in a PhD thesis. All data that will be collected is anticipated to be published.

Intention to publish date
31/08/2021

Individual participant data (IPD) sharing plan
Participant level data will not be available. Data will be stored on secure password protected Loughborough University or University Hospitals of Leicester NHS Trust computers and within locked stored cabinets where appropriate.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/07/2019	24/07/2019	Yes	No
HRA research summary			28/06/2023	No	No