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Pulmonary rehabilitation and actIvity after COPD exacerbations: the PRACTICE trial

Submission date
14/08/2014

Recruitment status
No longer recruiting

Registration date
23/09/2014

Overall study status
Completed

Last Edited
09/03/2018

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic Obstructive Pulmonary Disease (COPD) is a severe lung condition that affects a person's ability to exercise and perform normal physical functions due to a combination of breathlessness, poor physical fitness and loss of muscle strength. Patients with COPD often experience flare ups known as exacerbations due to chest infections, which result in their symptoms getting worse, more loss of function, and may require hospital treatment. Recovery from such exacerbations is often slow, and some patients never fully return to their previous level of activity. This can lead to permanent disability and premature death. The purpose of this study is to find out whether it is possible to undertake a larger study of exercise training in patients who have been admitted to hospital with a flare up of their COPD. We aim to find out whether patients will be willing to participate and perform exercise both during their time in hospital and then immediately after they get home, to see if this will allow patients to recover more quickly and get back to their previous level of activity without needing to stay in hospital for a prolonged period. Both of these periods of exercise will be started much earlier than the rehabilitation classes that are currently widely available to COPD patients after they have been in hospital. This study will help us to understand if exercising earlier after hospital admission has any benefits over exercising later and will help us to decide if a large study looking more closely at this is required.

Who can participate?
Patients who have been admitted to hospital with a flare up of their COPD

What does the study involve?
The study will look at two different sorts of exercise: a bedside bicycle-based activity that can be undertaken whilst the patient is sat at the edge of their bed in hospital, and a supervised exercise program to be undertaken during the first two weeks after they have been discharged. Both forms of exercise will be supervised by a physiotherapist. The study will look at whether participants will be prepared to take a walking test and a special movement watch that patients will wear at home. They will also be asked to complete several questionnaires that ask about their activities at home and how their breathing problems are affecting their quality of life. Whilst they are in hospital a measurement of their muscle size will be done to see whether the exercise helps stops the muscles from wasting away when they are unwell. We will assess

whether or not exercising participants early after a hospital admission has any affect in preventing further chest infections or flare ups of COPD, or reduces the number of re-admissions to hospital occurring within 3 months of discharge.

What are the possible benefits and risks of participating?
Participants may benefit from being in the study as exercise has been shown to help with recovery following COPD flare ups, and it is recommended that this activity starts within a month of being in hospital. However, in this study the exercise will happen in hospital and straight after discharge, which is earlier than what currently happens. There is the possibility that doing the exercise earlier may not be beneficial, and could cause some problems such as more difficulty breathing and muscle tiredness, but the activity will be carried out with a trained physiotherapist who is aware of these risks and will be looking out for them.

Where is the study run from?
The study will be run in Sheffield Teaching Hospitals NHS Foundation Trust and Aintree University Hospital NHS Foundation Trust (in Liverpool), with patients recruited from the Northern General Hospital and from Aintree University Hospital (UK).

When is the study starting and how long is it expected to run for?
January 2015 to December 2016

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Rodney Hughes
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Contact information

Type(s)
Scientific

Contact name
Dr Rodney Hughes

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 13/24/03

Study information

Scientific Title
Pulmonary Rehabilitation and ACTIvity after COPD Exacerbations: the PRACTICE trial: a randomised trial

Acronym
PRACTICE

Study objectives
This is a feasibility and pilot study.
Feasibility outcomes:
1. Feasibility of recruitment to main trial (recruitment of 76 participants in 7m from two centres (primary outcome)
2. Recruitment and attrition rates (CONSORT data)
3. Number of missing values/incomplete cases
4. Intervention adherence
5. Intervention fidelity
6. Participant views on acceptability of research procedures and intervention
7. Therapist views on intervention/research protocol acceptability
8. Feasibility of recruiting participating centres
9. Decision on primary endpoint for main trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health Research Authority

Study design
Parallel-group randomised pilot trial with nested qualitative research

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
Patients are randomised to:
1. In-hospital exercise training with or without in-home post-discharge early rehabilitation (n=38)
2. Standard in-hospital care with or without in-home post-discharge early rehabilitation (n=38)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Feasibility of recruitment to main trial (recruitment of 76 participants in 7m from two centres [primary outcome])
2. Six-minute walk distance at three months (clinical primary outcome)

Secondary outcome measures
Feasibility outcomes:
1. Recruitment and attrition rates (CONSORT data)
2. Number of missing values/incomplete cases
3. Intervention adherence
4. Intervention fidelity
5. Participant views on acceptability of research procedures and intervention
6. Therapist views on intervention/research protocol acceptability
7. Feasibility of recruiting participating centres
8. Decision on primary endpoint for main trial

Clinical outcomes:
1. London Chest Activity of Daily Living scale
2. EQ-5D-5L
3. COPD Assessment Test
4. Rectus femoris muscle cross-sectional area
5. MRC Breathlessness Score
6. SenseWear Armband and electronic diary
7. Serious adverse events
8. Health and social care resource use
9. Perceived necessity and concerns
10. Exacerbations
11. Readmission

Overall study start date
01/01/2015

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Clinically identified exacerbation of diagnosed COPD
2. pH above 7.35
3. Maintaining oxygen saturation (SpO2) within prescribed target range with or without controlled oxygen at rest
4. Glasgow Coma Scale (GCS) 15 and over

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
76

Key exclusion criteria
1. Predicted length of hospital stay <5 days
2. Acute MI/heart failure within last 6 weeks
3. Suspected/confirmed PE within last 6 weeks
4. Cardiovascular instability
5. Pulmonary fibrosis
6. Musculoskeletal conditions limiting exercise capacity

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Sheffield
United Kingdom
S10 2JF

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

Sponsor details
c/o Jim Lithgow
Clinical Research Office
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2018		Yes	No