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Early rehabilitation after hospitalisation for an acute exacerbation of chronic heart failure

Submission date
11/09/2010

Recruitment status
No longer recruiting

Registration date
08/12/2010

Overall study status
Completed

Last Edited
11/05/2017

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Patients with chronic heart failure (CHF) experience exacerbations (flare-ups) or worsening of their symptoms which sometimes require a hospital admission. Evidence strongly suggests that exacerbations cause levels of strength and physical activity to decline and also increase the chance of readmission to hospital. Rehabilitation (exercise and education) has been proven to be beneficial for patients with stable CHF in terms of improving muscle strength, exercise tolerance and quality of life. However, we currently do not know the effects of starting a rehabilitation programme immediately after hospitalisation for an acute exacerbation of CHF on physical functioning, psychological state and healthcare usage. This study is needed in order to tell us whether or not a programme of rehabilitation immediately after an exacerbation might be effective in improving patient care.

Who can participate?
Patients aged 40 - 90 admitted to the acute medical units of the trial hospital with an acute exacerbation of CHF.

What does the study involve?
Patients will be randomly allocated to one of two groups. One group receives standard best usual care and the other group receives usual care plus early rehabilitation (intervention group). We will take basic details (age, gender, current medication, height and weight etc.) and discuss previous medical history. Subjects will be asked to walk between two points at a set pace until they need to stop. Subjects will complete some questionnaires about health status. This will give us a guide to how their condition affects their daily life. The strength of the thigh muscle will be measured using a strain gauge. This involves sitting on a chair and extending the leg which is attached to a strap. Physical activity will be recorded for 24 hours whilst patients are in hospital (day 2 or 3 of admission) using a portable, lightweight activity monitor worn on the upper arm. After this, we will measure physical activity for two consecutive weekdays after their hospital discharge and 3-month assessment visits. We will record any GP visits, A&E visits or hospital admissions for the duration of the study. If patients are assigned to the standard care group they will receive best usual care from the medical and multidisciplinary teams managing them. This will involve follow-up at home from the Heart Failure Community Nursing Teams and an outpatient appointment with a consultant. These patients will be offered the chance to attend

rehabilitation after their 3-month assessment visit. If patients are assigned to the rehabilitation (intervention) group they will attend outpatient classes twice a week for 8 weeks within 4 weeks of leaving hospital. The exercise part of the class lasts for one hour and involves a circuit of exercises (walking, bike, hand weights etc.). Exercise will be individualised, that is, adapted and progressed depending on the subjects fitness level. The second hour of each class involves self-management education delivered by a multi-disciplinary team and checking of home exercise diaries.

What are the possible benefits and risks of participating?
There may not be any direct benefit to participants who decide to take part. However, it is hoped that we may find that the rehabilitation intervention will benefit patients in terms of improved muscle strength, improved physical activity levels and fewer readmissions to hospital. We would also hope that taking part in the research may help our understanding of the recovery process following an exacerbation. The study will inform both present and future rehabilitation services, therefore benefiting all CHF patients. There are minimal identified risks to taking part in this research. Patients may experience some muscle aching and general tiredness from starting the exercise programme and performing the walking tests. This is usually mild and wears off after a couple of days. The staff supervising the classes are highly experienced and will monitor patients closely. We appreciate that the wearing of an activity monitor might be a slight inconvenience for some patients. However, they are very light and we have used these monitors in recent research studies and they have been very well tolerated by patients. Patients will be asked to make additional visits to hospital over the 3-month study period. This is a potential inconvenience but in our experience, most patients are happy to attend. Travel expenses will be reimbursed or a taxi provided for these assessment visits.

Where is the study run from?
Glenfield Hospital (UK)

When is the study starting and how long is it expected to run for?
The study ran from November 2010 to August 2012

Who is funding the study?
National Institute for Health Research (NIHR) (UK) - Collaboration for Leadership in Applied Health Research and Care (CLAHRC)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Early REhabilitation after hospitalisation for an Acute exaCerbaTion of Chronic Heart Failure: a randomised controlled trial.

Acronym
REACT-CHF

Study objectives
An effective rehabilitation strategy delivered early after hospitalisation for an acute exacerbation (AE) of heart failure will lead to improvements in exercise capacity and health status, as it does in patients with stable disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicestershire, Northamptonshire and Rutland Research Ethics Committee 2, 02/08/2010, ref: 10/H0402/48

Primary study design
Interventional

Study design
Single-centre single-blind randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic heart failure (CHF)

Interventions
Patients admitted to the acute medical units of the trial hospital with an acute exacerbation of CHF and are able to give informed consent will be invited to participate in the study, on day 2 or 3 of their inpatient stay. Patients will be randomised to receive either:

1. Standard 'best usual' care: Patients in the control group can expect to be discharged with 'best usual' care. This will involve follow-up in Primary Care by the Heart Failure Community Nursing Teams and an outpatient appointment with a cardiology consultant, as per usual. They will also be required to attend the assessment visits (at baseline, at discharge from hospital and at 3 months; see section on outcomes). Those assigned to the control group will be offered rehabilitation after their 3-month assessment if desired.

2. Rehabilitation: Those assigned to the intervention group can expect to receive standard 'best usual' care in addition to an early rehabilitation programme. The rehabilitation intervention is designed to be a comprehensive package of care consisting of exercise training and self-management education, delivered by a multidisciplinary team. Prior to discharge from hospital, outcome measures will be taken and randomisation made. Patients will then attend the rehabilitation classes at the next available opportunity (within 10 days of hospital discharge). Rehabilitation will consist of supervised classes (1/2 per week) for 6 - 8 weeks. The exercise component of the class lasts for 1 hour (warm-up, aerobic and resistance exercises and cool-down). Patients are closely monitored throughout the classes for symptoms [Borg breathlessness and perceived exertion scores, heart rate (HR), blood pressure (BP)]. The classes are supervised by specialist Cardiac Rehabilitation Nurses and Physiotherapists. Patients will also be expected to complete a Home Exercise Programme (HExP) most days of the week. This programme will mirror exercise prescription from the supervised classes. There will be various education sessions delivered by a multidisciplinary team lasting for 1 hour: diet, exercise, disease education, self-management, medications, and living with a long-term condition and checking HExP diaries/setting new training targets.

3 month follow-up assessment to re-assess exercise tolerance and quality of life.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Maximal exercise performance: Incremental shuttle walk test (ISWT) at 3 months. Also collected at hospital discharge.

Key secondary outcome(s)
1. Endurance exercise performance: Endurance Shuttle Walk Test (ESWT) at hospital discharge and 3 months
2. Health status, at hospital discharge and 3 months:
2.1. Disease-specific (Minnesota Living with Heart Failure and Chronic Heart) questionnaires
2.2. Generic (SF-36 and EuroQoL-5D) questionnaires
3. Psychological status: Hospital Anxiety and Depression scale at hospital discharge and 3 months
4. Quadriceps muscle strength: static maximal voluntary contraction using a strain gauge chair at inpatient day 2/3, hospital discharge and 3 months
5. Physical Activity: energy expenditure and step count using the sensewear accelerometer at inpatient day 2/3, hospital discharge and 3 months for 24/48 hours
6. Healthcare utilisation, collected for duration of the study:
6.1. Number of GP/community heart failure nurse visits
6.2. Number of emergency hospital visits
6.3. Number of admissions

6.4. Length of stay
7. Safety and tolerability:
7.1. Adverse events/response to exercise
7.2. Adherence to rehabilitation
7.3. Number of and reasons for attrition

Completion date
06/05/2015

Eligibility

Key inclusion criteria
1. Patients admitted to the acute medical units of the trial hospital with an acute exacerbation of chronic heart failure (CHF)
2. Able to give informed consent
3. Aged 40 - 90 years
4. Patients admitted with an established diagnosis of CHF (documented left ventricular systolic dysfunction [LVSD]) will be independently assessed for suitability
5. Patients will have received optimal medical management
6. Impaired exercise tolerance (New York Heart Association [NYHA] classifications II - IV)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients admitted for planned surgery
2. Patients with musculoskeletal or neuromuscular condition that significantly contributes to exercise limitation
3. Psychiatric or neurological conditions that would render the patient unable to comply with the training either in hospital or at home
4. Patients who have a new diagnosis of heart failure on admission will be excluded as they are likely to need ongoing medical management (i.e. establishing the correct drug regimen) and probably wont display the same declines in physical activity as those with established chronic heart failure.
5. Usual exclusion criteria to our current out-patient exercise programme will apply:
5.1. Unstable ischaemic heart disease
5.2. Myocardial infarction (MI) within the previous 3 weeks
5.3. Planned coronary revascularization/pacemaker implantation in the next 6 months
5.4. New onset of atrial fibrillation (AF)
5.5. Complex ventricular arrhythmia
5.6. Significant regurgitant valvular disease requiring surgery
5.7. Moderate/severe aortic stenosis

5.8. Hypertrophic obstructive cardiomyopathy
5.9. Acute pericarditis or myocarditis
5.10. Recent embolism or thromboembolism
6. Terminal disease with an estimated survival time of less than 3 months to live. Medical advice may need to be sought in these cases.
7. Those with previous attendance at rehabilitation within the preceding 12 months. This includes CHF rehabilitation and rehabilitation for post-MI/angina/re-vascularisation.
8. We know in chronic obstructive pulmonary disease (COPD) that the benefits of rehabilitation have been shown to persist for 12 months. Due to the probability of multiple factors being present (such as inability to cope at home), patients will be excluded if they have had four or more hospitalisations for an acute exacerbation of their disease in the preceding 12-month period (currently only 1.1% of patients in UHL are readmitted more than four times within 12 months). In our experience these patients frequently have significant social and psychological problems triggering hospitalisation that would not be modifiable with the proposed intervention.

Date of first enrolment
08/11/2010

Date of final enrolment
01/08/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Glenfield Hospital
Groby Road
Leicester
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Sponsor information

Organisation
University Hospitals of Leicester NHS Trust

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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
The datasets generated during and/or analysed during the current study are/will be available upon request from Linzy.Houchen@uhl-tr.nhs.uk

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	01/01/2016		Yes	No