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A randomised controlled trial of the effect of exercise training on exercise capacity in older patients with heart failure

Submission date
29/05/2007

Recruitment status
No longer recruiting

Registration date
03/07/2007

Overall study status
Completed

Last Edited
21/05/2018

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Exercise training seems to offer benefits to younger people with heart failure, but many exercise programmes are not suitable for older people to take part in. An exercise programme has been developed specifically for older people with heart failure, and the aim of this study is to test whether the exercise programme improves physical function, symptoms and quality of life in older people with heart failure.

Who can participate?
Patients aged 70 or older with chronic heart failure

What does the study involve?
Participants are randomly allocated to one of two groups: either to an exercise training group or to a group who receives usual care i.e. no exercise. Participants come to the research clinic on three occasions: at the start of the study, again after 8 weeks, and after 24 weeks. At each visit, participants complete questionnaires about their symptoms, quality of life, how active they are, and about their mood. They undergo walking and leg strength tests and are asked to wear a small box clipped to their belt during the day for seven days to record how much walking and other activity they do. Participants in the usual care group receive the same care and treatment as they have at the moment. Participants in the exercise training group come twice a week for 8 weeks to small group exercise sessions at the hospital. Taxi transport is provided to bring them back and forward for each session. Each session is led by an experienced physiotherapist, who takes care that each person exercises to their own individual ability. The sessions last up to 1 hour. Most of the exercises are done sitting in a chair, and some involve using elastic bands to help the arm and leg muscles to work harder. The therapist also guides brief talks about exercise, its benefits, how to get started and how to deal with setbacks. A leaflet with this information is provided. After 8 weeks, participants have learned the exercises and continue with the exercises at home for 16 weeks more. During this time, the physiotherapist stays in touch by phone to encourage participants and to help them overcome any problems. Participants also record their exercises and activities in a diary.

What are the possible benefits and risks of participating?
The exercise programme may improve participants' symptoms, give them more energy, and allow them to do more. This is not guaranteed, which is this study is needed. The programme of exercise training has been shown to be safe, and the exercise is supervised by an experienced therapist for the first 8 weeks. Sudden, vigorous exercise can be hazardous for people of any age, but it is not part of this study. Participants may feel a bit more tired than usual immediately after the exercise session, or even the next day.

Where is the study run from?
University of Dundee (UK)

When is the study starting and how long is it expected to run for?
August 2007 to August 2010

Who is funding the study?
Chief Scientist Office (UK)

Who is the main contact?
Prof. Marion McMurdo
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Contact information

Type(s)
Scientific

Contact name
Prof Marion McMurdo

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
METM HF/ex

Study information

Scientific Title
A randomised controlled trial of the effect of exercise training on exercise capacity in older patients with heart failure

Study objectives
Exercise training is known to benefit younger patients with heart failure. However most heart failure patients are older. We aim to recruit heart failure patients aged 70 years or older to either 24 weeks of exercise training or usual care. The exercise training program was developed in a pilot study. The study question: Is the newly developed exercise program effective in improving exercise capacity in older people with chronic heart failure?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tayside Committee on Medical Ethics A, 09/02/2007, ref: 07/S1404/1

Study design
Randomised controlled trial

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 heart failure

Interventions
Intervention group: Eight weeks of twice per week therapist-led supervised small group intermittent functional aerobic exercise and strength training, with the duration of sessions gradually increased to 60 minutes. This will be followed by a 16-week home-based exercise phase, which will include self-monitoring and telephone instruction and encouragement from the therapist.

The control group will receive usual care.

Intervention Type
Behavioural

Primary outcome measure
Change in 6 minute walking distance, recorded at baseline, 8 and 24 weeks

Secondary outcome measures
The following will be recorded at baseline, 8 and 24 weeks:
1. Change in quadriceps muscle strength
2. Repetitive strength
3. Incremental shuttle walk test
4. Quality of life
5. Carer strain
6. Mood and self reported function

Overall study start date
06/08/2007

Completion date
05/08/2010

Eligibility

Key inclusion criteria
Patients will be recruited from day hospital, heart failure and cardiology clinics
1. Patients aged 70 years or older
2. Diagnosis of chronic heart failure according to the European Society of Cardiology guidelines
3. Evidence of Left Ventricular (LV) systolic dysfunction
4. In the New York Heart Association class II or III

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
112

Key exclusion criteria
1. Aortic stenosis with peak gradient >30 mmHg
2. Sustained Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF) outside of the context of an acute myocardial infarction
3. Unstable angina
4. Unable to walk without human assistance
5. Atrial fibrilation with a ventricular rate of >100/min
6. Currently enrolled in another trial

Date of first enrolment
06/08/2007

Date of final enrolment
05/08/2010

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Dundee
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee (UK)

Sponsor details
Research and Innovation Services
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Sponsor type
University/education

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type

Government

Funder Name
Chief Scientist Office (ref: CZH/4/426) (UK)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local 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
The protocol is available from the authors on request but is not available online. Study data are available for non-commercial, bona-fide academic analyses in collaboration with the authors; decisions on data access will be made between the investigators and the Sponsor (University of Dundee). Participant consent for unrestricted sharing of individual participant data was not obtained. Contact for data sharing: Dr Catrina Forde (c.forde@dundee.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2012		Yes	No
Basic results		18/05/2018	18/05/2018	No	No