

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

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| <b>Submission date</b><br>29/05/2007   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>03/07/2007 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>21/05/2018       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> 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 why 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

### Contact details

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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 fibrillation 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

11 Perth Road

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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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/03/2012   |            | Yes            | No              |
| <a href="#">Basic results</a>   |         | 18/05/2018   | 18/05/2018 | No             | No              |