## Effect of a Seated Exercise Program to Improve Physical Function and Health Status in Frail Patients ≥70 Years of Age With Heart Failure

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Eighty-two patients aged ≥70 years with heart failure were randomized to a gentle, seated exercise program or to usual care. Six-minute walk distance and quality of life did not change between groups, but daily activity as measured by accelerometry increased in the exercise group relative to the control group. ©2005 by Excerpta Medica Inc.

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e hypothesized that a seated exercise program designed specifically for older frail patients with heart failure (HF) would be well attended and would lead to improvements in exercise capacity, everyday activity, and health status. 1-6 To test this hypothesis, we undertook a randomized, single-blind, controlled trial comparing a multifaceted, seated exercise program (designed specifically for older, frail patients with HF) with a usual-care program.

We recruited patients from the local specialist HF clinic and from the local Medicine for the Elderly clinics. Patients aged ≥70 years with a clinical diagnosis of chronic heart failure according to European Society of Cardiology guidelines, New York Heart Association class II or III symptoms, and evidence of left ventricular systolic dysfunction on echocardiography, contrast ventriculography, or radionuclide ventriculography were eligible to participate. Exclusion criteria were patients with uncontrolled atrial fibrillation, significant aortic stenosis, sustained ventricular tachycardia, recent myocardial infarction, inability to walk without human assistance, abbreviated mental test score <6 of 10, or those currently undergoing physiotherapy or rehabilitation. Written informed consent was obtained from all participants; the study protocol was approved by Tayside Committee on Medical Research Ethics.

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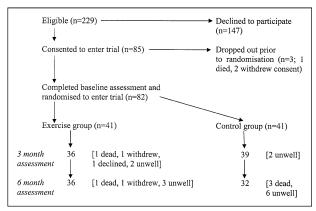


FIGURE 1. Participant flow and follow-up.

We randomized participants after performing baseline assessments. A researcher not otherwise connected with the operation of the study prepared cards contained in numbered, sealed envelopes from computer-generated random number tables. An experienced research nurse who was blinded to treatment allocation performed all assessments. Participants underwent assessments at baseline (before randomization) and at 3 and 6 months.

The primary outcome measure was the 6-minute walk distance.<sup>7,8</sup> Participants undertook a 6-minute walk along a 25-m corridor with standardized encouragement. Daily activity over a 7-day period was measured using the Stayhealthy RT3 triaxial accelerometer (Stayhealthy Inc, Monrovia, California). The device was mounted anteriorly on the participant's waistband, and recorded summed acceleration counts at 1-minute intervals. We asked participants to wear the device from when they first dressed in the morning to when they retired at night. Data from the first and last days were discarded to reduce the influence of incomplete days and transport artifacts. We administered the Guyatt chronic heart failure questionnaire<sup>7,10</sup> (a disease-specific health-related quality-of-life measure), the Hospital Anxiety and Depression score,11 the Philadelphia Geriatric Morale Scale, 12 and the modified Functional Limitations Profile—a United Kingdom version of the Sickness Impact Profile<sup>13</sup> in interview format during a home visit.

An experienced physiotherapist delivered the exercise intervention, which was divided into supervised and home phases. In the supervised phase (0 to 3 months), participants attended exercise classes as outpatients in groups of 3 to 4, twice a week during the first 3 months. Between 17 and 20 sessions were

<sup>\*</sup>Dr. McMurdo is a director of DD Developments, a University of Dundee company promoting exercise classes for subjects aged >60 years. Any profits are pledged to support research into the health of older people. We confirm that the conduct of the study, analysis, and publication of the results are independent of the study funders.

**TABLE 1** Baseline Characteristics of Patients Randomized Exercise Group Control Group (n = 41)Characteristic (n = 41)Mean age  $\pm$  SD  $80 \pm 6$  $81 \pm 4$ 26 (63%) 19 (46%) 25 vs 16 21 vs 20 New York Heart Association class II/III Ischemic etiology 31 (76%) 23 (56%) Left ventricular systolic dysfunction 15 (37%) 14 (34%) 13 (32%) Moderate 12 (29%) Severe 15 (37%) 13 (32%) Myocardial infarction 23 (56%) 18 (44%) Angina pectoris 12 (29%) 17 (39%) 7 (17%) 4 (10%) Stroke Peripheral vascular disease 6 (15%) 8 (20%) Diabetes mellitus 4 (10%) 4 (10%) Osteoarthritis 15 (37%) 12 (29%) Chronic obstructive pulmonary disease/asthma 11 (27%) 14 (34%) 29 (71%) 29 (71%) On ACE inhibitors 3 (7%) 6 (15%) On angiotensin receptor blockers 33 (80%) 33 (80%) On diuretics On  $\beta$  blockers 8 (20%) 8 (20%) 9 (22%) On digoxin 12 (29%) 19 (46%)\* On spironolactone 8 (20%) Living in own home 27 (66%) 32 (78%) Sheltered accommodation 13 (32%) 7 (17%) With relative 1 (2%) 2 (5%) 24 (59%) 19 (46%) Walking aids Marital status Single 2 (5%) 2 (5%) 20 (49%) 12 (29%) Married 1 (2%) 1 (2%) Divorced Widowed 18 (44%) 26 (63%) BMI  $(kg/m^2)$  (mean  $\pm$  SD)  $26 \pm 5$  $26 \pm 4$ Pulse (beats/min) (mean  $\pm$  SD) 71 + 11 $75 \pm 13$ Systolic blood pressure (mm Hg) (mean ± SD)  $144\,\pm\,20$  $141 \pm 29$ Diastolic blood pressure (mm Hg) (mean  $\pm$  SD)  $76 \pm 14$ 76 ± 10 Sinus rhythm/atrial fibrillation 36 vs 5 33 vs 8 \*p <0.05 exercise versus control group. ACE = angiotensin-converting enzyme; BMI = body mass index.

offered during the 3-month period. Each session began with a warm-up and ended with a cool-down sequence of movements. Further segments of exercise were added in between these sequences, consisting of upper limb exercise, lower limb exercise, slow whole body aerobic movements, and quicker whole body aerobic movements. A new segment was added at each session until the whole 6-part program was performed. The 6-part program took approximately 20 minutes to complete and was set to music. At this point, wrist and ankle weights were introduced in a similar sequential fashion until the 6 sessions were performed using 500-g wrist weights and 1.1-kg ankle weights. Weights and participation were adjusted to each participants ability and progress. We encouraged participants to use the Borg rating of perceived exertion scale, 14 aiming for a Borg level of between 11 and 13. We advised participants who rated their perceived exertion as >13 to rest or reduce the level of activity during the exercise session. After performing the exercises, participants undertook a series of breathing exercises and a 10-minute relaxation session to finish the session. We encouraged spouses or other family members to attend any or all of the sessions. Participants kept a diary detailing their main daily activities

over this 3-month period; the physiotherapist reviewed the diary with the participant weekly and set new targets for daily walking activity.

In the second phase (3 to 6 months), we asked participants to continue performing the exercises at home 2 to 3 times per week with the aid of a video or audio cassette with demonstrations, instructions, and music. There was no face-to-face contact with the physiotherapist during this period. Participants continued to keep a diary of their daily activities, which we used as a basis for a weekly telephone liaison. During these telephone calls, the physiotherapist gave encouragement and agreed on new targets for daily walking activity.

Participants in the control group received usual care. We gave standardized written information about the diagnosis and management of heart failure to participants in both groups. We told participants in the control group that exercise was not harmful for their condition and we did not ask the control group to restrict their activities in any way.

We calculated that 33 patients per group were required to provide 90% power to detect a 30-m difference at the 0.05 significance level, assuming a baseline 6-minute walk distance of 230 m and a SD of 50 m.<sup>7,15</sup> A 30-m change has previously been shown to be the minimum clinically important

change in the 6-minute walk. Allowing for dropouts, the final target number for recruitment to the trial was thus 84 patients. Data were analyzed using SPSS statistical software, version 11.5 (SPSS., Chicago, Illinois). Baseline variables were compared using Student's t test for continuous variables and chi-square testing for discrete variables. Percent changes between baseline and 3 months and also between baseline and 6 months were calculated and compared using the Student's t test for normally distributed variables, and the Mann-Whitney U statistic test for skewed variables. A p value <0.05 was considered statistically significant.

Participants were recruited between January 2002 and October 2003, and the 6-month follow-up was completed in April 2004. Figure 1 gives details of participant flow and follow-up; Table 1 lists baseline details of patients randomized into the study. Major reasons for declining participation were poor health, lack of interest in exercise, and frequent current activity and exercise. We offered a total of 758 personsessions of exercise to the 41 participants in the exercise group, a mean of 18.5 sessions (range 12 to 20) per participant. Participants attended a total of 626 person-sessions, a mean of 15.3 sessions (range 0 to

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