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## **Efficacy and cost of an exercise program for functionally impaired older patients with heart failure: a randomized controlled trial**

*Witham MD, Fulton RL, Greig CA, Johnston DW, Lang CC, van der Pol M, Boyers D, Struthers AD, McMurdo ME*

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### **Record Status**

This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

### **CRD summary**

This study assessed the efficacy and cost of an exercise programme for functionally impaired older patients, with heart failure. The authors concluded that the exercise programme did not improve outcomes, and it did not save NHS costs. The study was well reported and used appropriate statistical techniques. Its limitations and generalisability were considered, and the conclusions are appropriate.

### **Type of economic evaluation**

Cost-effectiveness analysis

### **Study objective**

This study assessed the efficacy and cost of an exercise programme, for functionally impaired older patients, with heart failure.

### **Interventions**

The exercise intervention was compared with usual care. Exercise consisted of eight weeks of guided aerobic and resistance training, with structured education on exercise, self-management, and perception, followed by 16 weeks of home exercise, with telephone calls from physiotherapists to monitor progress. Usual care consisted of a booklet with general advice on diet, exercise, and lifestyle.

### **Location/setting**

UK/out-patient.

### **Methods**

#### **Analytical approach:**

The evaluation was based on a randomised controlled trial. The analysis covered the 24-week trial period. The authors stated that the perspective was that of the UK NHS.

#### **Effectiveness data:**

The effectiveness data were from a single-centre, parallel-group, single-blind, randomised controlled trial of 107 patients, with heart failure, aged 70 years or older. The project coordinator was blind to treatment. The primary effectiveness measure was the change in six-minute walking distance at 24 weeks. Other outcomes were strength and activity levels, disease-specific quality of life (Minnesota Living With Heart Failure; MLWHF), carer burden, cognitive function, and generic health-related quality of life (EQ-5D). These outcomes were assessed at eight and 24 weeks. The trial was powered to detect a 30 metre change in six-minute walking distance (80% power; 0.05 significance). The change between baseline and follow-up was calculated for each outcome, and compared using analysis of variance, adjusting for significantly different factors at baseline. Multiple imputation was used for missing data.

#### **Monetary benefit and utility valuations:**

The utility was measured at eight and 24 weeks, using the EQ-5D, completed by participants in the trial.

#### **Measure of benefit:**

The primary measure of benefit was the change in six-minute walking distance; several other outcomes were reported.

#### Cost data:

The costs included physiotherapist time, travel expenses, equipment, and health care. Health care resources were assessed using patient questionnaires, which recorded primary, secondary and pharmaceutical care. Resource use was assessed at baseline, eight weeks, and 24 weeks. The unit costs for secondary care were from the Scottish Information Services Division. Those for primary care were from the Personal and Social Services Resource Unit, and pharmaceutical unit costs were from the British National Formulary. Mean total costs were compared, using ordinary least squares regression, adjusting for baseline differences. Nonparametric bootstrapping was used to estimate confidence intervals. Multiple imputation was used for missing data. All costs were in UK £.

#### Analysis of uncertainty:

Sensitivity analyses were conducted, for the primary outcome, testing different missing data assumptions. One analysis assumed zero for missing values, while another used the last value carried forward. For costs, the impact of analysing only patients with complete data, and that of removing outliers, were explored.

### Results

With multiple imputation for missing data, there was a mean difference of two metres in the six-minute walk distance, in favour of the intervention, at 24 weeks. Assuming zero for missing data, the difference was 4.7 metres, in favour of the intervention. With the last observation carried forward, the difference was -1.8 metres, favouring control.

The differences for most other outcomes, including health-related quality of life, were not statistically significant. Only the sit-to-stand test reported a statistically significant difference in favour of the exercise programme.

For costs, with multiple imputation, the intervention was £447.85 less expensive than control, at 24 weeks, but this difference was not statistically significant. Removing outliers (patients who spent more than 30 days in hospital for reasons other than heart failure or the exercise intervention) made the mean costs with exercise £417.04 higher than with usual care, but this was not statistically significant.

### Authors' conclusions

The authors concluded that the exercise programme did not improve outcomes for older patients with heart failure, and it did not save NHS costs.

### CRD commentary

#### Interventions:

The intervention and usual care were described, with more details available in other published papers.

#### Effectiveness/benefits:

The effectiveness data, and the trial that supplied them, were generally well reported. Adjusting for baseline differences, and using multiple imputation for missing data, were appropriate.

#### Costs:

Nonparametric bootstrapping, with multiple imputation for missing data, were appropriate ways to account for skew and missing cost data. The costs were generally well reported, with appropriate detail. They were from UK sources, appropriate for a UK NHS perspective. The price year was not reported, hindering reflation exercises.

#### Analysis and results:

No actual effectiveness and cost results were given for the intervention and control arms separately, only the differences between the two were reported. Otherwise, the results were presented comprehensively, with appropriate consideration of their limitations and generalisability. No incremental cost-effectiveness analysis was conducted.

#### Concluding remarks:

The study was well reported and used appropriate statistical techniques. Its limitations and generalisability were considered, and the conclusions are appropriate.

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