

## Randomised trial of telephone intervention in chronic heart failure: DIAL trial

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### Abstract

**Objective** To determine whether a centralised telephone intervention reduces the incidence of death or admissions for worsening heart failure in outpatients with chronic heart failure.

**Design** Multicentre randomised controlled trial.

**Setting** 51 centres in Argentina (public and private hospitals and ambulatory settings).

**Participants** 1518 outpatients with stable chronic heart failure and optimal drug treatment randomised, stratified by attending cardiologist, to telephone intervention or usual care.

**Intervention** Education, counselling, and monitoring by nurses through frequent telephone follow-up in addition to usual care, delivered from a single centre.

**Main outcome measure** All cause mortality or admission to hospital for worsening heart failure.

**Results** Complete follow-up was available in 99.5% of patients. The 758 patients in the usual care group were more likely to be admitted for worsening heart failure or to die (235 events, 31%) than the 760 patients who received the telephone intervention (200 events, 26.3%) (relative risk reduction = 20%, 95% confidence interval 3 to 34,  $P = 0.026$ ). This benefit was mostly due to a significant reduction in admissions for heart failure (relative risk reduction = 29%,  $P = 0.005$ ). Mortality was similar in both groups. At the end of the study the intervention group had a better quality of life than the usual care group (mean total score on Minnesota living with heart failure questionnaire 30.6 *v* 35,  $P = 0.001$ ).

**Conclusions** This simple, centralised heart failure programme was effective in reducing the primary end point through a significant reduction in admissions to hospital for heart failure.

### Introduction

Hospital readmission in chronic heart failure is often due to preventable factors, such as non-adherence to drugs and diet, inadequate social support, and failure to seek prompt medical attention when symptoms worsen.<sup>1,2</sup> Intervention programmes based on comprehensive care and intensive follow-up by a multidisciplinary team have recently achieved a promising reduction in admissions and costs.<sup>3-10</sup> However, such evidence comes from small, single centre trials, applying complex strategies to selected populations.<sup>11</sup>

We designed a large multicentre trial to test whether a single centralised telephone intervention could reduce morbidity and mortality in patients with chronic heart failure compared with usual care.<sup>11</sup>

### Methods

#### Study design

This was a randomised, controlled, multicentre trial comparing centralised telephone intervention with usual care in patients with chronic heart failure. The design and rationale of the study have been reported previously.<sup>11</sup>

#### Eligibility criteria

Attending cardiologists at each centre screened patients on a national multicentre chronic heart failure registry in Argentina. Patients had to be stable in ambulatory care, defined by no admissions in the previous two months, not needing more than one clinic visit a month, and with optimal heart failure treatment not modified for at least two months before inclusion (see [bmj.com](http://bmj.com)).

#### Intervention

A detailed description of the intervention has been reported previously.<sup>11</sup> All study patients were treated according to their attending cardiologists' criteria, with a follow-up visit at least every three months during the study period.

Patients allocated to the intervention received an education booklet. In addition, trained nurses made frequent follow-up calls starting within seven days after randomisation. The intervention was based on five main objectives: adherence to diet, adherence to drug treatment, monitoring of symptoms, control of signs of hydrosaline retention, and daily physical activity. Nurses could adjust the dose of diuretic or recommend non-scheduled medical or emergency visits. The first four telephone calls were made fortnightly or according to the needs of the patient and the nurse's decision. After the fourth telephone call, the interval was automatically determined using data recorded at each phone contact.

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Summary of primary and secondary end points. Values are numbers (percentages) unless stated otherwise

End point	Intervention (n=760)	Control (n=758)	Relative risk (95% CI)	P value
Primary end point:	200 (26.3)	235 (31.0)	0.80 (0.66 to 0.97)	0.026
Heart failure admission	128 (16.8)	169 (22.3)	0.71 (0.56 to 0.91)	0.005
All cause mortality	116 (15.3)	122 (16.1)	0.95 (0.73 to 1.23)	0.690
All cause admission	261 (34.3)	296 (39.1)	0.85 (0.72 to 0.99)	0.049
Cardiovascular admission	183 (24.1)	228 (30.1)	0.76 (0.62 to 0.93)	0.006
All cause admission and/or all cause mortality	299 (39.3)	339 (44.7)	0.86 (0.73 to 1.00)	0.057
Cardiovascular admission and/or all cause mortality	239 (31.4)	288 (38.0)	0.79 (0.65 to 0.95)	0.01

Patients in the control group were followed by their attending cardiologists and received similar care to the intervention group.

### Outcomes

The primary end point was all cause mortality or admission to hospital for worsening heart failure. Secondary end points included total mortality, all cause hospital admission, admission for worsening heart failure, cardiovascular admission, quality of life, all cause mortality or overall admissions, and the combined end point of all cause mortality or cardiovascular admission. A committee blinded to the patients' treatment group adjudicated all outcomes.

### Statistical methods

We based all analyses on the intention to treat principle. We used the log rank test and relative risk reduction to analyse the end points, and Cox proportional hazards model to estimate the adjusted effect. We ran tests to compare adherence, drug use, and functional class between intervention and control groups and to compare quality of life scores between groups (see [bmj.com](http://bmj.com)).

### Results

A total of 760 patients were allocated to the intervention group and 758 to the control group. We stopped the trial on 1 August 2002 when 400 primary events had been reported. Another 35 events occurred before the closing date and were included.

Baseline characteristics of the two groups were similar (see [bmj.com](http://bmj.com)). The mean length of follow-up was 16 (range 7-27) months. The primary outcome occurred in 200 (26.3%) patients in the intervention group and in 235 (31%) patients in the control group (relative risk reduction 20%, 95% confidence interval 3% to 34%,  $P=0.026$ ) (fig). We found no difference between the adjusted and unadjusted effect of the intervention for the primary outcome (adjusted for New York Heart Association class, age, baseline treatment, comorbidity, and systolic dysfunction).

The reduction in the incidence of the primary end point was mostly due to a relative risk reduction in the incidence of admissions for heart failure of 29% (9% to 44%,  $P=0.005$ ): 128 (16.8%) in the intervention group as compared with 169 (22.3%) in the control group. The effect on all cause mortality was not significant (relative risk reduction=5%, -27% to 23%,  $P=0.69$ ) (table).

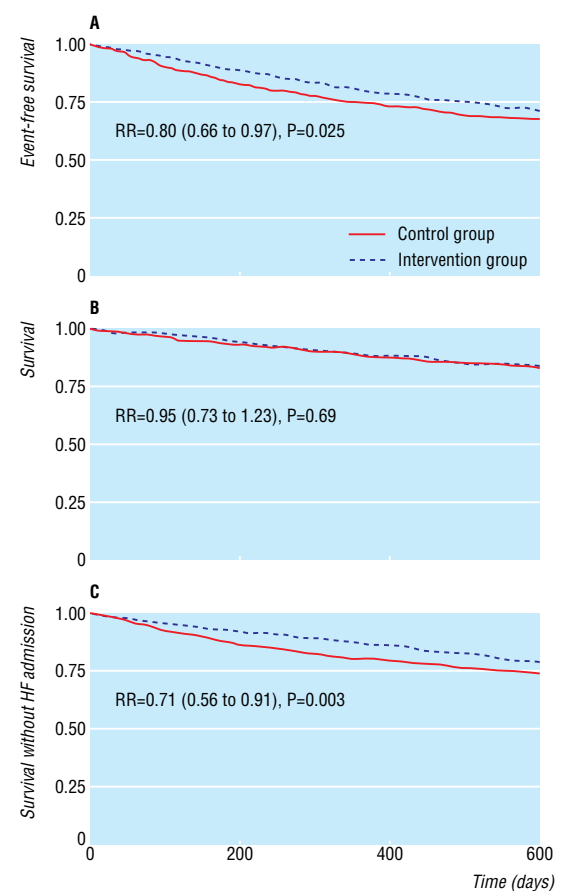
The rate of all cause admissions was also lower in the intervention group: 261 patients were admitted at

least once compared with 296 in the control group (reduction=15%, 0.1% to 28%,  $P=0.049$ ). Significantly fewer cardiovascular admissions were recorded in the intervention group than in the control group (183 *v* 228 patients, reduction=24%, 7% to 28%,  $P=0.006$ ) (table).

### Quality of life and adherence

A total of 1159 patients completed the Minnesota living with heart failure questionnaire. At the final visit, patients in the intervention group had better quality of life than control patients (mean total score in intervention group 30.6 *v* 35.0 in control group; mean difference=4.4, 95% confidence interval 1.8 to 6.9,  $P=0.001$ ). We also found a difference in the physical score (11.2 *v* 12.8,  $P=0.007$ ) and emotional score (6.7 *v* 7.9,  $P=0.002$ ).

At the end of the trial, significantly more patients in the intervention group than the control group were taking  $\beta$  blockers (450 (59.2%) *v* 391 (51.6%),  $P=0.003$ ), spironolactone (207 (27.2%) *v* 172 (22.6%),  $P=0.03$ ), digoxin (254 (33.4%) *v* 217 (28.6%),  $P=0.04$ ), and furosemide (588 (77.3%) *v* 535 (70.5%),  $P=0.007$ ). More patients in the control group stopped taking any drugs (138 (18.2%) *v* 61 (8.0%),  $P<0.001$ ) and reported dietary transgressions (492 (64.9%) *v* 154 (20.2%),  $P<0.001$ ).



Kaplan-Meier curves for rate of death from any cause or admission to hospital for heart failure (panel A), rate of death from any cause (panel B), and rate of admission for heart failure (panel C). HF=heart failure; RR=relative risk (with 95% confidence interval)

## Discussion

We have shown that a telephone intervention programme was effective in reducing the primary end point, mainly owing to a reduction in admissions for worsening heart failure. The number of heart failure patients who needed to be called in a year to prevent one admission for worsening heart failure was 16. In addition, all cause and cardiovascular admissions were significantly decreased and quality of life was greater at the end of the study in the intervention group.

This is the first multicentre randomised trial including more than 1500 patients followed for more than a year. Previous studies have shown a reduction in all cause and heart failure admissions in highly selected populations, with short follow-up, and by applying complex interventions.<sup>3-10</sup> In contrast, our study found similar results using a simple programme in a large, non-selected population of outpatients with heart failure, in very different clinical settings. The reported effect was additive to drug treatment, considering that most patients received optimal heart failure treatment prescribed by cardiologists.

Although we consider that the observed benefit is a direct consequence of the intervention, other explanations should be explored. Firstly, the end points may have been misclassified. To deal with this potential bias, we created an independent and blinded endpoint committee. Moreover, we did not notice a shift from heart failure admissions to other cause admissions, because the overall admissions also fell significantly. Secondly, owing to the open design of the trial, it might be argued that the benefit was a result of a deliberate intensification of medical follow-up or drug treatment in the intervention group. However, the number of total medical visits was similar in both groups and the drug treatment prescribed by physicians did not differ.

## Conclusion

Although multidisciplinary and complex strategies might provide greater advantage, the results of our simple intervention were similar to those of other reported combined strategies and at a reasonable cost.

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## What is already known on this topic

Multidisciplinary management programmes in post-admission patients with heart failure have suggested a reduction in hospital admissions and costs

This evidence, however, comes from small trials, at single university centres, applying complex strategies to selected high risk populations

## What this study adds

In this large scale multicentre trial, a telephone intervention by nurses reduced readmissions for worsening heart failure

A simple and centralised intervention is feasible and effective in heart failure outpatients with different risks in diverse clinical settings and geographical locations

Dohme, which had no participation in the design, conduction, data management, or the preparation of the manuscript. All researchers were independent of the funders.

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Ethical approval: The ethics committee at each centre approved the study protocol.

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## A case of mouth in foot disease

An elderly man was admitted to our hospital after being found wandering the streets disorientated. He was found to have had a myocardial infarction and was soon on our ward and making a good recovery. He continued to have some disorientation with reduced cognition and low mood. Progress was steady, however, until one day he developed a notable limp while walking on the ward. He moved his legs freely enough but clearly limped on the right leg.

Neurological examination was unremarkable, as was muscle and joint examination; there was no tenderness or swelling present. Radiographs of his hips and pelvis seemed normal, but

the limp persisted. The day of discharge was looming, and the team was increasingly uncomfortable with the prospect of the patient leaving with the cause of his limp still undiagnosed.

On his last day in hospital the consultant sat down with him and asked him straight: "Why do you have a limp?" The man looked at the consultant and then calmly bent down, removed his right shoe, and lifted out his top set of dentures and placed them gently on his table. The limp was immediately cured.

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