

Randomized, controlled trial of integrated heart failure management

The Auckland Heart Failure Management Study

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Aims To determine the effect of an integrated heart failure management programme, involving patient and family, primary and secondary care, on quality of life and death or hospital readmissions in patients with chronic heart failure.

Methods and Results This trial was a cluster randomized, controlled trial of integrated primary/secondary care compared with usual care for patients with heart failure. The intervention involved clinical review at a hospital-based heart failure clinic early after discharge, individual and group education sessions, a personal diary to record medication and body weight, information booklets and regular clinical follow-up alternating between the general practitioner and heart failure clinic. Follow-up was for 12 months. One hundred and ninety-seven patients admitted to Auckland Hospital with an episode of heart failure were enrolled in the study. There was no significant difference between the intervention and control groups for the combined end-point of death or hospital readmission. The physical dimension of quality of life showed a greater

improvement in the intervention group from baseline to 12 months compared with the control group (-11.1 vs -5.8 respectively, $2P=0.015$). The main effect of the intervention was attributable to the prevention of multiple admissions (56 intervention group vs 95 control group, $2P=0.015$) and associated reduction in bed days.

Conclusions This integrated management programme for patients with chronic heart failure improved quality of life and reduced total hospital admissions and total bed days. (Eur Heart J 2002; 23: 139–146, doi:10.1053/ehj.2001.2712)

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Key Words: Congestive heart failure, management, hospitalization, integrated care.

See page 101, doi:10.1053/ehj.2001.2828 for the Editorial comment on this article

Introduction

Hospital admissions for heart failure are common and appear to be increasing in frequency^[1,2]. These admissions account for 1–1.5% of total health budgets in developed countries^[1,3], with out-patient management costs contributing at least another 0.5–1%. In addition, quality of life for patients with heart failure is often markedly impaired. While pharmacological therapy has established benefits in the treatment of patients with heart failure, clinical outcomes may be improved further

by non-pharmacological strategies. Several studies have now shown that multidisciplinary, home-based interventions for patients with heart failure^[4–6] can reduce hospital readmissions and improve quality of life. Education, counselling and ongoing support for patients with heart failure would appear essential for effective long-term management^[7].

Hospital-based specialist heart failure clinics have been advocated to improve long-term management^[8]. However, such clinics are expensive to run and at present are often limited to tertiary institutions with specific purposes such as heart transplantation or research. Management of patients with heart failure may be improved by combined follow-up between specialists and general practitioners. Evidence of the benefits of such management programmes is required from randomized, controlled trials including a wide range of

Revision submitted 27 March 2001, accepted 28 March 2001, and published online 3 August 2001.

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patients before general recommendations are made. The aims of this study were to determine the effects of an integrated heart failure management programme on hospital readmissions and quality of life in patients with heart failure.

Methods

The study was a randomized, controlled single centre study. Eligible patients were those admitted to the general medical wards at Auckland Hospital with a primary diagnosis of heart failure. Exclusion criteria were kept to a minimum to allow a wide range of patients to be enrolled. Exclusions included: (i) a surgically remediable cause for heart failure, such as severe aortic stenosis, (ii) consideration for heart transplantation, (iii) inability to provide informed consent, (iv) terminal cancer and (v) participation in any other clinical trial. Potentially eligible patients were reviewed during their hospital stay by the study team. Heart failure was diagnosed on the basis of typical symptoms and signs, with review of the chest radiograph, ECG and echocardiogram. The Auckland Ethics Committee approved the study and written informed consent was obtained from each patient during the index admission just prior to hospital discharge.

Randomization

Contamination of the control group management may have occurred if a general practitioner had patients in both groups. Thus, cluster randomization was performed using the general practitioner as the unit of randomization. General practitioners (GPs) were randomly allocated, using computer-generated random numbers, to either the intervention or control groups. After consent was obtained, the patient was informed of their group allocation based on the randomization of their current general practitioner. The GP was approached regarding the study and informed of their patient's participation. No GP approached in this way declined to take part in the study.

Details of the clinical history, physical examination, blood biochemistry, ECG and chest radiograph were recorded at baseline. A transthoracic echocardiogram was performed in all subjects and ejection fraction measured (biplane Simpson's method) using an Acuson 128 or ATL HDI5000 ultrasound machine. The Minnesota Living with Heart Failure questionnaire^[9], for assessment of quality of life, was administered by trained interviewers. The study team had no input into the medical management of the patients during the in-patient stay. Thus the study commenced from the time of discharge following the index admission, although the actual intervention was delayed until the first outpatient visit following discharge.

Intervention

Patients randomized to the intervention group were scheduled for an outpatient clinical review with the

study team within 2 weeks of hospital discharge. At this initial clinic visit the patient's clinical status was reviewed, with particular attention to possible remediable exacerbating factors. Pharmacological treatment was based on evidence-based guidelines current at the time of the study^[10]. One-on-one education with the study nurse was initiated at the first clinic visit. A patient diary, for daily weights, medication record, clinical notes and appointments, and education booklet were provided (see acknowledgements). A follow-up plan was devised for each patient aiming for 6-weekly visits alternating between the GP and heart failure clinic, although the patients were free to see their GPs at any time they wished. A detailed letter was faxed to the GP on the same day as the patient visited the heart failure clinic. This letter included summary comments outlining the rationale for any changes in treatment, and was followed-up with a phone call to the patient's GP to discuss any relevant changes in the management plan. The aim was for a close liaison between the patient and family, the GP and the hospital heart failure clinic. GPs made changes to the patient's management as they saw fit but were encouraged to discuss aspects of the patient's management with the clinic team at any stage.

Subsequently, group education sessions (each lasting 1.5–2 h) were offered, two within 6 weeks of hospital discharge and a further after 6 months. These sessions were run by a cardiologist and the study nurse. The content of the one-on-one and group education included explanation of the symptoms and signs of heart failure, importance of monitoring of daily body weight and action plans should weight change, effects of medications and importance of compliance and recommendations regarding exercise and diet. The advice given was individualized and reinforced at each subsequent clinic visit by the study nurse. Monitoring of daily weights, with documentation in the diary and knowing what action to take should weight change, was reinforced at every available opportunity, either in the clinic or during phone calls with the patient. No assistance with travel costs or other incentives were provided for the patients in the intervention group.

The study team at the hospital heart failure clinic was available for consultation during normal working hours and received calls from both patients and their GPs. At times of worsening symptoms patients were initially advised to see their GP. No explicit criteria for readmission were pre-specified and the decision to request admission rested with the GP. If admission was not required then an earlier heart failure clinic visit could be arranged.

Patients randomized to the control group continued under the care of their GP with additional follow-up measures as usually recommended by the medical team responsible for their in-patient care.

Study end-points and data collection

Primary end-points were (1) combined end-point of death or hospital readmission (time to first event) and

(2) quality of life questionnaire^[9]. Secondary end-points included: (a) all-cause hospital readmissions; (b) all-cause hospital bed days; and (c) readmissions for worsening heart failure.

Patients were followed for 1 year. All surviving patients were invited for a clinical review after 12 months. At this visit the patient's symptoms and signs were determined and the quality of life questionnaires repeated. Blood was drawn for electrolytes and renal function, and the ECG and echocardiogram were repeated. For patients who were unable to attend the 12-month visit, information regarding clinical status and medication usage was obtained from primary care records. Data on deaths and hospitalizations after randomization were collected and reviewed at the time of the 12-month visit. Extensive checks for hospital admissions during the 12 months were made from patient reporting, GP records and hospital databases. Deaths were verified from death certificates and all hospital admissions were checked with the hospital records.

Statistical analysis

A provisional sample size of 180 patients per group was estimated to provide at least 80% power at the 0.05 level of statistical significance to detect a 30% reduction in the combined end-point of death or hospital readmission. Because of uncertainty of the actual rates of death or hospital readmission in this patient group, an independent interim analysis was prospectively planned after 100 patients had been followed for 6 months to allow recalculation of sample size. This independent analysis showed higher than expected event rates but no difference between the two groups for the combined end-point of death or readmission. Thus, recruitment was stopped, with a total of 197 patients randomized. Follow-up to 12 months continued to allow completion of the quality of life and total readmission end-points.

Data were analysed using two approaches. Firstly the unit of randomization was assumed to be the individual, as if simple randomization had been performed. Differences between treatment arms in categorical variables over 12 months were tested using Fisher's Exact test, whilst differences in continuous variables were sought using Student's t-test. In other analyses the unit of randomization was the GP, consistent with the actual method of cluster randomization. Similar analyses were performed where the average value per GP was weighted by the number of patients the GP contributed, by taking the proportion of patients in each general practice as the dependent variable and comparing a weighted mean between groups. Since the median number of participants per general practitioner was small (1.5 in each arm) the influence of clustering was small and only results from the first approach are presented. In no case did statistical significance differ depending upon the approach adopted.

The combined end-point of death or hospital readmission was analysed on a time to first event basis using the

Table 1 Baseline characteristics

	Intervention group	Control group
Number of patients	100	97
Number of GPs	64	68
Age, years (SD)	72.5 (11.6)	73.5 (10)
Age range	34–92	49–92
Female	36	43
Living alone	29	41
Ethnicity		
NZ European	77	79
Maori	8	7
Pacific Island	14	9
Other	1	2
NYHA (index admission)		
III	24	24
IV	76	73
Aetiology of HF		
Ischaemic	48	59
Non-ischaemic	52	38
No. prior admissions for HF*		
1	21	20
≥ 2	34	27
Medical history		
Prior myocardial infarction	42	48
Prior revascularization†	12	13
Prior stroke	20	21
Treated hypertension	46	56
Diabetes	32	25
CORD	20	17
Atrial fibrillation	34	30
Heart rate, beats . min ⁻¹ (SD)	80.9 (13.2)	78.6 (11.8)
Systolic BP, mmHg (SD)	123.6 (21.0)	126.3 (21.6)
Diastolic BP, mmHg (SD)	70.8 (11.5)	72.0 (12.5)
LV ejection fraction, % (SD)	30.6 (12.7)	33.8 (12.7)
Creatinine clearance, ml . min ⁻¹ (SD)	48.6 (23.2)	49.2 (24.9)

Values represent number unless stated.

*Index admission not included; †Coronary artery bypass surgery or coronary angioplasty.

HF=heart failure; BP=blood pressure; CORD=chronic obstructive respiratory disease.

methods of Kaplan–Meier. All analyses were performed on an intention-to-treat basis, all tests were two-tailed (2P) and a 5% significance level was used throughout.

Results

One hundred and ninety seven patients were enrolled in the study (100 in the intervention group (64 GPs) and 97 in the control (68 GPs)). The groups were well matched at baseline (Table 1). The mean age at entry to the study was 73 years (SD 10.8). Three quarters of the patients were classified as being in NYHA functional class IV on admission, but all patients had improved sufficiently to be discharged from hospital. Heart failure was considered due to ischaemic heart disease in 54%, and, while the remainder were classified as non-ischaemic, many of these patients had multiple potential causes of heart

Table 2 Medications at baseline and 12 months

	Intervention group (n=100)	Control group (n=97)	2P
No. prescribed drugs* (range)	6 (2–14)	6 (2–14)	
Frusemide			
% receiving drug at baseline	97%	93%	
Dose at baseline, mg . day ⁻¹	116.9 (86.2)	117.3 (80.1)	0.97
Digoxin			
% receiving drug at baseline	20%	26%	
Dose at baseline, mg . day ⁻¹	0.15 (0.06)	0.15 (0.07)	0.80
ACE inhibitor†			
% receiving drug at baseline	88%	89%	
% receiving drug at 12 months	83%	73%	0.58
Dose at baseline, mg . day ⁻¹	11.9 (36.3)	11.3 (37.7)	0.63
Dose at 12 months, mg . day ⁻¹	15.4 (43.2)	12.4 (41.8)	0.052
Change baseline to 12 months	+3.5 (7.4)	+1.1 (6.7)	0.095

*Number of prescribed drugs is median. †Most patients were receiving enalapril, captopril, or lisinopril: the dosages were converted to an enalapril-equivalent dose for the comparison. Values represent mean (SD), unless stated.

failure with the exact cause often being uncertain. Forty-six percent of all patients had a history of documented prior MI, 52% prior hypertension, and 29% diabetes. Fifty-two percent had a prior admission for heart failure before the index admission. Most were receiving frusemide and 88% were receiving an ACE inhibitor (Table 2). The average left ventricular ejection fraction at entry to the trial was 32% (SD13). Renal function was impaired with an average creatinine clearance of 48.9 ml . min⁻¹ (SD 24) (normal range 90–140 ml . min⁻¹).

Follow-up

The median time to the first outpatient visit, which marked the onset of the management programme for patients in the intervention group, was 11 days. Patients in the intervention group attended the hospital heart failure clinic on average four times during the 12 months. Sixty percent of the intervention group attended the first group education session, and 40% attended the 6-month session. There was a trend for a higher proportion of the intervention group to be receiving an ACE inhibitor and at a higher dose at 12 months although these differences were not statistically significant (Table 2). Other medications were similar in the two groups at baseline and during follow-up.

Death and hospital admissions

Figure 1 shows the flow of patients through the trial. Seven patients in each group were unable to attend the clinic review at 12 months. Mortality and hospital admission data were available for 196 patients, including the patients who did not attend the 12 month review,

with one patient lost to follow-up. During the 12 months of follow-up, 43 (22%) patients died and 123 (62%) were admitted to hospital. For the combined end-point of death or hospital readmission, there was no significant difference between the intervention and control groups (68 vs 61 respectively, Chi-square=0.95, 2P=0.33, Fig. 2).

Overall, there were 120 hospital readmissions for all causes in the intervention group compared with 154 in the control group. There was a decrease in the hospital admission rate in the intervention group compared with the control group, with hospital admission rates of 1.37 and 1.84 per patient year, respectively, and an incident rate difference of 0.47 per patient year (95% CI 0.16, 0.78). The rate ratio of 0.74 suggests a 26% decrease in the hospital admission rate (95% CI 0.52, 0.96). There were fewer total hospital bed days associated with this reduction in hospital admissions in the intervention group compared with the control group, 1074 vs 1170 bed days, respectively. Thus, there were 12.3 bed days per patient year of follow-up in the intervention group compared with 13.9 bed days per patient year in the control group, a reduction of 1.6 bed days per patient year (95% CI 0.51, 2.7). The mean time to the first hospital readmission was not significantly different between the two groups: 102 (SD 104) days in the intervention group vs 122 (SD 116) days in the control group (2P=0.4).

The main effect of the intervention was attributable to the prevention of multiple readmissions. First readmissions for all causes were similar in intervention and control groups (64 vs 59 respectively). However, subsequent all-cause readmissions were fewer in the intervention group compared with the control group (56 vs 95 respectively, 2P=0.015, Table 3). There were more hospital bed days in the intervention group during the first readmissions compared with the control group

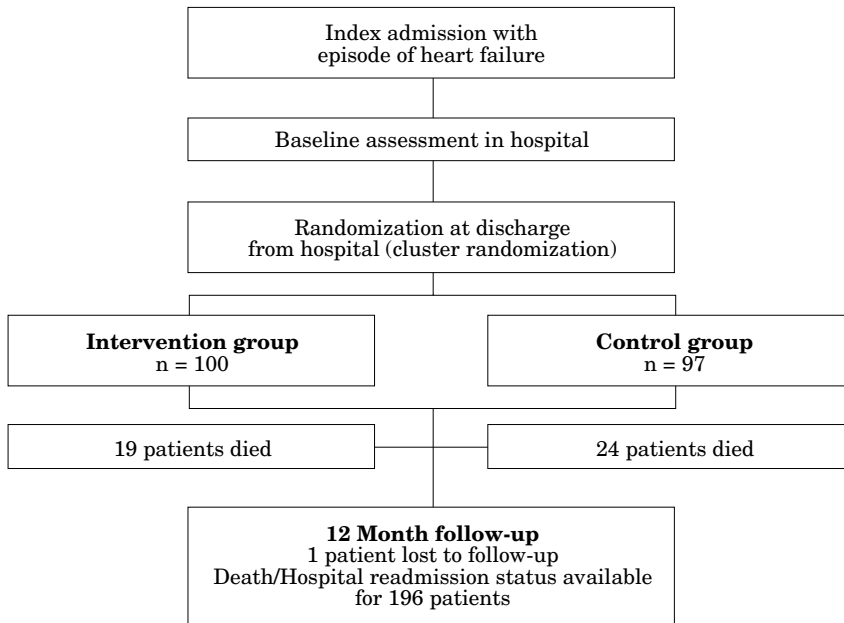


Figure 1 Study flow chart.

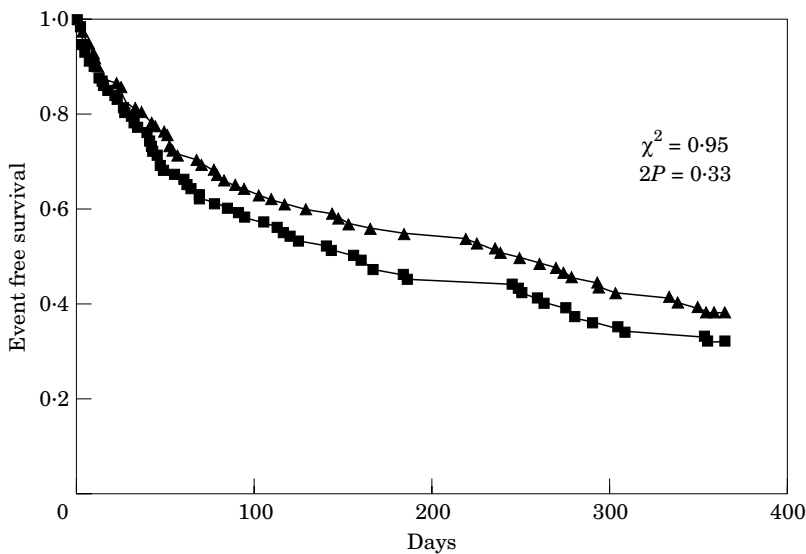


Figure 2 Death or hospital readmission in the intervention (■) and control (▲) groups during 12 months of follow-up.

(546 vs 444 respectively), but fewer bed days during subsequent readmissions (528 intervention group vs 726 control group, $2P=0.0001$).

There were 36 readmissions (358 bed days) with a primary diagnosis of heart failure in the intervention group compared with 65 readmissions (561 bed days) in the control group. First readmissions for heart failure were similar in intervention and control groups (21 vs 23 respectively). However, subsequent readmissions for heart failure were fewer in the intervention group compared with the control group (15 vs 42 respectively, $2P=0.036$, Table 3). Hospital bed days were similar in the intervention group during the first readmissions

compared with the control group (219 vs 195 respectively), but there were fewer bed days during subsequent readmissions (139 intervention group vs 366 control group, $2P=0.0001$).

Quality of life

The Minnesota Living with Heart Failure scores at baseline showed markedly impaired quality of life: mean baseline physical functioning score was 25.6 (SD 12.4) and emotional score 10 (SD 7.8). There was a significant improvement in physical functioning from baseline to

Table 3 Death, hospital readmissions and bed days during 12 months follow-up

	Intervention group	Control group
Deaths (all-cause)	19	24
All-cause readmissions		
First readmission	64	59
Subsequent readmissions	56	95*
Total	120	154
Readmissions for heart failure		
First readmission	21	23
Subsequent readmission	15	42*
Total	36	65
Hospital bed days		
All-cause readmissions	1074	1170
Heart failure readmissions	358	561

* $2P < 0.05$, Fishers exact test.

12 months between the intervention and control groups (-11.1 and -5.8 respectively, $2P = 0.015$) (Fig. 3). There was no significant change in the emotional score between the two groups from baseline to 12 months (-3.3 and -3.3 respectively, $2P = 0.97$).

Discussion

This is the first randomized controlled trial of an integrated approach to heart failure management, involving patients and their families, with primary and secondary

care. The study involved a broad range of patients who are representative of those from a general hospital setting. The study demonstrated improvements in the physical dimensions of quality of life, and a reduction in multiple hospital admissions over 12 months. While many have advocated the benefits of such integrated management^[8], this is the first evidence of benefit from a randomized controlled trial. The intervention group received support and education from their general practitioner, a specialist at the heart failure clinic and a nurse practitioner. Early clinical review occurred after hospital discharge and education was provided both individually and in group sessions. Follow-up was shared between the general practitioner and heart failure clinic with easy access to the clinic as required. There were 34 fewer hospital readmissions and 96 less bed days in the intervention group compared with the control group, with the main effect attributable to the prevention of multiple admissions. This overall effect, while relatively modest, is likely to be a reliable indication of the effect of this management approach and generalisable to similar health-care settings.

The effect of the intervention is delayed, as can be seen from the lack of effect on the first readmissions. This may, in part, have occurred as the intervention did not start until after the patients were discharged following the index admissions. Thus there was a lag time until the intervention started when patients attended the first heart failure clinic visit (median of 11 days). Given the delayed effect of the intervention it is possible that the effect may continue and perhaps be greater in second or subsequent years, although longer-term follow-up would be required to determine this. The control group also

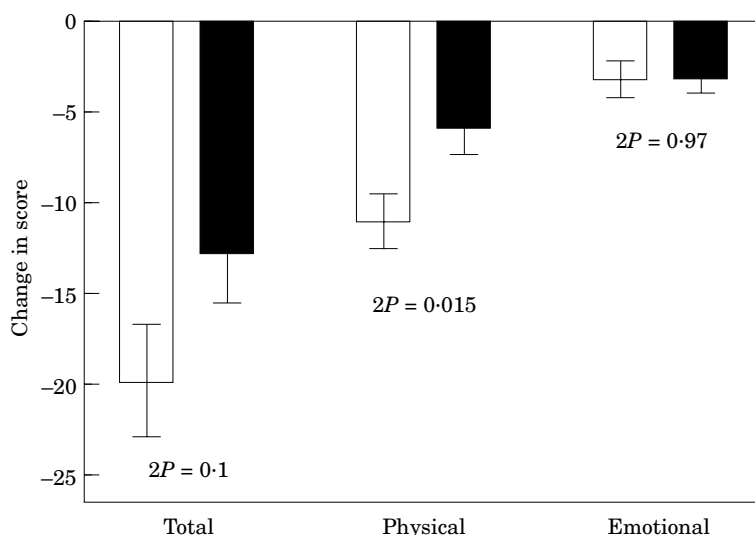


Figure 3 Change in quality of life scores from baseline to 12 months for intervention (□) and control (■) groups (Minnesota Living with Heart Failure questionnaire). Minnesota score is positively scored such that a higher score implies worse quality of life. A negative value for change in score from baseline to 12 months indicates improvement in quality of life. Values shown are mean change with error bars representing standard error.

appears to have received a good standard of care in the Auckland setting. This may reflect the influence of local clinical research, opinion leaders and clinical practice guidelines. ACE inhibitors, as one clinical indicator, were used in 89% of the control group at baseline. Dosages may be considered suboptimal although it is notable that the patients had markedly impaired renal function, making lower dosages appropriate. Beta-blocker therapy was minimal in this patient group, as the study was carried out prior to the definitive beta-blocker trials^[11,12]. Some authors have advocated audit of pharmacological therapy prior to using scarce resources on nurse practitioners or clinics^[13]. One component of the intervention in the current study was to review and optimize pharmacological therapy. There were trends for more patients to be receiving ACE inhibitor therapy and at a slightly higher dose, although overall these were only relatively small changes and thus it is unlikely that this alone would have accounted for the beneficial effects observed.

The patients enrolled in the current study had multiple coexisting medical conditions, including diabetes, chronic respiratory disease, prior stroke and gout, their renal function was impaired and they were taking a median of six medications. As such, this group are representative of those patients commonly admitted to medical wards with exacerbations of heart failure. Readmission rates were high, although notably only a third of readmissions in these patients were attributed primarily to heart failure. The greatest effect of the intervention was to almost halve the readmissions for worsening heart failure. The high rate of readmissions associated with other conditions highlights the need for attention to co-morbidities as well as management of heart failure. In the model in the current study a cardiologist, nurse practitioner and general practitioner were combined although greater benefits may be gained by the involvement of general physicians and/or geriatricians.

This study has important differences in design compared with the other intervention trials in heart failure management. In a study by Weinberger *et al.*^[14], 1396 US Veterans with diabetes, congestive heart failure (n=504) or chronic obstructive pulmonary disease were randomly assigned to either an intensive primary care intervention or usual care. Patients were identified at the time of hospital admission although one of these three medical conditions did not have to be the primary reason for the admission. The intervention involved close follow-up by a nurse and a primary care physician beginning before discharge and continuing for 6 months. The patients in the intervention group had significantly higher rates of readmission than the controls (0.19 vs 0.14 per month, $P=0.005$). In addition, more patients in the intervention group had multiple readmissions than controls. One potential reason for the increase in admissions may have been that the increased care may have led to the detection of previously unrecognised medical conditions that required admission for treatment. In addition, a disease-specific protocol and integration

of primary with specialist care, as in the current study, may be important requirements for the success of such management programmes.

Cline *et al.*^[15] studied the effects of a nurse-led hospital-based clinic for the management of heart failure. The effects of this intervention were modest with an increase in the time to first readmission but only a trend to fewer hospital admissions in the intervention group. The design of this study is different to the Auckland study, as it did not involve a structured approach to integration between the patient and primary and secondary care. Several studies have now demonstrated that home-based multidisciplinary interventions can reduce readmissions in patients with heart failure^[4-6]. These trials have, in general, targeted certain subgroups of patients with heart failure and have demonstrated larger effects of these interventions in these selected patient subgroups. Provision of the management programmes outside of the hospital setting, including home-visiting, does appear to have a greater potential for benefit.

Implications for clinical practice

Hospital admissions for heart failure have consistently increased over the last 10–20 years and the cost of these admissions alone account for 1–1.5% of total health budgets in most developed countries^[3,16]. There is thus an urgent need for strategies to reduce these admissions. Several randomized, controlled trials have now assessed different approaches in the management of patients with heart failure^[4,5,14,17-19]. The current study supports the role of integrated management involving the patient/family and primary and secondary care, although the overall effects are more modest than seen with the home-based interventions. Further benefits may be achieved with earlier intervention in hospital prior to discharge, use of agents proven to reduce admissions such as beta-blocker therapy^[11,12], and further attention to the co-morbidities commonly found in these patients. It is important to remember that every patient has different and distinct educational and medical needs and thus flexible and practical approaches should be employed that allow tailoring to individual needs.

The combined dataset from these trials is still relatively small, and at present it is uncertain which components of the interventions actually produces the beneficial results observed. While the intervention trials have utilized different designs, the heart failure nurse practitioner is common to all the trials and appears to have a key role in heart failure management. Further studies are obviously required to develop these management strategies further. It should be noted that such management programmes have only been applied in patients who have been admitted to hospital. Consequently, there is no evidence of benefit in reducing the first admission for patients with newly diagnosed heart failure. In addition, the programmes have generally only followed patients for a relatively short period and the longer-term effects remain uncertain. Further

development of these evidence-based management programmes has the potential to improve the quality of life for patients with heart failure and to reduce the public health burden of this disease.

The study was funded by a project grant from the National Heart of New Zealand and an unrestricted educational grant from Merck Sharp Dohme (NZ) Ltd. RND was the recipient of the New Zealand Heart Foundation BNZ Senior Fellowship. The Patient Diary and Patient Education Booklet have now been produced by the New Zealand Heart Foundation, copies are available from the corresponding author on request.

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Appendix

We wish to thank the following Auckland general practitioners who participated in this study: Doctors Abeysekera, Addis, Antunovich, Atlas, Bailey, Baker (Ron), Baker (Robyn), Barrett, Batt, Beatham, Beer, Beltowski, Bond, Botica, Bowden, Boyd, Broom, Budelman, Cairney, Caldwell, Cameron, Carns, Chaffey, Chan, Cheung, Collinson, Connell, Cook, Cotton, Cotton-Barker, De Lacey, Dhana, Dublessis, Farquharson, Ford, Fowler, Fox (Jonathan), Fox (Judith), Frye, Gabriel, Gardyne, Gibson, Grieve, Gulbransen, Haydon, Heath, Hefford, Hewitt, Hill, Hillman, Hoadley, Hodder, Hopcroft, Horne, Hough-Lee, Hulley, Hurly, Isted, Jansen, Jennings, Johnson, Kara, Karetai, Kidd, King, Lam, Large, Lawson, Leggatt, Lello, Levenberg, Liang, Long, Lusk, MacGibbon, MacLachlan, Madgwick, Marshall, Martley, McAllister, Mok, Ng, Nola, O'Sullivan, Parbhu, Parr, Patel, Paul, Peak, Pettit, Pohl, Raj, Ramirez, Rasalingham, Robertson, Rushmer, Russell, Ryan, Sanders, Selvakuma, Settle, Short, Skinner, So, Solomon, Soysa, Strange, Stubbs, Sullivan, Svensen, Tagg, Thomas, Tseung, Twigg, Tye, van Roekel, Vather, Vickers, Wah, Wardrope, Washer, Waterfall, Watson, Way, Weeramuni, Wernham, Wiles, Williams (A), Williams (J), Wong, Woolford, Zink.