

Randomized Controlled Clinical Trial of a Home Care Unit Intervention to Reduce Readmission and Death Rates in Patients Discharged From Hospital Following Admission for Heart Failure

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Introduction and objectives. To determine the effectiveness of a primarily educational intervention in heart failure (HF) patients implemented in a home care unit.

Methods. This randomized controlled clinical trial involved 279 HF patients who were discharged from a tertiary-care hospital between February 2001 and June 2002. Patients with dementia, terminal non-cardiac disease, or chronic obstructive pulmonary disease were excluded. Data collected included the cause of cardiac decompensation. A primarily educational intervention was implemented in the patient's home for up to 15 days after hospital discharge. Treatment was adjusted during the first week if necessary. The primary outcome measure was the 1-year cumulative incidence of readmission or death. Secondary measures were the incidence of readmission, mortality, and emergency department admission. Telephone interviews were carried out 3, 6, and 12 months after discharge, and clinical records were updated when necessary. Emergency department admission in the first 6 months was monitored.

Results. At 1-year follow-up, 62 of the 137 patients (45.3%) in the intervention group had been readmitted or died, compared with 75 of the 142 (52.8%) in the control group, (relative risk=0.86, $P=.232$). Among patients who suffered decompensation because failure to adhere to treatment, 16 of the 45 (35.6%) in the intervention group

were readmitted or died, compared with 34 of the 56 (60.7%) control group patients (relative risk=0.59, $P=.016$).

Conclusions. This intervention is feasible but, when applied indiscriminately to every discharged heart failure patient, the best that can be expected is only a modest reduction in readmission and death rates, which, in this study in particular, did not achieve statistical significance.

Key words: Heart failure. Randomized clinical trial. Managed care programs. Patient adherence.

Ensayo clínico aleatorizado y controlado para valorar una intervención por una unidad de hospitalización domiciliaria en la reducción de reingresos y muerte en pacientes dados de alta del hospital tras un ingreso por insuficiencia cardiaca

Introducción y objetivos. Evaluar la eficacia de una intervención de educación en pacientes con insuficiencia cardiaca (IC) realizada por hospitalización a domicilio.

Métodos. Ensayo clínico aleatorizado y controlado. Se incluyó a 279 pacientes con diagnóstico clínico de IC dados de alta de un hospital terciario entre febrero de 2001 y junio de 2002. Se excluyó a los pacientes con demencias, enfermedad terminal no cardiológica o enfermedad pulmonar obstructiva crónica. La información recogida incluyó las causas de la descompensación. La intervención fue fundamentalmente de tipo educativo, en el domicilio del participante, y se extendió hasta 15 días después del alta. Se realizaron ajustes de tratamiento durante la primera semana cuando fue necesario. El objetivo principal fue determinar la incidencia acumulada de reingreso o muerte. Los objetivos secundarios fueron la incidencia de reingreso y la mortalidad, así como la utilización de los servicios de urgencia. Se llevó a cabo un seguimiento telefónico a los 3, 6 y 12 meses, y una revisión de las historias clínicas si era necesario. Asimismo, se valoró la utili-

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zación de servicios de urgencias los primeros 6 meses.

Resultados. Al año, 62 pacientes de 137 (45,3%) ingresaron o murieron en el grupo de intervención, en comparación con 75 de 142 (52,8%) en el grupo control ($p = 0,232$; riesgo relativo [RR] = 0,86). En los pacientes que se descompensaron por incumplimiento terapéutico, 16 de 45 (35,6%) ingresaron o murieron en el grupo de intervención, en comparación con 34 de 56 (60,7%) en el grupo control ($p = 0,016$; RR = 0,59).

Conclusiones. Esta intervención es factible pero, administrada de manera indiscriminada a todo paciente dado de alta por IC, en el mejor de los casos sólo podemos esperar un beneficio modesto, que en este estudio en particular no llegó a alcanzar significación estadística.

Palabras clave: *Insuficiencia cardíaca. Ensayo clínico aleatorizado. Programas de cuidados gestionados. Adhesión del paciente.*

ABBREVIATIONS

ACEI : angiotensin-converting enzyme inhibitors
ARA II : angiotensin II receptor antagonists
HF : heart failure

INTRODUCTION

Heart failure (HF) is a major public health problem. Relatively uncommon before age 45 years, its incidence approximately doubles for every decade of life thereafter.¹ The overall aging of the population, and the lengthened survival of patients with ischaemic heart disease and arterial hypertension, have both increased its prevalence,² and it is now the most frequent cause of hospitalization among patients older than 65 years.^{1,3} The death rate among HF patients is high (60% die within 5 years of diagnosis), and attention to these patients accounts for 1%-2% of the total health care budget in industrialized countries. Most of this expense is incurred by re-hospitalization events, 29%-47% of HF patients being readmitted to hospital between 3 and 6 months after release following admission due to HF.³ In Spain, half the patients hospitalized on account of HF have previously been admitted for the same reason at least once.⁴

The causes of readmission for HF are various,^{5,6} the most important being failure to adhere to the prescribed therapeutic regimen, prescription of an inappropriate regimen, lack of social support, and inadequate post-release follow-up.⁷ Many crises requiring readmission, could be avoided. In particular, numerous studies have shown that appropriate multidisciplinary programmes,

mainly with a patient education content, can significantly reduce the number, duration and cost of readmissions and even the death rate among HF patients.⁸⁻²² A recent meta-analysis has identified 27 randomized and 27 non randomized studies that evaluated the efficacy of different disease management programs in elderly patients with heart failure.²³ In summary, based in 10 randomized studies, the interventions reduced the combined event of readmission or death by 18%. These interventions were designed and adapted to local possibilities and resources, with a wide variety of contents and professionals involved. The question thus arises of how local resources may best be used: the provision of multidisciplinary care in the patient's home is beyond the means of many centres, while limiting readmission reduction efforts to in-clinic action or purely educational measures may prove ineffective.

Here we report the results of an evaluation, in terms of 1 year-reduction of readmission rate and deaths, of a short-term, largely educational programme carried out in patients' homes using an existing home care unit, a kind of unit that forms part of many Spanish hospitals.

METHODS

Study Design

This was a randomized controlled clinical trial carried out among patients of a tertiary care hospital following approval by the clinical research ethical committee of the regional health authority.

Patients

The candidates for inclusion in the study were patients released between February 2001 and June 2002 from the internal medicine, cardiology, and short-stay services of our centre following heart failure. Candidates were invited to participate if they lived in the area covered by the collaborating home care unit, had sufficient family support, and had neither severe cognitive deficits, advanced psychiatric disease, non-cardiological terminal disease, nor chronic obstructive pulmonary disease. All basal information was obtained prior to the discharge of the patient, prior to group assignment, including most likely cause of decompensation according to the attending physician. Patients in whom the latter was bad compliance with treatment recommendations were classified as non adherents.

Randomization and Sample Size

Upon release from hospital, patients participating in the study gave written informed consent and were randomly assigned to the control group or the group administered the programme being evaluated (the

intervention group) by means of closed envelopes prepared at the Instituto de Ciencias de la Salud. The randomization process was stratified with respect to the services involved (internal medicine, cardiology, and short-stay). The sequence was concealed until interventions were assigned. Assuming no losses to follow-up and a 1 year event rate of 40% in the control group, the sample size of 279 allows for detection of a reduction in relative risk of 40% by a 2-tailed test, keeping $\alpha=0.05$ and $\beta=0.2$ (power=80%). The actual study group, completed between February 2001 and June 2002, comprised 137 patients assigned to the programme group and 142 controls. Only 2 of the 281 patients invited to take part in the study declined to do so. None of the staff members attending these patients during the next 12 months, other than those belonging to the home care unit, were aware of whether patients belonged to the intervention or control group.

Intervention

Between release from hospital and stabilization (up to 15 days later), patients assigned to the programme group were attended in their homes by physicians and nurses belonging to the home care unit. This is not solely for HF patients. These units are intended to reduce hospitalization in a great variety of medical and surgical conditions. This attention included clinical examination, additional tests, and analyses when needed, and adjustment of the therapeutic regimen in the light of the patient's progress. In addition, nursing staff visited each patient 2, 5, and 10 days after release to administer the educational programme being evaluated, teaching patient and relatives basic facts about HF and its management (symptoms, lifestyle, diet, therapy). Each patient was also given a printed manual with the same information, and a telephone number that could be called for resolution of queries. Every nurse visit had an approximate duration of 1 hour. Although the possibility existed, no special emphasis was done to the patients in the use of the phone facility, which was rarely used beyond those 15 days after randomization. Special emphasis was placed on adherence to the therapeutic regimen, control of weight and blood pressure, ingestion of liquids, and how to recognize, and respond appropriately to signs of decompensation. Adjustment of treatments were done, when needed, during the first week by a physician. The strongest part of the intervention was the one carried out by the nurse.

Follow-Up Period

After the intervention, patients assigned to this group were referred to their primary care physician for further attention, as were control group patients upon release from hospital. All patients were followed up for 12 months post release or until death if this occurred within that period. Follow-up was done by means of telephone

interviews carried out 3, 6, and 12 months after release, supplemented by review of the clinical records of the patients participating in the study.

Measures of Effect and Statistical Analysis

The primary variable employed to evaluate the efficacy of the programme was the combined cumulative incidence of readmission or death 6 and 12 months following release from hospital. Secondary variables evaluated were the separate cumulative readmission and death rates, duration of readmission, and the use of emergency services during the first 6 months. Planned admissions were not considered events. Programme and control group patients were compared with regard to the primary variable not only in the whole study group, but also in groups defined with respect to age (younger or older than 75 years), sex, ejection fraction (less or greater than 40%), aetiology (ischaemic or other), and causes of the decompensation leading to the original admission (non adherence to treatment regimen vs any other). All these variables were clearly defined in the protocol. No subgroup analysis was defined in the original proposal. The statistical significance of differences between groups was estimated using χ^2 and Student *t* tests for discrete and continuous variables, respectively, or the log rank test for comparison of Kaplan-Meier survival curves. All analysis were done by intention to treat.

RESULTS

Of the 279 patients taking part in the study, 207 (74.2%) were recruited in the internal medicine service, 70 (25.1%) in the short-stay service, and 2 (0.7%) in the cardiology service. Of the 137 assigned to the programme group, 127 (92.7%) were considered to be collaborative by the home care unit personnel who administered the programme. There were no dropouts from the study.

At entry into the study, the programme and control groups did not differ significantly with regard to any of the variables considered to be of interest (Table 1). In the whole 279-member study group, mean age was 75.8 years, hypertensive cardiopathy was the most frequent aetiology (43%), non adherence to therapeutic regimen was the most frequent cause of decompensation leading to admission (36.2%), and mean ejection fraction was 49.6%. Most patients (84%) were prescribed angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers upon release from hospital; only 12% were prescribed beta-blockers.

During the 12-month follow-up period, the programme and control groups behaved very similarly as regards the cumulative incidence of readmission and death (Table 2). Although the combined readmission and death rate was higher in the control group than in the programme group, as were the separate readmission and death rates (except for the 1-year death rate), in no

TABLE 1. Characteristics of the Programme and Control Groups Upon Randomization (Values Are Percentages, Unless Otherwise Stated)*

	Programme (n=137)	Control (n=142)
Age, mean (SD), year	75.3 (11.1)	76.3 (9.4)
Women	61.3	59.9
Living alone	14.6	12.0
Primary schooling or less	86.8	90.9
First admission due to HF	54.0	53.5
Background		
Arterial hypertension	66.4	69.0
Arrhythmia	46.7	46.5
Diabetes	35.8	35.2
Prior acute myocardial infarct	19.7	17.6
Kidney failure	25.5	22.5
Aetiology		
Hypertensive	43.1	43.0
Ischaemic	29.2	31.7
Immediate cause of admission†		
Non-adherence to therapy	32.8	39.4
Arrhythmia	32.1	36.6
Infections	29.2	33.8
Others/unknown	13.9	7.7
Atrial fibrillation	53.3	52.1
Ejection fraction, mean (SD), %	50.9 (16.6) (n=130)	48.3 (17.6) (n=124)
Treatment on release		
ACEI/AIIRA	85.4	82.4
Beta-blockers	13.1	10.6
Anticoagulants	39.4	37.3

*ARA II indicates angiotensin II receptor antagonists; HF, heart failure; ACEI, angiotensin-converting enzyme inhibitors.

†More than one possible (so percentages do not sum to 100).

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case was the difference statistically significant (Table 2 and Figure 1).

Not only the number but also the characteristics of the readmissions were similar between groups. In the

programme group, 59 patients experienced unplanned readmission on a total of 125 occasions (against 71 patients involved in 118 readmission events in the control group), and 39 experienced 59 admissions to a casualty department (against 42 patients and 57 admissions in the control group); for every 100 programme group patients followed up for 1 year there were 91 unplanned readmissions, 43 admissions to a casualty department in the first 6 months, and 16 deaths (against 83 unplanned readmissions, 40 admissions to a casualty department, and 15 deaths in the control group). None of the differences between the programme and control groups in regard to the above characteristics are statistically significant (Table 3).

In the subgroup analysis, there was not any statistically significant difference between programme and control group patients in the subgroups defined by age, sex, aetiology, or ejection fraction, or among patients whose original admission did not include non adherence to their therapeutic regimen among its causes (Table 4). But among patients whose original admission was mainly attributed to non adherence, the combined readmission and death rate was significantly greater among control patients than among programme group patients (Table 4 and Figure 2a); in this group of non adherents, administration of the education programme was associated with an absolute reduction of 25.1% in the risk of readmission or death within 12 months of release, amounting to a reduction in relative risk of 41.4% ($P=.016$). In fact, comparison of Figures 2a and 2b clearly shows that the slight, non-significant difference in readmission-free survival between the whole programme group and the whole control group (Figure 1) was due entirely to the influence of the programme on non adherents.

DISCUSSION

This clinical trial shows that the short, basically educational programme tested has, at best, a very modest

TABLE 2. Cumulative Incidence of Outcomes 6 and 12 Months After Release from Hospital Following Heart Failure

Event	Length of Follow-Up	Group		Relative Risk†	95% Confidence Interval	P
		Programme (n=137)	Control (n=142)			
Readmission* or death	6 months	32.1	38.0	0.85	0.61-1.16	.318
	1 year	45.3	52.8	0.86	0.67-1.09	.232
Readmission*	6 months	30.7	35.9	0.85	0.61-1.19	.376
	1 year	43.1	50.0	0.86	0.67-1.11	.280
Death	6 months	5.8	9.9	0.59	0.26-1.37	.268
	1 year	16.1	14.8	1.08	0.63-1.88	.769

*Excluding programmed admissions.

†Incidence programme/incidence control.

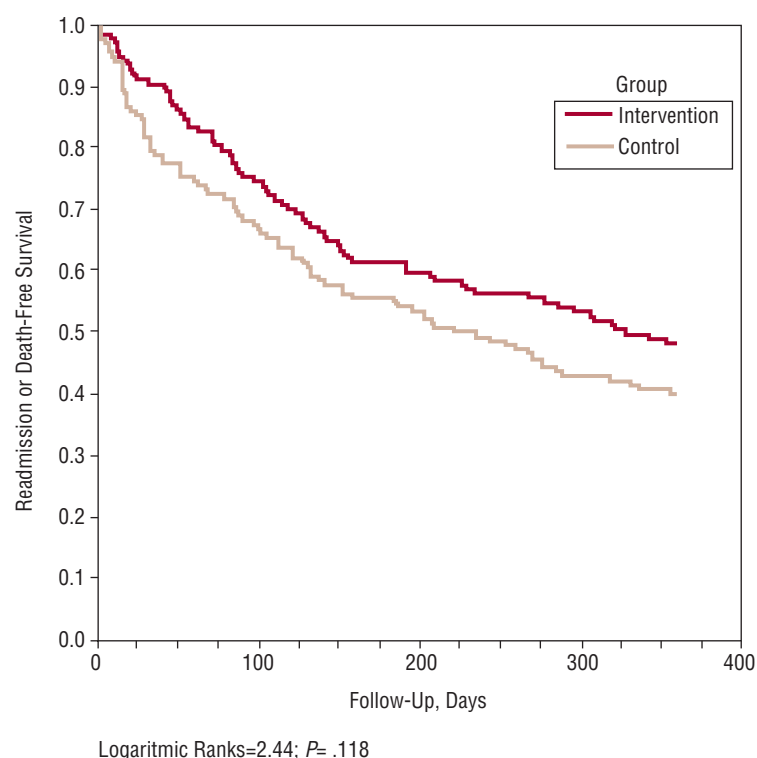


Figure 1. Readmission or death-free survival in the programme and control groups.

TABLE 3. Outcomes During 12 Months' Follow-Up of Patients Released Following Heart Failure*

	Group	
	Programme	Control
Number of readmissions	146	137
Programmed	21	19
Unprogrammed	125	118
Heart failure	55	57
Some other cardiovascular cause	25	21
Non-cardiovascular cause	45	40
Duration, mean (SD), days	8.4 (7.7)	9.6 (13.0)
Programmed	7.3 (10.3)	6.5 (14.0)
Unprogrammed	8.6 (7.2)	10.1 (12.9)
Heart failure	8.5 (6.4)	8.4 (11.6)
Some other cardiovascular cause	6.1 (4.6)	10.9 (10.7)
Non-cardiovascular cause	10.0 (8.6)	12.0 (15.4)
Number of admissions to emergency departments†	59	57
Heart failure	7	10
Some other cardiovascular cause	5	5
Other causes	27	35
Not well defined	18	6
Deaths	22	21
Cardiovascular cause	16	18
Non-cardiovascular cause	6	3

*The values express the number or mean (SD).

†During the first 6 months of follow-up.

effect in the reduction of readmissions if administered to all HF patients discharged from hospital. The size of the effect in the whole group, non-significant in this study, is very similar to that reported in a recent meta-analysis.²³ Nevertheless, the subgroup of patients that are admitted due to failure to adhere to their therapeutic regimen may greatly benefit from such an intervention.

HF is a chronic syndrome with high morbidity and mortality rates that do not appear unequivocally to have been lowered to any substantial degree by the therapeutic advances of recent decades. Appropriate self-care can reduce the risk of crises requiring readmission, but the acquisition and habitual application of self-care skills by HF patients is hampered by their usually being of advanced age. To increase the proportion of HF patients with the desired understanding of proper self-care practices and awareness of their importance, numerous research groups have designed programmes that have varied in intensity from a simple telephone call from a nurse to intensive follow-up by a multidisciplinary team. In general, programmes based on periodic contacts have performed better than one-off interventions; programmes combining clinical and educational attention have performed better than those affording only education; and programmes carried to the patient's home have performed better than those requiring attendance at a clinic.⁸⁻²² Two recent

TABLE 4. Twelve-Months Cumulative Incidence† of Readmission‡ or Death in Subgroups of the Programme and Control Groups*

	Programme	Group Control	Relative Risk, %§	95% CI	P
Age					
<75 years	40.6 (26/64)	45.3 (24/53)	0.90	0.59-1.36	.708
≥75 years	49.3 (36/73)	57.3 (51/89)	0.86	0.64-1.15	.344
Sex					
Men	49.1 (26/53)	50.9 (29/57)	0.96	0.66-1.40	1.000
Women	42.9 (36/84)	54.1 (46/85)	0.79	0.58-1.09	.167
Aetiology					
Ischaemic	57.5 (23/40)	56.5 (26/46)	1.02	0.70-1.47	1.000
Other	40.2 (39/97)	51.0 (49/96)	0.79	0.58-1.08	.149
Ejection fraction					
≤40%	62.2 (23/37)	76.2 (32/42)	0.82	0.60-1.10	.223
>40%	41.9 (39/93)	52.4 (43/82)	0.80	0.58-1.10	.175
Immediate causes include non-adherence to therapy					
Yes	35.6 (16/45)	60.7 (34/56)	0.59	0.37-0.91	.016
No	50.0 (46/92)	47.7 (41/86)	1.05	0.78-1.42	.766

*CI indicates confidence interval.

†Expressed as percentages and, in parenthesis, the ratio of the number of patients affected to the number in the group.

‡Excluding programmed admissions.

§Incidence programme/incidence control.

systematic reviews offer differing views on the role of the type of intervention. While one of them suggests that this is important,²⁴ in the other, the results “were observed regardless of the type of healthcare delivery within disease managed programmes.”²³ Since these publications, at least 2 other large randomized studies have been published. One of them shows no effect in all-cause rehospitalization,²⁵ while in the other, that included more than 1000 patients, a benefit in mortality was observed (although relative risk reductions are not provided) without reduction in costs.²⁶ The accompanying editorial of the latter²⁷ makes emphasis again on the importance of the type of intervention. Our study suggests that those who may benefit most from an educative intervention are those who do not consistently adhere to suggested health care recommendations. Different interventions could benefit most to other type of patients, stressing the need for careful patient selection for these programs. The interest of our study was to evaluate a programme designed to exist within the capabilities of our centre’s home care unit. Hence, the intervention is easily transferrable to the many other Spanish hospitals in which this kind of unit has been introduced in order to allow the release of patients who require hospital-level medical supervision but do not require intensive nursing or immediate access to other hospital facilities. Though quite short and not including periodic contacts with targeted patients, the programme tested was based on attention in the patient’s home and combined clinical and educational care, with the accent on the latter. By the very nature of the intervention being tested, neither the patients taking part in this study nor

the home care unit personnel were blind to their treatment, but the staff attending them in other services were unaware of whether patients belonged to the programme or control group. Events assignment was, therefore, blinded. There were no drop-outs, and the characteristics of the programme and control groups appear to reflect efficient randomization.

Unlike some other studies,^{3,9,10} ours was not restricted only to patients with a high risk of readmission (patients with ischaemic aetiology, systolic dysfunction, a history of multiple admissions for HF in the past year, etc). On the contrary, the study group constituted a fairly representative sample of patients released from hospital following HF, its main limitation in this respect being the exclusion of patients with chronic obstructive pulmonary disease. A high proportion of patients were treated with ACE inhibitors at discharge, leaving little room for improvement. However, beta-blockers were not introduced in many patients due to the duration of the intervention. Most of the effect has, therefore, to be attributed to the educational components of the intervention.

In general, we think that our intervention took place during a short time period in which physicians and nurses concentrated on optimizing treatment and health education issues. The long term telephone consultation service was hardly resorted to by the members of the programme group, perhaps because of this possibility having been emphasized by the home unit personnel less than in some other studies of programmes with similar telephone services.^{8-11,19,20} Regarding intervention design, the most

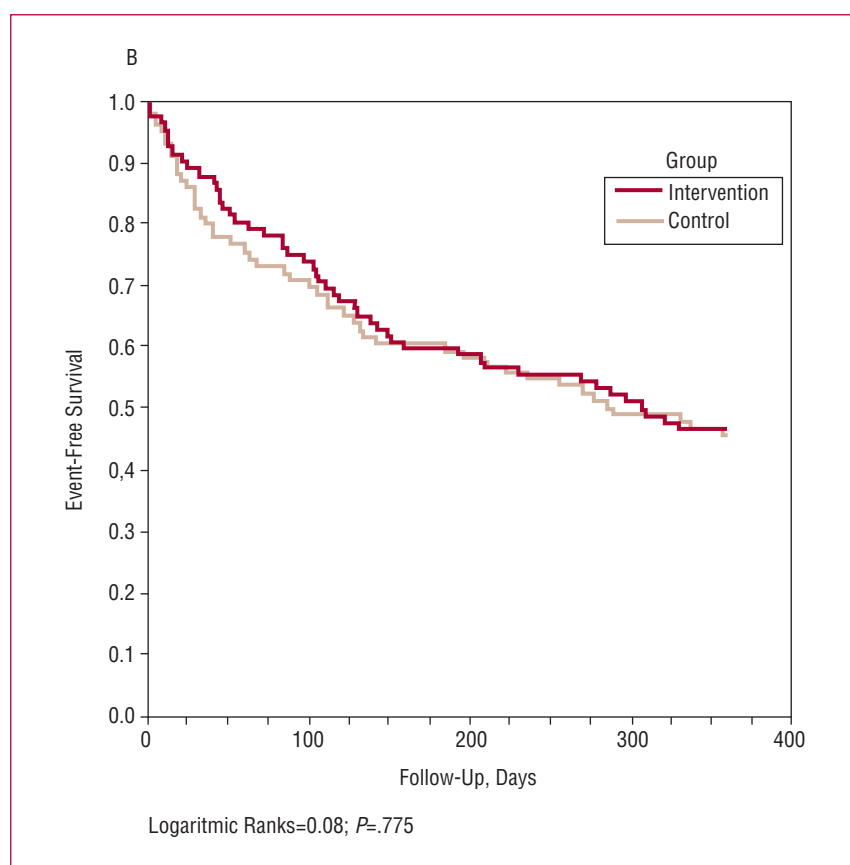
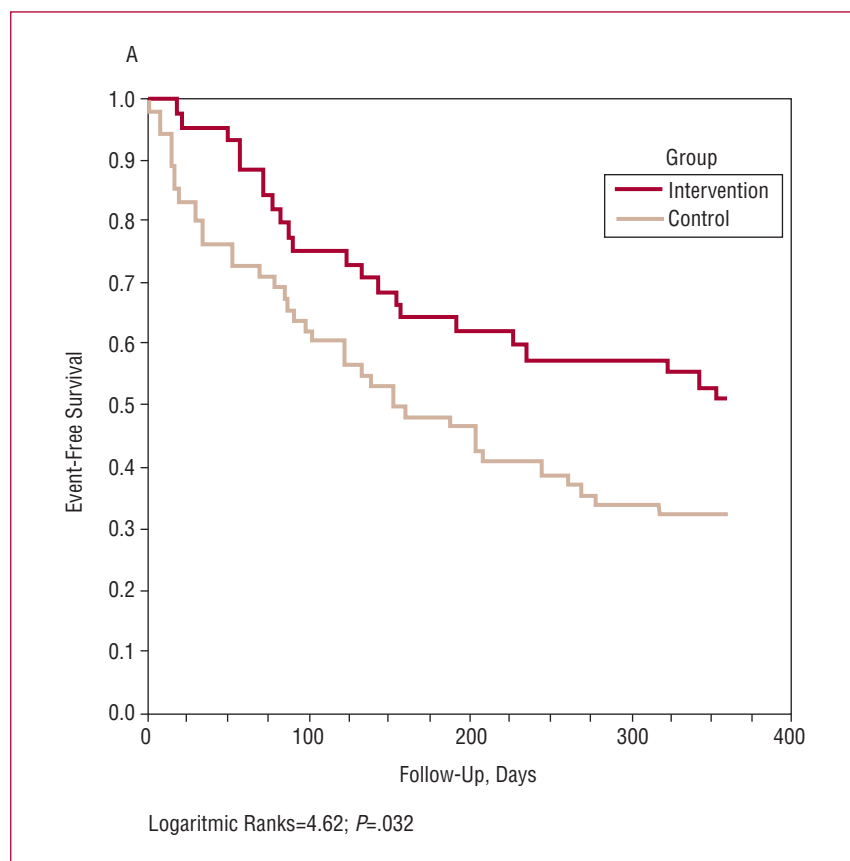


Figure 2. Event-free survival in the subgroups of the programme and control groups consisting of A patients whose original admission was due in part to failure to adhere to their therapeutic regimen, and B the others.

successful programmes combine periodic clinical attention in the patient's home (evaluation of clinical condition and adjustment of treatment) with selfcare education²²; programmes that only provide education are less expensive but also much less effective,^{11,13} and programmes requiring the patient's attendance at a clinic also perform relatively poorly.¹⁷

A recently published Spanish trial²⁸ reports reductions of 90% in readmissions, 84.2 in attendance to the emergency wards, and 82.4% in deaths. These enormous differences with our results (with reductions in the range of 15%) are not due to the type of intervention because it was similar to ours but shorter in duration (only one 2-hour visit without any reinforcement). One possible explanation are differences in the type of patient. In the referred study, patients are more educated (82% attained medium-high study level compared with 88% with only primary studies in our study) and with a worse prognosis (lower ejection fraction and more ischaemic heart disease) reflected in the high mortality in the control group (11/36 or 30.5% in 6 months) than in ours, which may have caused the intervention to be more efficacious. Disbalances between groups in a very small study like this (70 patients compared to 279 in ours) may also play a role in the explanation of the differences.

Limitations

Among the limitations of this study is that it refers to a short intervention and that later adjustments in the treatment were not measured. Nor was any intermediate effect of the intervention (ie, improvements in compliance among non-adherents).

Finally, the information coming from the subgroup analyses has to be interpreted with caution because it was obtained by means of post-hoc analyses.

In conclusion, the existing resources of our home care unit proved sufficient for administration of a basically educational programme during a short period of time to patients discharged after a hospital admission due to heart failure. The intervention did not reduce the incidence of readmission or death among such patients (only a 14.3% relative risk reduction, non statistically significant was observed). A post-hoc analysis suggests that all the benefit may concentrate among heart failure patients whose hospitalization was due in part to failure to adhere to their therapeutic regimen. The efficient application of such a resource in the future would require that hospitalized HF patients be questioned specifically in such a way as to identify nonadherents. Similarly, its generalization to all HF patients with a view to preventing first admissions for HF would require the identification of factors predictive of nonadherence. Since the kind of unit that administered the programme is common in Spanish hospitals, the programme should be easily transferrable to these other centres.

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