

Clinical service organisation for heart failure (Review)

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Clinical service organisation for heart failure

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ABSTRACT

Background

Chronic heart failure (CHF) is a serious, common condition associated with frequent hospitalisation. Several different disease management interventions (clinical service organisation interventions) for patients with CHF have been proposed.

Objectives

To update the previously published review which assessed the effectiveness of disease management interventions for patients with CHF.

Search methods

A number of databases were searched for the updated review: CENTRAL, (the Cochrane Central Register of Controlled Trials) and DARE, on *The Cochrane Library*, (Issue 1 2009); MEDLINE (1950-January 2009); EMBASE (1980-January 2009); CINAHL (1982-January 2009); AMED (1985-January 2009). For the original review (but not the update) we had also searched: Science Citation Index Expanded (1981-2001); SIGLE (1980-2003); National Research Register (2003) and NHS Economic Evaluations Database (2001). We also searched reference lists of included studies for both the original and updated reviews.

Selection criteria

Randomised controlled trials (RCTs) with at least six months follow up, comparing disease management interventions specifically directed at patients with CHF to usual care.

Data collection and analysis

At least two reviewers independently extracted data and assessed study quality. Study authors were contacted for further information where necessary. Data were analysed and presented as odds ratios (OR) with 95% confidence intervals (CI).

Main results

Twenty five trials (5,942 people) were included. Interventions were classified by: (1) case management interventions (intense monitoring of patients following discharge often involving telephone follow up and home visits); (2) clinic interventions (follow up in a CHF clinic) and (3) multidisciplinary interventions (holistic approach bridging the gap between hospital admission and discharge home delivered by a team). The components, intensity and duration of the interventions varied, as did the 'usual care' comparator provided in different trials.

Case management interventions were associated with reduction in all cause mortality at 12 months follow up, OR 0.66 (95% CI 0.47 to 0.91, but not at six months. No reductions were seen for deaths from CHF or cardiovascular causes. However, case management type interventions reduced CHF related readmissions at six month (OR 0.64, 95% CI 0.46 to 0.88, $P = 0.007$) and 12 month follow up (OR 0.47, 95% CI 0.30 to 0.76). Impact of these interventions on all cause hospital admissions was not apparent at six months but was at 12 months (OR 0.75, 95% CI 0.57 to 0.99, $I^2 = 58\%$).

CHF clinic interventions (for six and 12 month follow up) revealed non-significant reductions in all cause mortality, CHF related admissions and all cause readmissions.

Mortality was not reduced in the two studies that looked at multidisciplinary interventions. However, both all cause and CHF related readmissions were reduced (OR 0.46, 95% CI 0.46-0.69, and 0.45, 95% CI 0.28-0.72, respectively).

Authors' conclusions

Amongst CHF patients who have previously been admitted to hospital for this condition there is now good evidence that case management type interventions led by a heart failure specialist nurse reduces CHF related readmissions after 12 months follow up, all cause readmissions and all cause mortality. It is not possible to say what the optimal components of these case management type interventions are, however telephone follow up by the nurse specialist was a common component.

Multidisciplinary interventions may be effective in reducing both CHF and all cause readmissions. There is currently limited evidence to support interventions whose major component is follow up in a CHF clinic.

PLAIN LANGUAGE SUMMARY

Clinical service organisation following hospital discharge for adults with chronic heart failure

Chronic heart failure (CHF) is a serious condition, mainly affecting elderly patients. It is becoming increasingly common as the population ages, and carries high risks of emergency hospitalisation and death. This is an update of an earlier review, including clinical trials published since the previous version.

We examined 25 clinical trials with nearly 6000 patients that tested different methods of organising the care of CHF patients after leaving hospital. Although the quality of reporting was unclear in about a third of the trials, most appeared to be of high quality so confidence can be placed in their results. We classified these into three models: 1) case-management interventions, where patients were intensively monitored by telephone calls and home visits, usually by a specialist nurse; 2) clinic interventions involving follow up in a specialist CHF clinic; 3) multidisciplinary interventions (a holistic approach bridging the gap between hospital admission and discharge home delivered by a team). Where possible, we combined studies to find the overall effect on a larger group of patients.

Seventeen studies reported a case-management intervention. Patients who received this had less all cause mortality a year after discharge than patients who received usual care. There was no real difference between groups in deaths related to heart failure (HF), although few studies reported this. Case management patients were less likely to be readmitted to hospital for HF six months after discharge. They were also less likely to be readmitted for HF a year after discharge, although the studies reporting this were not similar enough to draw strong conclusions from the combined data. A year after discharge, case management patients were less likely to be readmitted to hospital for any reason than people who received usual care. Telephone follow-up by a specialist nurse was a common feature of more successful programs.

Six studies looked at heart failure clinics, and there was no real difference in all cause mortality, readmissions for HF or between patients who attended a clinic and those who received usual care. Only two studies looked at multidisciplinary interventions. There were slightly fewer deaths from any cause in the treatment group than in the usual care group, and both all cause and heart failure related readmissions were substantially lower for patients receiving multidisciplinary care.

No studies reported any adverse events associated with the interventions.

BACKGROUND

Chronic heart failure (CHF) is a serious and increasingly common condition (Cleland 1999; Cowie 1997; Eriksson 1995) with a crude prevalence of three to 20 per 1000 in the general population (Cowie 1999). Both the incidence and prevalence of CHF increases with age, from around one percent in those aged 50-59 years to 10 percent in those aged 80-89 years (Kannel 1991). Most patients with heart failure (HF) are elderly. In Scotland the mean age at first hospital admission for CHF in the 1990s was 74 years (Cleland 1999) and in the United States of America (USA) half of all patients over 65 years admitted with CHF are over 80 years old (Havranek 2002). With an aging population, mean age of those admitted with HF is likely to be increasing. The condition carries a substantial risk of death - in community studies between a quarter and a third of patients were dead one year after the onset of heart failure (Cowie 2000; Levy 2002), and around two thirds of men and half of women were dead after five years (Levy 2002). In a study of Scottish data the median survival time after a first hospital admission with CHF was sixteen months and the five year survival rate was 25% - worse than that for all common malignancies except lung and ovarian cancer (Stewart 2001b). A Canadian population based study of survival after a first hospital admission for heart failure reported a case fatality rate of 31% at one year follow up (Jong 2002). In addition to the risk of death the condition has a profound impact on patients' quality of life (Stewart 1989).

Hospital admissions for heart failure have steadily increased and heart failure is now one of the most common reasons for admission in older people (AHA 2004; Cleland 1999; McMurray 1993). In 2000 around 1.9% of the total budget of the National Health Service (£905 million) was spent on patients with heart failure and most of this cost was incurred by hospital admissions (Stewart 2002a). A community study from England found 55% of patients in primary care being treated with loop diuretics and with a clinical diagnosis CHF had an acute admission to hospital with heart failure (Clarke 1994). Early hospital readmission in patients with heart failure is extremely common. In Connecticut, USA, between 1991 and 1994, 44 % of all patients admitted for congestive heart failure were re-admitted (all causes) within six months (Krumholz 1997). In the EuroHeart Failure survey, which included 24 countries, 24% of patients admitted with confirmed or suspected heart failure were readmitted to hospital within 12 weeks - HF was the

principal cause of readmission (20% of readmissions) and contributed to a further 16% of readmissions (Cleland 2003). Studies suggest that many early readmissions for HF are preventable (Feenstra 1998; Michalsen 1998; Vinson 1990).

Drug therapy is the mainstay of treatment for CHF, although invasive procedures and devices are indicated for some patients, and patients are usually managed with a combination of medications and lifestyle advice (NICE 2010). The management of patients with HF has evolved from a traditional model with its emphasis on crisis intervention towards much more proactive, preventative disease management models. These care models, described in more detail below and in the [Methods](#) section, offer "aggressive care" in hospital, home or clinic (Riegel 2001). In addition to different settings such "clinical service interventions" may differ in their components, duration, intensity and the number and type of health care professionals involved.

This review is an update of our original review (Taylor 2005), which attempted to identify which clinical service organisation models were most effective in terms of reducing hospital admissions and deaths in patients at high risk of unscheduled hospital readmission for HF. In the original review we identified 16 relevant studies, the majority of which we classified as being concerned with "case management" type interventions (intense monitoring of patients following hospital discharge often involving telephone follow up and home visits). We found a suggestion that such interventions might be associated with a reduction in all cause mortality and weak evidence that they might be associated with a reduction in HF related readmission. There was little available evidence to support HF clinic based interventions. The single study of a multidisciplinary intervention (bridging the gap between hospital admission and discharge home and delivered by a team) showed reduced heart failure related readmissions in the short term. Since the publication of the original review there have been a number of new trials published in this area. In view of the enduring importance of HF both to patients and to health services as a whole, we have updated our review of clinical service and disease management interventions aimed at reducing hospital readmissions in heart failure to help inform health care providers in the provision of most effective models of care for these patients.

OBJECTIVES

Primary objective

To compare the effects of different clinical service interventions, including disease management interventions, which are not primarily educational in focus, versus 'usual care' on death and/ or hospital readmissions in patients who have previously been admitted to secondary care with a diagnosis of heart failure.

Secondary objective

To compare the effects of the different clinical service interventions versus usual care on hospital bed days and health related quality of life (HRQL).

METHODS

Criteria for considering studies for this review

Types of studies

In our original review we included randomised controlled trials (RCTs) reporting any follow up period, for this update we only included randomised controlled trials with a minimum of six months follow-up.

Types of participants

This review focused on adults aged 18 and over who had at least one admission to secondary care with a diagnosis of heart failure. Studies dealing *principally* with patients with cardiac disorders other than heart failure, or with heart failure arising from congenital heart disease and/ or valvular heart disease, were excluded.

Types of interventions

Clinical service interventions (defined as inpatient, outpatient or community based interventions or packages of care) directed specifically at patients with heart failure were included. This excluded the simple prescription or administration of a pharmaceutical agent(s) to patients with heart failure. Interventions could include or exclude patients' relatives or carers.

These interventions included:

- Case management, defined as "the active management of high-risk people with complex needs, with case managers (usually nurses) taking responsibility for caseloads working in an integrated care system" (DoH 2004)

- Clinical interventions such as enhanced or novel service provision (for example the introduction of a specialist nurse led heart failure clinic)

- Multidisciplinary interventions such as disease management interventions, defined as "a system of coordinated healthcare interventions and communications for populations with long-term conditions in which patient self-care is significant" (Royal College of Physicians 2004)

The following types of interventions were not included in this review:

- Interventions that were primarily educational in focus
- Interventions that only consisted of exercise programmes
- Interventions described as cardiac rehabilitation

programmes. Cardiac rehabilitation was defined as a structured programme offered to individuals after a cardiac event to aid recovery and prevent further cardiac illness. Cardiac rehabilitation programmes typically achieve this through exercise, education, behaviour change, counselling and support and strategies that are aimed at targeting traditional risk factors for cardiovascular disease (Taylor 2010).

- "Generic" interventions, not exclusively aimed at patients with heart failure, directed at reducing readmission or morbidity in populations of older people with a variety of long term conditions.

Because they were the focus of another Cochrane review (Inglis 2010), studies of solely telemedicine interventions, where telemedicine is defined as the "transfer of physiological data via digital cable e.g. electrocardiograph (ECG), blood pressure (BP), weight, pulse oximetry (SPO2), respiratory rate and medicine administration", were excluded. For the same reason interventions that only consisted of structured telephone or videoconferencing support, including computer-assisted education and monitoring, (Clark 2007) were also excluded. Interventions that included structured or unstructured telephone or videoconferencing support alongside other non-telemedicine components, such as attendance at a clinic or home visiting, were not excluded.

Types of outcome measures

Primary outcomes

- Total deaths
 - deaths due to heart failure
 - deaths due to all cardiac causes (sometimes reported instead of deaths due to heart failure)
 - deaths due to non cardiac causes
 - all cause mortality
- Total number of readmissions to secondary care
 - readmissions due to heart failure
 - readmissions due to all cardiac causes

- readmissions due to non cardiac causes
- unplanned readmissions and elective readmissions

Secondary outcomes

- Total hospital bed days
- Length of time between index hospital discharge and readmission
- Event free survival, with an event defined as death or hospital readmission
- HRQL assessed using validated outcome measures

We did not consider cost analyses in this updated review.

Search methods for identification of studies

The search strategies are based on an update search done in 2005 by the Trials Search Co-ordinator at the Cochrane Heart Group. For this update, an information specialist at the Peninsula Technology Assessment Group (PenTAG) conducted all searches. The main differences from the original review are the addition of an RCT filter and the removal of terms associated to exercise therapy and fitness. Further details and the searches for the individual databases are shown in [Appendix 1](#) and [Appendix 2](#). No language restrictions were applied.

We searched the following electronic databases for the updated review:

- CENTRAL (Cochrane Central Register of Controlled Trials), The Cochrane Library Issue 1, 2009 (searched on 23/01/2009)
- Ovid MEDLINE 1950 to January Week 1 2009 (searched on 21/01/2009)
- EMBASE 1980 to 2009 Week 03 (searched on 23/01/2009)
- DARE (Databases of Abstracts of Reviews of Effectiveness) via The Cochrane Library Issue 1, 2009 (searched on 23/01/09)
- CINAHL (Cumulative Index to Nursing and Allied Health Literature) via NLH Search 2.0 version 1982 to January 2009 (searched on 23/01/09)
- AMED (Allied and Alternative Medicine Database) via NLH Search 2.0 version 1985 to January 2009 (searched on 23/01/09)

The following additional databases were searched for the original review but not the updated review due to low additional yields in the original review and limited resources for the update:

- Science Citation Index expanded searched January 1981 to March 2001 (forward and backwards search);
- SIGLE (grey literature database) Jan 1980 to July 2003

The following databases were not searched in the updated review as they have been discontinued:

- National Research Register (searched to July 2003 in previous version of review)

- Cardio-Vascular Disease Trials Registry at McMaster University (searched to February 2001 in previous version of review)

- Chartered Society of Physiotherapy Library Catalogue (searched to June 2001 in previous version of review)

Since this update did not include economic evaluations we did not search the NHS Economic Evaluations Database, although this was searched until March 2001 for the original review.

In addition, we screened reference lists of retrieved articles and published reviews on the topic.

Personal communication with the principal investigators of the identified RCTs and with national and international experts in the field was conducted for the original review in 2001. Since the yield of new studies identified by this means was very low (no additional relevant studies were identified by this method), this was not repeated for the update.

Data collection and analysis

- (1) Originally CENTRAL was searched by the Cochrane Heart Group. All other electronic searches were conducted by two members of the group working independently. A librarian with extensive expertise in electronic databases provided advice on searching. For this update, an information specialist at the Peninsula Technology Assessment Group (PenTAG) conducted all searches.
- (2) Group training was conducted on the first 100 references retrieved from searches of two different databases to ensure that the group had a consistent approach to assessing titles and abstracts.
- (3) Two members of the team independently assessed the title and abstract of each reference (ST, RT, FK for the update).
- (4) Two members of the team independently assessed the full texts of all potentially eligible papers retrieved (RT, AT, ST, FK for the update). Non English language papers which appeared to be eligible for inclusion on the basis of the translation of title and abstract were fully translated in to English for the first version of the review. For the update, it was not possible to translate full papers, so any papers which appeared to be eligible were listed in the table of Studies awaiting classification. These will be obtained and translated for the next update of this review.
- (5) Any disagreements about eligibility were resolved by discussion between at least two members of the group.
- (6) A data abstraction form was developed and the group worked together on several papers to ensure that members had a consistent approach to data abstraction.
- (7) At least two members of the group formally abstracted all eligible papers (RT, AT, ST, FK for the update), working independently and using the data collection form. Any disagreements were resolved by discussion with another member of the group.
- (8) Where we were unclear about issues arising from their published papers we attempted to contact the authors for clarification.

Assessing the methodological quality and external validity of the trials

Two reviewers (AT, ST, RT for the update) assessed each study's quality in terms of the Cochrane Risk of Bias criteria (Higgins 2011). This tool was not available for the previous version of this review. In the earlier version, in order to enhance our understanding of the studies, we also considered the criteria for quality assessment of RCTs developed by Verhagen (Verhagen 1998), excluding the two items "was the patient blinded/masked?" and "was the care provider masked?", since these make less sense in the context of the type of interventions under study. We also report these criteria for the studies in this updated review. These quality items are:

- (1) Treatment allocation
 - (a) Was a method of randomisation performed?
 - (b) Was the treatment allocation concealed?
- (2) Were the groups similar at baseline regarding the most important prognostic indicators?
- (3) Were the eligibility criteria specified?
- (4) Was the outcome assessor masked?
- (5) Were point estimates and measures of variability presented for the primary outcome measures?
- (6) Did the analysis include an intention to treat analysis?

We also commented on the risk of attrition bias.

Categorising the interventions

Riegel proposed three types of heart failure disease management models, and we have used her typology to group the different interventions for synthesis (Riegel 2001). The models are described as follows :

Case management models

Case management models consist of intense monitoring of the patients following discharge from hospital, this is usually done by a nurse and typically involves home visits and/or telephone calls.

Clinic models

Clinic models involve outpatient clinics for HF, they are usually run by cardiologists with a special interest in HF or by specialist nurses using agreed protocols to manage medication.

We attempted to categorise all interventions using this scheme; two reviewers (AT, ST for the update) worked independently to categorise each intervention with disagreements resolved by discussion.

Multidisciplinary models

Multidisciplinary models offer a holistic approach to the individuals' medical, psychosocial, behavioural and financial circumstances and typically involve several different professions working in collaboration. "The gap between hospitalisation, other health care

delivery systems (for example skilled nursing facilities, hospice) and home is bridged by a team of individuals knowledgeable about heart failure and committed to patient care."

Data analysis

We analysed the data using Cochrane Review Manager software, RevMan 5. We synthesized results in a narrative review and, where possible and appropriate, combined the trial results statistically using meta-analytic methods. We synthesized outcomes using standardised effect sizes, for example odds ratios (ORs), and assessed heterogeneity using the I^2 estimate. Given the high degree of heterogeneity expected in the studies due to differences in interventions, usual care definitions, and patient groups, we applied a random-effects model for the meta-analyses.

Subgroup analyses

Where possible we performed subgroup analyses using stratified meta-analysis, according to a subjective measure of the "intensity" of intervention, agreed for each study between two reviewers (AT, ST), and based on the amount of particular components, for example telephone follow-up, home visits, mentioned in the published studies. These were not pre-defined for the update but were agreed during the analysis process. We also assessed the impact of delivery of the intervention by particular professional groups (for example pharmacists, specialist nurses). We also undertook sensitivity analysis that restricted meta-analysis to those studies which reported concealment of allocation.

RESULTS

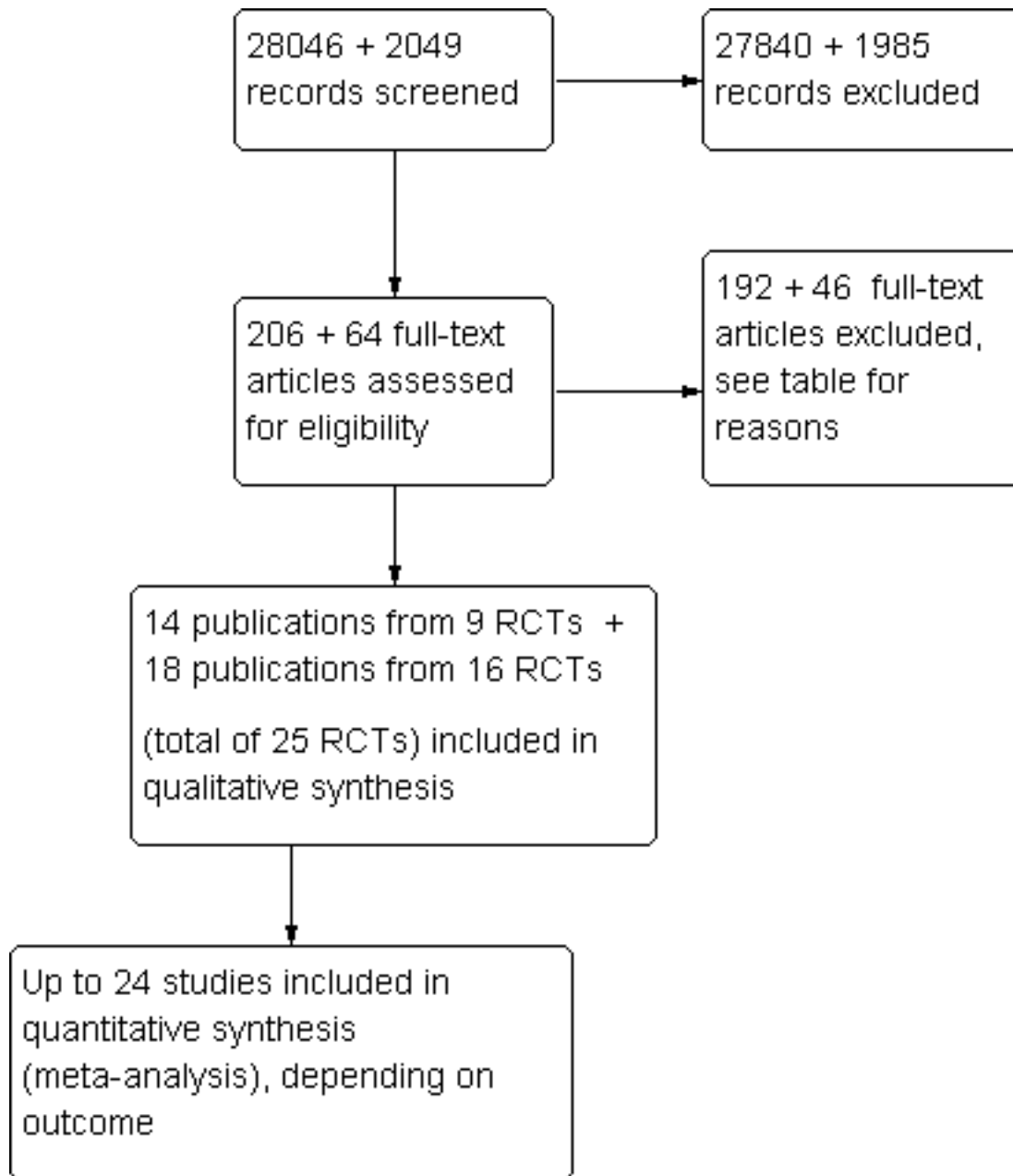
Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of studies awaiting classification](#); [Characteristics of ongoing studies](#).

The numbers of papers assessed at each stage of the study are shown in [Figure 1](#). In the original review (Taylor 2005) the search strategy identified 28,046 papers including duplicates and a number of reviews and guidelines. We excluded 27,838 references by removing duplicates and after screening titles and abstracts. Two hundred and six papers, including major review articles and guidelines, were retrieved in the original review, examination of the full papers led to the exclusion of a further 185 papers, and we originally included 16 individual RCTs described in 21 papers. Seven of these RCTs no longer meet the revised inclusion criteria for the updated review; the study by Riegel 2000 is a purely telemonitoring intervention, and nine publications describing six studies had less than six months follow up (Ekman 1998; Harrison 2002;

Laramée 2003; McDonald 2002; Rich 1993; Rich 1995) (Figure 1). This leaves nine of the original studies to be included in the current review.

Figure 1. Study flow diagram.



For the updated review, we identified a further 2049 citations, of which 1985 were excluded based on title and abstract screening. We retrieved sixty four as full texts for assessment against the inclusion criteria, leading to the subsequent exclusion of 46 studies. Excluded studies which relate to the area reviewed are described in the [Characteristics of excluded studies](#) table. We tabulated titles where it was not possible to classify a new study from the searches, for example studies awaiting translation, ongoing studies or in cases where we were unable to identify a publication despite extensive web searching and attempts to contact authors ([Characteristics of studies awaiting classification](#), [Characteristics of ongoing studies](#)). After excluding these, the update included 18 publications relating to 16 new RCTs. Thus, 25 individual RCTs with a total of 5942 patients are included in the updated review ([Characteristics of included studies](#)), including [Thompson 2005](#) and REACT ([Tsuyuki 2004](#)), which were ongoing studies in the original review.

Control patients received unrestricted 'usual' or 'routine' care in all the studies except one, where both control and intervention patients received a programme of 'optimised' medical care after discharge from the index hospitalisation ([Del Sindaco 2007](#)).

In the original review, all the included studies were conducted at a single centre with the exception of one which involved two centres ([Kasper 2002](#)). However, for the update of this review, the majority (n = 11) of the new studies were multicenter RCTs. The largest was that by [Jaarsma 2008](#), which was conducted at 17 centres. Otherwise, studies were carried out at two centres ([Kwok 2008](#); [Lopez 2006](#); [Thompson 2005](#)) three centres ([Atienza 2004](#); [Holland 2007](#); [Stromberg 2003](#)), five centres ([De Busk 2004](#)) or six centres ([Kimmelstiel 2004](#); [Naylor 2004](#)). [Tsuyuki 2004](#) was described as a multicenter RCT with up to 10 hospitals contributing patients to the programme.

All the studies were led by professionals from secondary or tertiary care. As determined by scrutiny of the published accounts, none of the 25 interventions were delivered in exactly the same way by the same type of personnel, although some were very similar and all the interventions had overlapping content (see [Table 1](#)). The interventions varied in site, intensity and duration (see [Table 1](#), [Characteristics of included studies](#)). Length of follow up ranged from six months to two years.

Content of the interventions as described in the published reports

[Table 1](#) lists the components of the interventions as described in the published papers against the studies.

Telephone follow up

The majority (20 out of 25) of the studies in the updated review included telephone follow-up or help-line access for patients.

Education

Education aimed at patients, and in some cases carers, appears to have been a *major component* in 16 of the studies included in this review. The education typically covered the diagnosis, symptoms and treatment of heart failure, and when to seek expert help.

Self management

Many of the interventions actively sought to promote better patient self management and patients were sometimes given heart failure diaries or notebooks to aid self management.

Weight monitoring

Daily or regular weight monitoring, or the importance of weight monitoring, was mentioned in 14 of the studies. Patients in these studies were often given charts or diaries in which to log their weight.

Sodium restriction and/or dietary advice

Sixteen of the studies mentioned patients receiving dietary advice, often from the nurse at a home visit.

Exercise recommendations

In the updated review a total of 10 studies mentioned advice about exercise in stable heart failure or exercise promotion.

Medication review

Only one of the earlier intervention in the original review specifically mentioned a review of the patients' medications. However many more (12 in total) of the studies in the updated review noted that there was the opportunity to review patients' medications as part of the disease management programme.

Social support and psychological support

Social workers assessed patients' needs in two interventions in the original review, outpatient support groups featured in one intervention and one study stated that the heart failure specialist nurse gave patients psychological support. Only two of the more recent studies identified for the update review specifically offered social or psychological support to patients included in the intervention.

Inclusion and Exclusion Criteria

The studies differed in their inclusion and exclusion criteria. All of the studies identified patients during or following an index hospital admission for CHF (one of this review's inclusion criteria), but several reports did not specify the criteria they used for identifying CHF. One study required patients to have had at least one

other admission for acute heart failure prior to the index admission (Stewart 1999a) and another intervention was targeted at patients the researchers considered to be at high risk for readmission (Kasper 2002). Two studies excluded patients with diastolic heart failure/ heart failure with preserved systolic function (Blue 2001; Tsuyuki 2004). Several of the studies mentioned excluding patients with valvular heart disease requiring surgery (De Busk 2004; Del Sindaco 2007; Doughty 2002; Holland 2007; Jaarsma 2000; Kasper 2002; Stewart 1999a; Mejhert 2004) and/or excluded patients awaiting cardiac surgery (Atienza 2004; Holland 2007; Jaarsma 2008; Thompson 2005). Three studies specifically excluded CHF associated with acute myocardial infarction (Blue 2001; Ducharme 2005; Kasper 2002) and one excluded CHF associated with cor pulmonale (Nucifora 2006). The presence of serious co-morbidity or other terminal illness was a common exclusion criterion and most of the studies excluded patients discharged to long term care facilities such as nursing homes.

The patients enrolled in the studies

The majority of studies (21/25) had between 100 and 350 participants. However, the COACH study reported by Jaarsma 2008 randomised 1049 people, and two studies (Krumholz 2002; Rainville 1999) had fewer than 100 participants. For the majority of the 25 included studies, the mean/ median age of patients was between approximately 67 and 80 years old. The mean/ median ages of patients in 12 of the studies were in the late 60s or early 70s, eight of the studies had patients whose mean/ median ages were in the mid 70s (Aldamiz-Echevarria 2007; Blue 2001; Cline 1998; Holland 2007; Krumholz 2002; Lopez 2006; Mejhert 2004; Naylor 2004), and three studies had patients whose mean or median age was 77 or more (Del Sindaco 2007; Kwok 2008; Stromberg 2003). Two studies had considerably younger patients, with a median of 63.5 (range 25-88) in the study by Kasper 2002 and a mean of 56 (SD = 10) in the Capomolla 2002 study.

The severity of heart failure ranged across studies, 18 of the studies reported a summary statistic for participants' baseline the New York Heart Association (NYHA) grade. The percentage of patients with moderate (grade 3) or severe (grade 4) heart failure ranged from only 16% in the study by Lopez 2006 to 75% or more in eight of the studies (Blue 2001; Del Sindaco 2007; Doughty 2002; Ducharme 2005; Jaarsma 2000; Rainville 1999; Stromberg 2003; Thompson 2005).

Most studies were carried out in Europe (n = 14). Others took place in the USA (n = 6), Canada (n = 2), Australasia (n = 2) and Hong Kong (n = 1), thus all the studies were conducted in World Bank defined high income economies (<http://data.worldbank.org/about/country-classifications/country-and-lending-groups#High+income>). Only five studies reported the ethnicity of study participants. (De Busk 2004; Doughty 2002; Kasper 2002; Krumholz 2002; Naylor 2004).

Levels of comorbidity varied between studies in different countries. Of the 22 studies reporting this baseline variable, four of the North American studies (Kasper 2002; Kimmelstiel 2004; Krumholz 2002; Tsuyuki 2004) had the highest proportions of people with diabetes (37-52% of patients in the intervention groups). The five studies reporting the lowest levels of diabetes (< 25%) took place in Europe (Blue 2001, Cline 1998, Nucifora 2006; Stromberg 2003, Thompson 2005). Five of the studies presented baseline data on COPD, and prevalence varied from 17% in the study by De Busk 2004 to 39.5% in the study by Del Sindaco 2007.

Categorising the interventions

The types of personnel involved in the interventions differed, but specialist nurses were common to most studies, although the level of their involvement varied. As in the earlier version of this review we used Riegel's classification (Riegel 2001) to group the interventions based on the content and nature of the interventions as they were described in the papers. In practice there appears to be considerable overlap between these disease management models and it was not always easy to classify them, Table 1 summarises some of the similarities and differences between the interventions. One intervention involved a day hospital heart failure management programme (Capomolla 2002) and was difficult to categorise. We considered that the remaining interventions fell predominantly into the following groups:

- Seventeen studies and the intensive intervention arm of Jaarsma 2008 were variations on the case management approach.
- Six studies represented clinic models (Cline 1998; Doughty 2002; Jaarsma 2008 (basic intervention arm); Mejhert 2004; Stromberg 2003; Thompson 2005)
- Two studies reflected a multidisciplinary approach (Del Sindaco 2007; Ducharme 2005)

We also attempted to classify the studies according to the key person delivering the intervention. A specialist nurse was responsible for delivering the intervention in 12 of the studies (Blue 2001, Cline 1998, Jaarsma 2000, Jaarsma 2008 (basic intervention), Kasper 2002, Kimmelstiel 2004, Krumholz 2002, Naylor 2004, Nucifora 2006, Stewart 1999a, Stromberg 2003, Thompson 2005). Specialist nurse intervention typically included home visits by the specialist nurse to assess health status, offer dietary advice and assess patient compliance. In some cases (e.g. Kimmelstiel 2004; Thompson 2005) physical examinations were performed at home visits. Patients had access to telephone helplines, and in some cases nurses phoned patients to assess compliance, offer support and reinforce education (for example Jaarsma 2008; Nucifora 2006). Specialist nurses visited patients in hospital prior to discharge in some interventions (Naylor 2004) and offered outpatient clinics in others (Thompson 2005). Teaching materials such as patient handbooks (for example Kimmelstiel 2004, Nucifora 2006) and patient diaries (Jaarsma 2008) were

used to support and promote patient education and self-management.

Three studies were predominantly delivered by a pharmacist (Holland 2007; Lopez 2006; Rainville 1999) and four by a nurse or community nurse (Aldamiz-Echevarria 2007; De Busk 2004; Kwok 2008; Mejhert 2004). In five of the studies, the intervention appeared to be delivered by two or more professionals, although this did not necessarily mean they met the Riegel 2001 formal classification for multidisciplinary models, (Capomolla 2002; Del Sindaco 2007; Doughty 2002; Ducharme 2005; Jaarsma 2008 (intensive intervention)). The intervention described by Atienza 2004 was delivered by a cardiologist, and Tsuyuki 2004 describes the research coordinator as being responsible for delivering the intervention.

Risk of bias in included studies

We assessed the studies against the following risk of bias criteria: sequence generation, allocation concealment, selective reporting, and other potential sources of bias (Figure 2). Twenty of the studies reported an adequate sequence generation (Figure 3), with

information being missing or unclear for the remaining studies (Capomolla 2002; De Busk 2004; Del Sindaco 2007; Mejhert 2004; Nucifora 2006). Ten of the studies reported adequate allocation concealment (Aldamiz-Echevarria 2007; Cline 1998; De Busk 2004; Ducharme 2005; Kasper 2002; Kwok 2008; Lopez 2006; Naylor 2004; Stewart 1999a; Stromberg 2003) with information being unclear in more than half of the studies (Atienza 2004; Blue 2001; Capomolla 2002; Doughty 2002; Holland 2007; Jaarsma 2000; Jaarsma 2008; Kimmelstiel 2004; Krumholz 2002; Mejhert 2004; Nucifora 2006; Rainville 1999; Thompson 2005; Tsuyuki 2004). Allocation concealment was judged to be inadequate in the study by Del Sindaco 2007. The majority of studies were judged to be free of selective reporting, although this information was unclear in the study by Kimmelstiel 2004 and inadequate in the study by Cline 1998. We assessed the majority of studies to be free of other potential sources of bias (Figure 3). The remaining studies did not contain sufficient information to assess this (Atienza 2004; Cline 1998; Lopez 2006; Stewart 1999a). None of the studies were assessed to have a definite risk of other potential sources of bias.

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Selective reporting (reporting bias)	Other bias
Aldamiz-Echevarria 2007	+	+	+	+
Atienza 2004	+	?	+	?
Blue 2001	+	?	+	+
Capomolla 2002	?	?	+	?
Cline 1998	+	+	?	?
De Busk 2004	?	+	+	+
Del Sindaco 2007	?	+	+	+
Doughty 2002	+	?	+	+
Ducharme 2005	+	+	+	+
Holland 2007	+	?	+	+
Jaarsma 2000	+	?	+	?
Jaarsma 2008	+	?	+	+
Kasper 2002	+	+	+	+
Kimmelstiel 2004	+	?	?	+
Krumholz 2002	+	?	+	+
Kwok 2008	+	+	+	+
Lopez 2006	+	+	+	?
Mejhert 2004	?	?	?	+
Naylor 2004	+	+	+	+
Nucifora 2006	?	?	+	?
Rainville 1999	+	?	+	?
Stewart 1999a	+	+	+	?
Stromberg 2003	+	+	+	?
Thompson 2005	+	?	+	+
Tsuyuki 2004	+	?	+	+

Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

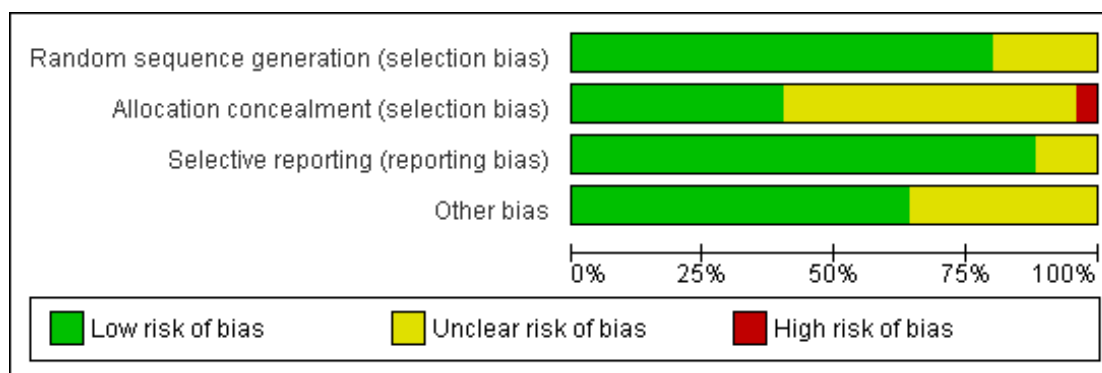


Table 2 reports the Delphi quality assessment for each study, for comparability with the earlier version of this review. We considered patients to be similar at baseline in the majority of studies (22/31) but noted imbalances in key baseline characteristics in three studies (Rainville 1999; Lopez 2006; Stromberg 2003). In a further five studies it was not clear whether the patients were similar at baseline. For example the study by Jaarsma 2000 only reported baseline characteristics for those remaining in the study at nine months, and since the study suffered from a large attrition rate it was not clear whether or not the randomised patients were similar at baseline. Incomplete baseline data were reported by Kasper 2002, and in four studies the patients were generally similar at baseline but with differences in some characteristics (Ducharme 2005; Kimmelstiel 2004; Nucifora 2006; Tsuyuki 2004).

The outcome assessor was masked in 12 of the studies (Blue 2001; Kasper 2002; Krumholz 2002; Stewart 1999a; Stromberg 2003; De Busk 2004; Kimmelstiel 2004; Naylor 2004; Thompson 2005; Del Sindaco 2007; Jaarsma 2008; Kwok 2008) (see Table 2). Two of the studies did not report results on an intention-to-treat basis (Rainville 1999; Jaarsma 2000). This information was unclear in seven of the studies (Cline 1998; Blue 2001; Capomolla 2002; Krumholz 2002; Kimmelstiel 2004; Lopez 2006; Aldamiz-Echevarria 2007), and the remaining 16 studies were considered to have reported ITT results (Stewart 1999a; Doughty 2002; Kasper 2002; Stromberg 2003; Atienza 2004; De Busk 2004; Mejhert 2004; Naylor 2004; Tsuyuki 2004; Ducharme 2005; Thompson 2005; Nucifora 2006; Del Sindaco 2007; Holland 2007; Jaarsma 2008; Kwok 2008).

Overall, we assessed the studies as having a low risk of bias (Figure 3), although a lack of clarity in reporting mean that the assessment

was 'unclear' for almost one third of the cells in this figure. In only one instance was a study known to have a high risk of bias in any of the criteria in Figure 3 (lack of allocation concealment in Del Sindaco 2007).

Effects of interventions

The Table of results of included studies (Table 3) documents results of primary and secondary endpoints.

Synthesis of the findings from the included studies

We have presented the results of Capomolla's study separately because of the unique characteristics of both the intervention and the patients it was directed at (see Characteristics of included studies Table). For this reason, only 24 analyses are presented in Analysis 1.1.

All interventions

Twenty four of the studies provided information on all cause mortality Analysis 1.1. Overall intervention showed a reduction on all cause mortality, OR 0.74 (95% CI 0.60 to 0.90, $P = 0.003$). Twelve studies (13 datasets, $n = 3135$ patients) provided information on HF readmissions Analysis 1.2. Intervention showed a reduction on HF readmission, OR 0.57 (95% CI 0.43 to 0.75, $P < 0.0001$).

Event free survival

Information on event free survival (survival without all cause readmission or death) was provided for 14 of the 25 included RCTs.

This was reported in various ways, most commonly as survival curves and log-rank tests, hazard ratios or Cox's proportional hazards regression analyses. It was not feasible to conduct a statistical meta-analysis on these results.

Health related quality of life

HRQL was the principal outcome of one case management study (Jaarsma 2000) and was mentioned as a secondary outcome in three other studies in the original review and five more in the updated review. Given both the heterogeneity in outcome measures and methods of reporting findings, we did not undertake a meta-analysis.

The five new studies in the updated review reported very little difference in HRQL scores between patients in intervention groups and those in usual care groups. However, there was often large attrition, with small proportions of patients actually completing questionnaires at all time points.

Case management vs usual care

Deaths

Few studies reported deaths attributed to HF or cardiovascular causes (here combined with heart failure mortality). Meta-analysis of the three case management interventions (n = 1423 patients) reporting this outcome showed a non specific trend in reduction of mortality at 12 months or more: OR 0.87 (95% CI 0.64 to 1.17, P = 0.35, I² = 0%, Analysis 2.1).

Capomolla's study (Capomolla 2002) of a day hospital based heart failure management programme reported a significant reduction in cardiac related deaths in the intervention group. However total deaths were not reported, it is not clear how cardiac related deaths were identified, and the study population appears to be highly selected so generalisability of this finding is unclear.

There were sufficient case management studies reporting all cause mortality for us to conduct a meta-analysis of the effects on mortality at around six months follow up or at around 12 months follow-up. At six months, meta-analysis of seven trials (n = 1454 patients) revealed no significant evidence that these interventions were associated with reduced mortality, OR 0.85 (95% CI 0.54 to 1.32, P = 0.46, I² = 48%) (Analysis 2.2). However these interventions differed in content and duration (see Characteristics of included studies table). At around twelve months follow-up, reduction in all cause mortality with case management in the 11 included studies (n = 2801 patients) was substantial and statistically significant: OR 0.66 (95% CI 0.47 to 0.91, P = 0.01, I² = 60%) (Analysis 2.3), although there was moderate statistical heterogeneity. We undertook sensitivity analysis which limited the meta-analysis to only those studies which reported allocation concealment (any duration of follow-up). The reduction in mortality in the intervention arm was again substantial and significant,

OR 0.60 (95% CI 0.43 to 0.84, P = 0.003, I² = 37%) (Analysis 2.4). There was considerable variation in the mortality rates in the usual care arms ranging from 12.4% (De Busk 2004) to 45.4% (Atienza 2004) for studies with more than six months follow up, and from 5.2% (Kimmelstiel 2004) to 28% (Stewart 1999a) for studies with six months follow-up.

Of the case-management interventions, only the study by De Busk 2004 reported mortality in a way that allowed deaths from non-cardiac causes to be ascertained. They reported that 13 of the 21 deaths (62%) in the treatment group and 23 of 29 (79%) in the usual care group were due to cardiac causes, implying that there were eight (38%) and six (21%) non-cardiac deaths in the treatment and control arms, respectively.

Readmissions to secondary care

In studies reporting follow up at six months (three studies, total n = 655, Analysis 2.5) (OR 0.64, 95% CI 0.46 to 0.88, P = 0.007, I² = 0%) and at around 12 months (7 studies, total n = 1726, Analysis 2.6) (OR 0.47, 95% CI 0.30 to 0.76, P = 0.002, I² = 76%) there was a reduction in readmissions favouring the intervention. However, the I² statistic in the latter analysis may indicate substantial statistical heterogeneity. We repeated this analysis limiting it to those three studies (n = 604 patients) in which allocation concealment was reported: this analysis found a substantial, highly significant overall effect in favour of the intervention (OR 0.42, 95% CI 0.29 to 0.62, P < 0.00001, I² = 9%) (Analysis 2.7). Again, where data were available, we have conducted meta-analysis for results separately for duration of follow up. At six months follow up there was a non significant tendency towards fewer admissions in the intervention arm (Analysis 2.8, four studies, n = 694 patients): OR 0.77 (95% CI 0.50 to 1.20, P = 0.25, I² = 46%). In the seven studies (n = 2199) reporting follow up at around 12 months or longer the difference favouring the intervention just reached statistical significance (Analysis 2.9): OR 0.75 (95% CI 0.57 to 0.99, P = 0.05, I² = 58%).

Days spent in hospital

Four of the case management studies reporting this outcome found no statistically significant difference in all cause hospital bed days during follow-up. However, Stewart 1999a found a reduction in unplanned days in hospital in the intervention group at both six months (460 vs. 1174) and 18 months (875 vs. 1476). Tsuyuki 2004 reported significantly fewer days in hospital (all cause) for the intervention group than the control group (627 vs. 1082; p < 0.001). Lopez 2006 and Aldamiz-Echevarria 2007 reported lower days in hospital for intervention groups than control groups but did not state whether differences were statistically significant (410 vs. 611 days and mean stay of 8.4 (SD 7.7) vs. 10.1 (SD 12.9) for the two studies, respectively). Three studies reported days spent in hospital for readmissions associated with heart failure. Blue 2001

reported significantly fewer bed days in the case managed groups (mean (SD) days 3.43 (12.2) vs. 7.46 (16.6); $P = 0.005$), whilst [Krumholz 2002](#) reported a reduction in bed days for cardiovascular readmissions including heart failure (mean (SD) days 6.3 (9.2) vs. 12.3 (14.3); $P = 0.03$) but not for heart failure readmissions alone (4.1 (6.4) vs. 7.6 (12.1); $P = 0.1$). The study by [Tsuyuki 2004](#) reported a lower number of days for readmissions associated with cardiovascular disease (341 vs. 812, $P = 0.003$).

Event free survival

Thirteen case management interventions reported event free survival. Of the four studies with six months follow up, three found no significant difference between the intervention and usual care groups ([Cline 1998](#); [Kasper 2002](#) and [Nucifora 2006](#)). [Stewart 1999a](#) found more patients in the intervention group survived without an unplanned readmission than the control group 51% vs. 38%, $P = 0.04$, (95% CIs not given).

At 12 months or more follow up, nine case-management studies reported results. Of these, four reported no significant difference between treatment groups ([Cline 1998](#); [De Busk 2004](#); [Aldamiz-Echevarria 2007](#); [Jaarsma 2008](#) (intensive intervention). Two moderate quality studies reported HR for event free survival which favoured the case management intervention ([Blue 2001](#), HR 0.61, 95% CI 0.38-0.96, $P = 0.03$; [Krumholz 2002](#), HR 0.5, 95% CI 0.29 to 0.09, $P = 0.02$). A very small study judged to be of lower quality also significantly favoured the intervention group ([Rainville 1999](#), $P < 0.01$ log rank test). Of the more recent studies, [Atienza 2004](#) reported an event rate of 0.7 vs. 1.17 per year in the intervention and control groups, respectively, with the difference of 0.47 being statistically significant (95% CI 0.29 - 0.65, $P < 0.001$). Similarly, [Naylor 2004](#) reported death or readmission in 47.5% vs. 61.2%, $P = 0.01$.

Health related quality of life

Jaarsma's largely educational case management intervention study ([Jaarsma 2000](#)) suffered severe attrition and was assessed to be of lower quality - no difference in HRQL between intervention and control groups was noted. In a randomly selected sub-sample of 68 patients Stewart found a statistically significant difference in change in Minnesota Living with Heart Failure Questionnaire (MLHFQ) favouring the intervention group in survivors at three months but not at six months ([Stewart 1999a](#)). A third case management intervention study ([Kasper 2002](#)) found a clinically significant improvement in MLHFQ scores after six months follow up in intervention patients compared to controls.

[Naylor 2004](#) reported a small but statistically significant difference in QoL between intervention and control group patients at 12 weeks, with a score of 3.2 vs. 2.7 in MLHFQ ($P < 0.05$). Differences between the two groups MLHFQ scores were not significantly different at 26 or 52 weeks. [Lopez 2006](#) reported very similar EuroQol (EQ-5D) scores for intervention and control group

patients at six months (mean (SD) 62.9 (14.9 vs. 62.8 (14.1); $P = \text{ns}$). By 12 months there was a small but not statistically significant difference between the two groups (64.0 (15.4) vs. 60.6 (17.8)). [Holland 2007](#) reported the adjusted mean difference in both EQ5D and MLHFQ scores for patients completing questionnaires (approximately two thirds of the patients for EQ5D and half for the MLHFQ). At six months follow up, the adjusted mean difference (95% CI) for the EQ5D was 0.07 (-0.01 to 0.14); $P = 0.08$, and 3.73 (-3.67 to 11.13) for the MLHFQ.

Clinic vs usual care

Deaths

All six of the clinic studies ($n = 1486$ patients) were included in our meta-analysis of the effect of the intervention on mortality at any reported duration of follow-up ([Analysis 3.1](#)); here there was a non-significant tendency towards a reduction in mortality, OR 0.74 (95% CI 0.51 to 1.09, $P = 0.13$, $I^2 = 45\%$). There was considerable variation in the mortality rates in the usual care arms ranging from 14.6% ([Thompson 2005](#)) to 37.0% ([Stromberg 2003](#)).

Only the clinic-based study by [Stromberg 2003](#) distinguished between deaths from cardiac causes and non-cardiac causes. Five of seven deaths in the intervention group and 18 of 20 in the control group were due to cardiovascular causes, suggesting that two patients in each group died from non-cardiac causes.

Readmissions to secondary care

Only two clinic studies ([Cline 1998](#); [Jaarsma 2008](#)) reported heart failure related readmissions - neither showed evidence of any effect with ORs of, or very close to, unity ([Analysis 3.2](#)). We were able to conduct a meta-analysis on the data on all cause readmissions for four of the clinic studies, three of which had follow up at 12 months or more ([Analysis 3.3](#), total $n = 1129$). There was little evidence of fewer admissions in the intervention arm: OR 0.78 (95% CI 0.48 to 1.26, $P = 0.31$, $I^2 = 65\%$) with substantial statistical heterogeneity.

Days spent in hospital

There was no evidence from four studies that clinic models are associated with any statistically significant reduction in days spent in hospital during follow up ([Dougherty 2002](#); [Stromberg 2003](#); [Mejthert 2004](#); [Jaarsma 2008](#), basic intervention). However, [Thompson 2005](#) reported that the total days spent in hospital by all readmitted patients were significantly lower in the clinic intervention group than in the control group (108 vs. 459; $P < 0.01$).

Event free survival

None of the three studies of clinic interventions reporting this outcome found a significant difference in event free survival between intervention and control groups (Doughty 2002; Thompson 2005; Jaarsma 2008 (basic intervention)).

Health related quality of life

Only one study of a clinic model intervention reported HRQL (Doughty 2002). There was no difference in MLHFQ total scores between intervention and control patients at one year, although the physical score showed a significantly greater improvement in the clinic managed patients compared to the control group. Capomolla 2002 measured quality of life in his day hospital managed patients compared to his control group using the time trade off method and found that the intervention group had significantly higher quality of life. Cline reported no difference in Quality of Life in Heart Failure Questionnaire scores at 12 months between intervention and control groups (Cline 1998). Thompson 2005 reported a small difference in change from baseline scores of -14.2 for intervention patients and -13.7 for control group patients (indicating similar levels of improvement). However, fewer than 50% of patients in the study completed the MLHFQ outcome.

Multidisciplinary versus usual care

There was little evidence of an effect of multidisciplinary interventions on mortality (two studies, $n = 403$ patients) (Analysis 4.1): OR 0.70 (95% CI 0.43 to 1.14, $P = 0.15$, $I^2 = 0\%$). There was considerable variation in the mortality rates in the usual care arms ranging from 16.5% (Ducharme 2005) to 36.8% (Del Sindaco 2007), respectively.

Readmissions to secondary care

Both of the studies of multidisciplinary interventions (different follow up times) reported reductions in HF readmissions with the intervention. On meta-analysis (Analysis 4.2, total $n = 403$), the effect size was substantial and statistically significant (OR 0.45, 95% CI 0.28 to 0.72, $P = 0.001$, $I^2 = 0\%$). The odds for all cause readmission (two studies, $n = 403$) were halved in the intervention arm and this effect was highly significant: OR 0.46 (95% CI 0.30 to 0.69, $P = 0.0002$, $I^2 = 0\%$) (Analysis 4.3). Capomolla 2002 noted a highly significant reduction in hospital readmissions in his intervention group (total number of hospital readmissions at mean 12 (SD 3) months follow up: 13 vs. 78, $P < 0.00001$) but the generalisability and quality of this study are very unclear. It is also unclear if these are all cause readmissions or readmissions for haemodynamic instability.

Days spent in hospital

Multidisciplinary management may also lead to a reduction in hospital bed days in the first six months after discharge. Ducharme 2005 reported that the total length of hospital stay during all cause readmissions was lower in intervention than in usual care groups (HR 0.59, 95% CI 0.38-0.92).

Event free survival

Only one multidisciplinary intervention study reported event free survival. Del Sindaco 2007, with a long follow up of 24 months reported death or readmission in 46.5% vs. 64.4%, of intervention and control groups, respectively (RR = 0.360, 95% CI 0.17-0.51; $P < 0.001$).

Health related quality of life

Ducharme 2005 reported a “substantial improvement” in both emotional and physical quality of life scores for intervention vs. control ($P < 0.001$) but did not report actual scores.

Post hoc analyses

Intensity of the intervention

In post hoc analyses we examined subgroups of the studies to explore the possible effects of the intensity of the intervention as described in the published reports (see Methods) on all cause mortality and heart failure related readmission. For this work we pooled all types of interventions and all follow up times. Of studies with usable mortality or heart failure readmissions data, we judged eight studies to be have the “most intensive” interventions (Blue 2001; Capomolla 2002; Del Sindaco 2007; Doughty 2002; Kasper 2002; Kwok 2008; Naylor 2004; Thompson 2005) and a further study to have an “intensive but brief” intervention (Aldamiz-Echevarria 2007). Meta-analysis of the eight studies (total $n = 1868$) with the longer, intensive interventions gave an overall OR for reduction in all cause mortality of 0.67 (95% CI 0.52 to 0.86, $P = 0.002$, $I^2 = 9\%$) (Analysis 5.1). The brief but intensive intervention essentially showed no effect on mortality. Meta-analysis of the ten “moderately intensive” intervention studies (total $n = 3126$) (Atienza 2004; De Busk 2004; Ducharme 2005; Holland 2007; Jaarsma 2000 (intensive group); Kimmelstiel 2004; Krumholz 2002; Nucifora 2006; Lopez 2006; Stewart 1999a) found a significant overall reduction in mortality: OR 0.74 (95% CI 0.57 to 0.96, $P = 0.02$, $I^2 = 36\%$) (Analysis 5.2) However meta-analysis of those five interventions ($n = 1156$) judged “low” intensity (Cline 1998; Jaarsma 2000 (basic group); Lopez 2006; Rainville 1999; Tsuyuki 2004) found an effect size close to unity (Analysis 5.3). There was little difference in overall effect sizes for heart failure

readmissions for all three grades of intensity (“most intensive” to “low”) with each grouping showing a statistically significant reduction in readmissions in favour of the intervention ([Analysis 5.4](#), [Analysis 5.5](#), [Analysis 5.6](#)).

Professional groups delivering the intervention

We also attempted to look at outcome by the professional group who delivered the intervention. Multidisciplinary interventions have already been discussed in detail above and data were too sparse to report this work for any other outcome than all cause mortality. We looked at overall summary effect sizes for all cause mortality for interventions delivered by a specialist heart failure nurse, by a community nurse and by a pharmacist (community or hospital) at all follow up times. Twelve studies ([Blue 2001](#); [Cline 1998](#); [Jaarsma 2000](#); [Jaarsma 2008](#); [Kasper 2002](#); [Krumholz 2002](#); [Kimmelstiel 2004](#); [Naylor 2004](#); [Nucifora 2006](#); [Stewart 1999a](#); [Stromberg 2003](#); [Thompson 2005](#)) involved a specialist nurse and on meta-analysis ($n=2387$ patients) their summary overall effect size favoured intervention but did not quite reach formal statistical significance: OR 0.72 (95% CI 0.52 to 1.00, $P = 0.05$, $I^2 = 54\%$) ([Analysis 6.1](#)), and suggested moderate statistical heterogeneity. Meta-analyses of both the four community nurse led studies ([Aldamiz-Echevarria 2007](#); [De Busk 2004](#); [Kwok 2008](#); [Mejhert 2004](#)) ([Analysis 6.2](#)), the three pharmacist led studies ([Holland 2007](#); [Lopez 2006](#); [Rainville 1999](#)) ([Analysis 6.2](#)), and the four multidisciplinary studies ([Del Sindaco 2007](#); [Doughty 2002](#); [Ducharme 2005](#); [Jaarsma 2008](#)) ([Analysis 6.6](#)) found no evidence to support an effect on all cause mortality.

Specialist nurses (six studies, $n=1381$) were found to decrease HF readmissions OR 0.55 (95% CI 0.37 to 0.81, $P = 0.002$, $I^2 = 58\%$) ([Analysis 6.5](#)) although in only one study community nurses were not shown to have an effect ([Analysis 6.4](#)). One study of community pharmacists showed an effect on HF readmissions ([Rainville 1999](#), OR 0.22 95% CI 0.05, 0.95, $P = 0.04$).

Adverse Events

None of the studies noted any adverse events arising from their interventions.

Generalisability of the results

To estimate the generalisability of results to all patients with heart failure admitted to hospital, we considered the proportion of patients who were eligible for the interventions out of those screened and the proportion of eligible patients who were entered into the trials. These data were not always available. Of the 25 included studies, seven did not report numbers screened or admitted, only the total number of patients randomised. Five studies reported that between 25% and 50% of patients were eligible, and three had higher proportions ([Arienza 2004](#) 59%; [Ducharme 2005](#) 85%; [Mejhert 2004](#) 73%). A further eight studies reported that

fewer than 25% of patients screened or admitted to the relevant hospital department were eligible for inclusion in the study. Of these, the studies reported by [Stewart 1999a](#); [Stromberg 2003](#) and [Thompson 2005](#) reported particularly low eligibility rates (5.4%, 5% and 1.8%, respectively). [Thompson 2005](#) explain their low proportion of eligible patients by the difficulty in obtaining evidence of left ventricular systolic dysfunction, and stated that 642 otherwise eligible patients were not able to be included in the study for this reason, leaving only 119 possibly eligible patients.

Only 13 of the 25 studies reported the proportion of eligible patients who were actually randomised, or gave sufficient information for this to be inferred (for example by stating how many patients were eligible but declined to take part). In five of these, more than 75% of eligible patients agreed to take part in the study ([Aldamiz-Echevarria 2007](#); [Capomolla 2002](#); [Jaarsma 2000](#); [Mejhert 2004](#); [Thompson 2005](#)). [Ducharme 2005](#) had the lowest participation rate at only 23% of the 1019 eligible patients. The other studies reporting the proportion of patients eligible had participation rates of between approximately 36% ([Tsuyuki 2004](#)) and 70% ([Stewart 1999a](#)).

One intervention deliberately targeted patients considered to be at high risk of readmission. In this case management study by [Kasper 2002](#), 67% of heart failure patients screened were considered to be at high risk of readmission; 70% of these had one or more exclusion criteria and 20% of the eligible patients participated in the study (14% of all the patients with CHF).

DISCUSSION

This review systematically evaluated 25 different clinical service organisation or disease management interventions targeted at patients who have already experienced one hospital admission for heart failure. The frailty of the populations targeted by these interventions is evidenced by the high levels of baseline co-morbidity and the overall mortality rates in many of these studies. The generalisability of the findings of the studies has slightly improved since the earlier version of this review but only half of the studies reported the proportion of eligible patients who were actually randomised ([Characteristics of included studies](#)).

As in the earlier version of this review, we attempted to divide the different interventions into three disease management models proposed by [Riegel 2001](#): multidisciplinary; case management; and clinic. There is now much more available evidence than for our previous review and we were able to limit the included studies to those reporting follow up of at least six months. The majority of studies reported case management type approaches with only six exploring clinic models and, as earlier, relatively few (just two) studies of multidisciplinary type approaches. Within these groupings there remained considerable heterogeneity between the components of the interventions, their duration, and the patient pop-

ulations they were directed at (Table 1). Overall the studies were assessed as having a low risk of bias but for many of the criteria examined there was insufficient information to determine the risk of bias (Characteristics of included studies).

Case management type interventions

All but one of these interventions involved telephone follow up from a specialist nurse to the patient at home and many had a major educational component, but the interventions did vary in their other components (Table 1). Their duration also varied but most of these interventions continued to end of study follow up. Compared with the earlier version of this review, there is now strong evidence that case management interventions are associated with a substantial, statistically significant reduction in all cause mortality at around 12 months follow up, OR 0.66 (95% CI 0.47 to 0.91, $P = 0.01$, $I^2 = 60\%$). No significant reduction in mortality was seen in the case management studies reporting at six months, OR 0.84 (95% CI 0.56 to 1.26, $P = 0.41$, $I^2 = 39\%$). Data were very sparse but there was a non significant tendency for case management interventions to be associated with a reduction in deaths from heart failure or cardiovascular causes (OR 0.87 (95% CI 0.64 to 1.17, $P = 0.35$, $I^2 = 0\%$).

There is good evidence that case management type interventions reduce heart failure related readmissions in studies reporting follow up at six months (OR 0.64, 95% CI 0.46 to 0.88, $P = 0.007$, $I^2 = 0\%$) or at around 12 months, although here there was considerable statistical heterogeneity between studies (OR 0.47, 95% CI 0.30 to 0.76, $P = 0.002$, $I^2 = 76\%$). Evidence for an impact of these interventions on all cause admissions at six month follow up is less apparent, in studies with follow up around 12 months there was a significant reduction in all cause admissions (OR 0.75, 95% CI 0.57 to 0.99, $P = 0.05$, $I^2 = 58\%$). Overall it is not clear whether these interventions reduce the total days spent in hospital during readmission for any cause but there is a strong suggestion that days spend in hospital for heart failure or cardiovascular causes may be reduced. It was not possible to synthesise the results for event free survival other than narratively, but considering all the case management studies as a whole there is much more evidence that these interventions are associated with an improvement in event free survival at 12 months than at six months.

Clinic interventions

There is now more evidence on heart failure clinic interventions than in the earlier version of this review (six vs. two studies), with all but one reporting follow up to at least 12 months. Pooled data revealed a non-significant tendency for these interventions to be associated with a reduction in all cause mortality at follow up (OR 0.74, 95% CI 0.51 to 1.09, $P = 0.13$, $I^2 = 45\%$), with no clinic studies reporting on heart failure related deaths separately.

There is currently no evidence that these interventions reduce heart failure related admissions, but only two studies have reported this outcome. In the four studies whose results we were able to meta-analyse (three with follow up at 12 or more months) there was little evidence that these interventions were associated with a reduction in all cause readmissions (OR 0.78, 95% CI 0.48 to 1.26, $P = 0.31$, $I^2 = 65\%$) with substantial statistical heterogeneity. Only one study of a clinic intervention reported a reduction in total days spent in hospital and this was the only study reporting just six months follow up. There was no evidence of improvement in event free survival in the clinic studies.

Multidisciplinary interventions

There were only two studies included in the review looking at these types of interventions with follow up of six months or more. A non significant tendency for a reduction in all cause deaths was seen on pooling the data (OR 0.70, 95% CI 0.43 to 1.14, $P = 0.15$, $I^2 = 0\%$). There was no evidence on heart failure related deaths. Both all cause and heart failure related readmissions were significantly reduced when the results of these two studies were pooled (ORs 0.46, 95% CI 0.46 to 0.69, $P = 0.0002$, and 0.45, 95% CI 0.28 to 0.72, $P = 0.001$, respectively, no statistical heterogeneity).

Day hospital Based Programme

The single study of a day hospital based heart failure programme directed at a very particular patient population (relatively young, male and many awaiting heart transplantation) showed a reduction in deaths from cardiac causes and hospital readmissions in the group receiving the intervention, however the quality of this study is unclear and its results may not be generalisable.

Health related quality of life

HRQL remains a less commonly reported outcome, bedeviled by attrition in several studies. There are more studies reporting HRQL in this updated review, but we found little evidence that any of these types of interventions significantly improve patient's quality of life compared to control.

In post hoc analyses we found some evidence that low intensity interventions might have less effect on mortality than moderate or high intensity interventions but low intensity interventions had a similar or greater effect on heart failure readmissions than nor intensive interventions and it should be note that our assessment of "intensity" was crude. We also looked at the professional discipline of the person delivering the intervention interventions with specialist heart failure nurses were by far the most common and these were the only professional group in which there was evidence of effectiveness. There was little evidence to support pharmacist or community nurse led interventions but here the evidence was

very sparse. It was not possible to identify the most effective the components of the interventions any further.

Low and middle income countries

We found no studies or interventions based in low or middle income countries and it is not clear how applicable the relatively resource intensive interventions included in this review would be to such settings.

Comparison with telemonitoring

This review is complementary to that by Inglis (Inglis 2010), of structured telephone support or telemonitoring for patients with heart failure which found such interventions were effective in reducing all cause mortality and heart failure related hospital admissions. Only four studies were common to these two reviews (Capomolla 2002; De Busk 2004; Rainville 1999; Tsuyuki 2004). Our review concentrates on the components of disease management and describes models of care rather than concentrating on the medium of delivery. Our review will be relevant to those designing the content of true telemedicine and of hybrid telemedicine / face to face interventions.

AUTHORS' CONCLUSIONS

Implications for practice

Amongst heart failure patients who have previously been admitted to hospital this condition there is now good evidence that case management type interventions led by a heart failure specialist nurse reduce heart failure related readmissions and, after 12 months follow up, all cause readmissions and all cause mortality. It is not possible to say what the optimal components of these case management type interventions are but telephone follow up by the nurse specialist was a very common component.

Multidisciplinary interventions have been much less researched but also appear to be effective in reducing both heart failure and all cause readmissions. There is little currently available evidence to support interventions whose major component is follow up in a heart failure clinic.

Implications for research

Future well designed and adequately powered studies might include:

(1) Head-to-head comparisons between different interventions, particularly comparisons of interventions which have short du-

ration (usually around discharge) and those which have a much longer duration;

(2) The effect of interventions on patients' and carers' HRQL and their satisfaction with the interventions;

(3) An assessment of costs and cost-effectiveness of interventions (not included in this review);

(4) A clearer and more detailed reporting of the core elements of these types of interventions and a systematic examination of changes in drug therapies that might have contributed to changes in outcomes with the intervention.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Aldamiz-Echevarria 2007

Methods	<p>Single centre RCT</p> <p>Recruitment dates: Feb 2001- June 2002</p> <p>Follow up: 12 months</p>
Participants	<p>Country: Spain</p> <p>N Randomised: 279</p> <p>intervention (n=137) vs. control (n=142)</p> <p>Mean (SD) age: 75.3 (11.1) vs. 76.3 (9.4)</p> <p>Percentage male: 38.7 vs. 40.1</p> <p>Ethnicity: not stated</p> <p>NYHA functional class intervention / control not stated</p> <p>Mean (SD) EF: 50.9 (16.6), n=130 vs. 48.3 (17.6), n=124</p> <p>Inclusion/exclusion criteria:</p> <p><i>Inclusion</i></p> <ul style="list-style-type: none"> • All patients had been hospitalised for HF • Lived in area covered by the collaborating home care unit • Sufficient family support <p><i>Exclusion</i></p> <ul style="list-style-type: none"> • Severe cognitive deficits • Advanced psychiatric disease • Non-cardiological terminal disease • COPD
Interventions	<p>Duration of intervention: 15 days</p> <p>Intervention:</p> <ul style="list-style-type: none"> • Home visits by physicians and nurses, for clinical examination, tests/analyses as required, and adjustment of medication as required (n.b. this intervention was not HF-specific, but was intended to reduce readmissions across a range of medical and surgical conditions). • Additional nursing staff home visits 2, 5 and 10 days after discharge for education for patients and relatives about HF (basic facts and management, i.e. symptoms, life style, diet and therapy) • Patients received educational manual and a phone number for queries <p>Comparator: usual care (referral to primary care physician)</p>
Outcomes	<p>Primary: cumulative unplanned readmission or death 6 and 12 months after discharge</p> <p>Secondary:</p> <ul style="list-style-type: none"> • cumulative unplanned readmissions • cumulative mortality • Duration of readmission • Use of emergency services during 1st 6 months after discharge

Notes	Data source: published data only planned admissions were not considered events Generalisability: Paper does not state how many patients were screened or admitted, but notes that 281 were eligible, of whom 279 (99.29%) were randomised	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Closed envelopes prepared by the Instituto de Ciencias de la Salud. The randomisation process was stratified with respect to the services involved (internal medicine, cardiology and short-stay)
Allocation concealment (selection bias)	Low risk	The sequence was concealed until interventions were assigned
Selective reporting (reporting bias)	Low risk	Stated outcomes reported clearly
Other bias	Low risk	“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”

Atienza 2004

Methods	Multicentre RCT (3 centres) recruiting: January 1999 - June 1999 Follow up: Median duration 509 days (IQR 365-649)
Participants	Country: Spain Participants: 164 in intervention group, 174 in usual care group Median age (IQR) 69 (61-74) in intervention group, 67 (58-74) in usual care group Male sex (both groups) 203 (60%), (intervention group 101/164, 62%), (control group 102/174, 59%) Ethnicity: not given Actual severity of heart failure in study subjects at recruitment: NHYA class, n.: intervention group I 11, II 39, III 40, IV 10; control group I 10, II 40, III 40, IV 10 median EF% (IQR) intervention 36 (30-53) control 40 (30-55) Study inclusion criteria: All patients with congestive heart failure discharged from cardiology wards of three hospitals in Spain were eligible. HF diagnosis based on the presence of symptoms and signs of heart failure with objective evidence of major cardiac dysfunction at rest. All patients had been hospitalised for HF Exclusion criteria:

	<ul style="list-style-type: none">● expected survival < 3 months● discharge to a nursing home or long term care facility● living > 30km from hospital● impossible to contact by phone● dementia or psychiatric illness● on a waiting list for invasive cardiology or heart surgery on discharge	
Interventions	Median duration of intervention: 509 days (IQR 365-649) Intervention: discharge and outpatient management program <ul style="list-style-type: none">● 1 to 1 single education session for patients and carers prior to discharge and session with primary care physician post discharge to reinforce education● teaching brochure to reinforce education, covering: diagnosis of HF, information about the disease (pathogenesis etc), symptoms of HF, symptoms and signs of worsening HF, what to do if condition worsens, lifestyle advice, medication education for carers● cardiologist outpatient clinic every 3 months, including medication review● patient given specific/ tailored self management plan● visit with primary care physician scheduled within 2 weeks of discharge● telemonitoring component -a facilitated telephone monitor (SCT) providing a 24 hour mobile phone contact number which patients were encouraged to contact as necessary. Patients could also telephone the HF team for advice during office hours Comparator:discharge planning according to the routine protocol of the study hospitals	
Outcomes	Primary outcome: event free survival (survival without readmission to hospital) at 1 year secondary outcomes: total number of hospital admissions (all cause and for HF) at 1 year other outcomes: readmission rate (all cause and for HF); HRQoL (Minnesota Living with heart Failure questionnaire); costs; rate of deaths per observation year; time to readmission (all cause+ HF); time to death	
Notes	Data source: published data only Generalisability: 572 people were admitted/screened, but the number of eligible patients is not stated. A total of 338 patients were randomised, i.e. 59% of admitted patients	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	An independent assistant allocated patients using a computer-generated randomisation list. Block stratified randomisation performed according to age and sex
Allocation concealment (selection bias)	Unclear risk	C, unclear (concealment approach not reported)
Selective reporting (reporting bias)	Low risk	Stated outcomes reported clearly

Other bias	Unclear risk	Nature of study meant that blinding of patients was not possible, performance bias could therefore have affected outcomes such as QoL assessments Data analysed on ITT principles, but one patient in each arm transferred to a nursing home during the study so their data were included in analyses but censored at time of transfer
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Blue 2001

Methods	RCT, single centre Recruiting: March 1997 to November 1998. Duration of follow up: 12 months (mean follow up)
Participants	Country: Scotland Participants: 81 patients (41 males, 51%) in comparison group, 84 (54 males, 64%) in intervention group Actual age of study subjects: usual care mean 75.6 years (SD 7.9), intervention 74.4 years (SD 8.6). Male sex: 58% Ethnicity: not given Actual severity of heart failure in study subjects at recruitment: NHYA class, n,: control group II 16 (20%), III 33 (42%), IV 30 (35%), intervention group II 19 (23%), III 28 (34%), IV 36 (43%) LVEF: not given Study inclusion criteria: Patients admitted as an emergency to the acute medical admissions unit at one hospital with HF due to LV systolic dysfunction. All patients had been hospitalised for HF Study exclusion criteria: 1. Unable to give informed consent or to comply with the intervention. 2. Acute MI (unless they had a previous history of CHF). 3. Co-morbidity (such as advanced malignancy) likely to lead to death or readmission in the near future. 4. Awaiting cardiac surgery. 5. Planned discharge to long term residential care. 6. Residence outside the hospital catchment area.
Interventions	Duration of intervention: up to 12 months Intervention Group: "Specialist nurse intervention" During index hospitalisation: Patients were seen by a HF nurse prior to discharge. After discharge: Home visit by HF nurse and within 48 hours of discharge Subsequent visits by HF nurse at 1, 3, and 6 weeks and at 3, 6, 9 and 12 months. Scheduled phone calls at 2 weeks and at 1, 2,4,5,7,8,10 and 11 months after discharge. Patients and their families encouraged to contact nurses with problems or questions by

	<p>phone during office hours (answering machine where they could leave messages after hours).</p> <p>Additional unscheduled home visits and telephone contacts as required</p> <p>Home visits covered:</p> <p>Patient education about HF and its Rx, self-monitoring and management (especially the early detection and treatment of decompensation).</p> <p>Patients were given a booklet about HF which included a list of their drugs, contact details for HF nurses, blood test results and clinic appointment times.</p> <p>The trained HF nurses used written drug protocols and aimed to optimise patient treatment (drugs, exercise and diet) and</p> <p>HF nurses also provided psychological support to the patient.</p> <p>HF nurses liaised with the cardiology team and other health care and social workers as required</p> <p>Comparison Group: usual care</p> <p>”Patients in the usual care group were managed as usual by the admitting physician and, subsequently, general practitioner. They were not seen by the specialist nurses after discharge.“</p>	
Outcomes	<p>Primary endpoints:</p> <p>Unplanned readmissions within 90 days of discharge.</p> <p>Total number of days hospitalised during follow up (12 months)</p> <p>Also looked at:</p> <p>readmission rates in the moderate risk subgroup compared to the high risk sub group</p>	
Notes	<p>Data source: published data only</p> <p>Generalisability:</p> <p>801 patients thought to have heart failure on admission were screened; 361 (45%) were eligible for the study and survived to have echocardiography; 12 (3%) refused consent; 184 (51% of 361) did not have LV systolic dysfunction; and 165 (46%, 21% of those screened) of these were randomised</p>	
<i>Risk of bias</i>		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	”Study nurses phoned the Robertson Centre for Biostatistics and the patient was allocated to one or other randomisation group from a randomisation list.“
Allocation concealment (selection bias)	Unclear risk	no information
Selective reporting (reporting bias)	Low risk	Stated outcomes reported clearly
Other bias	Low risk	Risk of care giver performance bias: possible, since HF nurses did not see control patients but hospital cardiology team may have been aware of randomisation group of patients.

Blue 2001 (Continued)

		<p>Risk of attrition bias: low.</p> <p>Risk of detection bias: low, "all hospital admissions were adjudicated blind to treatment" by a masked endpoint committee</p> <p>ITT results</p>
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Capomolla 2002

Methods	<p>RCT, single centre</p> <p>Recruitment: January 1999 to January 2000.</p> <p>Duration of follow up: mean follow up of 12 months</p>
Participants	<p>Country: Italy</p> <p>Participants: 122 patients (102 males, 84%) in comparison group, 112 (94 males, 84%) in intervention group</p> <p>Actual age of study subjects: mean age 56 years (SD 10)</p> <p>Male sex: 84%</p> <p>Ethnicity: not given.</p> <p>Actual severity of heart failure in study subjects at baseline:</p> <p>NYHA class I-II/III-IV: 158/81 (68% I-II)</p> <p>LVEF: 29% (SD 7)</p> <p>Study inclusion criteria:</p> <ol style="list-style-type: none"> 1. Patients with CHF referred for admission to the Heart Failure Unit at one centre or the Heart Transplantation Programme (unclear if at the same centre) 2. A diagnosis of CHF supported by clinical history, physical signs and symptoms, and by LVEF <40% <p>All patients had been hospitalised for HF</p> <p>Study exclusion criteria:</p> <p>None given.</p>
Interventions	<p>Duration of intervention: not clear.</p> <p>Intervention Group: Comprehensive Heart Failure Outpatient Management Program delivered by the day hospital</p> <p>During index hospitalisation:</p> <p>cardiac prognostic stratification and prescription of individual tailored therapy following guidelines and evidence</p> <p>After discharge:</p> <p>Attendance at day hospital staffed by a multidisciplinary team (cardiologist, nurse, physiotherapist, dietician, psychologist and social assistant). Patient access to the day hospital 'modulated according to demands of care process'.</p> <p>Care plan developed for each patient.</p> <p>Tailored interventions covering: cardiovascular risk stratification; tailored therapy; tailored physical training; counselling; checking clinical stability; correction of risk factors for haemodynamic instability; and health care education.</p> <p>Patients who deteriorate re-entered the day hospital through an open-access programme</p> <p>Day hospital also offered: intravenous therapy; laboratory examinations; and therapeutic changes as required</p> <p>The education given covered: knowledge about CHF and drug treatments and self</p>

	<p>management including daily weights, fluid restriction and nutrition</p> <p>Comparison Group: usual care</p> <p>During admission: cardiac prognostic stratification and prescription of individual tailored therapy following guidelines and evidence</p> <p>After discharge:</p> <p>'The patient returned to the community and was followed up by a primary care physician with the support of a cardiologist'</p>
Outcomes	<p>Primary outcomes (evaluated at a mean of 12 months):</p> <p>readmissions because of haemodynamic instability.</p> <p>Deaths from cardiac causes.</p> <p>Cardiac mortality and urgent heart transplant</p> <p>Secondary outcomes (evaluated at a mean of 12 months):</p> <p>'Tailored therapy management'</p> <p>QOL</p> <p>NYHA functional class</p> <p>Also looked at:</p> <p>Cost utility of the two strategies.</p> <p>Analysis done on intention to treat basis? Not clear</p>
Notes	<p>Data source: published data only</p> <p>Generalisability: 234 patients admitted the HFU with a diagnosis of CHF; 234 randomised (100%)</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patients referred to our HFU had a prognostic evaluation, their therapy was optimised, and they were then randomised to one of two management strategies."
Allocation concealment (selection bias)	Unclear risk	No information in paper
Selective reporting (reporting bias)	Low risk	Stated outcomes reported clearly
Other bias	Unclear risk	<p>Risk of care giver performance bias: unclear.</p> <p>Risk of attrition bias: unclear</p> <p>Risk of detection bias: likely because after 12 months all patients were re-evaluated in the Heart Failure Unit and the Day Hospital is part of this unit</p>

Cline 1998

Methods	<p>RCT, single centre</p> <p>Recruitment: December 1991 to October 1993.</p> <p>Duration of follow up: 12 months.</p>
Participants	<p>Country: Sweden</p> <p>Participants: 110 patients (57 males, 52%) in comparison group, 80 (44 males, 55%) in intervention group.</p> <p>Actual age of study subjects: mean 75.6 years (SD 5.3)</p> <p>Male sex: 53%</p> <p>Ethnicity: not given</p> <p>Actual severity of heart failure in study subjects at baseline:</p> <p>NYHA class, mean: controls 2.6 (SD 0.7), intervention group 2.6 (SD 0.7)</p> <p>LVEF: control group mean 35.7% (SD 12.3), intervention group 31.6% (SD 8.4). (75% LVEF <40%)</p> <p>Study inclusion criteria:</p> <ol style="list-style-type: none">1. Patients hospitalised primarily because of heart failure.2. Heart failure diagnosed on symptoms and signs with "at least one objective sign present on admission such as pulmonary rales, peripheral oedema, congestion on CXR, or a 3rd heart sound".3. Aged 65-84 years. <p>Study exclusion criteria:</p> <ol style="list-style-type: none">1. The presence of other serious disease that either prevented participation or was expected to significantly influence quality of life, morbidity or mortality in the following year.2. Forseeable follow up problems including residence outside the hospital catchment area.3. Serious alcohol or drug abuse.4. Psychiatric disease.5. Inability to understand or answer study questionnaire.6. Participation in another clinical trial.7. Discretion of treating physician.
Interventions	<p>Duration of intervention: 12 months</p> <p>Intervention Group: "Management programme for heart failure"</p> <p>During index hospitalisation:</p> <p>Patients received an education programme from HF nurse consisting of two 30 minute visits</p> <p>After discharge:</p> <p>Two weeks after discharge patients and their families were invited to a one hour group education session led by the HF nurse which included an oral presentation by the nurse, and educational video and a question and answer session.</p> <p>Patients were also offered a seven day medication dispenser if deemed appropriate.</p> <p>Patients were followed up at a nurse directed o/p clinic and there was a single prescheduled visit by the nurse at 8 months after discharge.</p> <p>The HF nurse was available for phone contact during office hours.</p> <p>Patients encouraged to contact the study nurse at their discretion, if unsure, if diuretic adjustments did not ameliorate symptoms in 2-3 days, or if there were "profound changes in self management variables".</p> <p>Patients were offered cardiology outpatient visits one and four months after discharge</p>

	The inpatient and outpatient education programme covered: HF pathophysiology, pharmacological and non-pharmacological treatment. Patients were also given guidelines for self-management of diuretics in the event of fluid overload or fluid depletion. Patients were given a "heart failure diary" containing information on HF, list of HF medications, names and contact phone numbers for the HF clinic and in which to regularly record bodyweight, ankle circumference and HF symptoms Comparison Group: usual care These patients were "followed up at the outpatient clinic in the department of cardiology by either cardiologists in private practice or by primary care physicians as considered appropriate by the discharging consultant."	
Outcomes	Primary endpoint: Not specified, abstract states that main outcome measures were: time to readmission, days in hospital and health care costs during one year Other endpoints: Quality of life (at 1 year) using The Quality of Life in Heart Failure Questionnaire, Nottingham Health Profile and patients' global self assessment (all self-administered) Also looked at: Deaths at 90 days Event free (i.e. death or readmission) survival at 90 days	
Notes	Data source: published data only Generalisability: no information supplied on number of patients screened for entry to the study or on the number of patients excluded. 206 eligible patients were randomised before consenting, 16 patients (8%) randomised to the intervention group withheld their consent, no patient randomised to the control group withheld consent	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"computer generated random allocation"
Allocation concealment (selection bias)	Low risk	"Patients were invited to participate and informed consent was given on the basis of information relevant to the allocated study group. This procedure avoided bias arising from control patients being informed of the intervention strategy."
Selective reporting (reporting bias)	Unclear risk	Stated outcomes reported clearly. However, not strictly ITT as readmission data only presented for survivors (i.e. not clear if patients who died were also readmitted prior to death)

Cline 1998 (Continued)

Other bias	Unclear risk	<p>slightly lower LVEF in intervention group at baseline: Mean (SD) left ventricular EF (%) Control: 35.7 (12.3), Intervention: 31.6 (8.4) < 0.05</p> <p>Risk of care giver performance bias: possible that some of the control patients were also seen by cardiologists involved in the study.</p> <p>Risk of attrition bias: low "all patients were accounted for". Unclear if ITT</p> <p>Risk of detection bias: possible, not clear who collected data on patients and not clear if this data collection was masked</p>
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De Busk 2004

Methods	<p>Multicentre RCT (5 centres)</p> <p>Recruitment: May 1998 - Oct 2000</p> <p>Duration of follow-up: 12 months</p>
Participants	<p>Country: USA</p> <p>N Randomised: 462 (intervention n=228, control n=234)</p> <p>NHYA class, n, (%) intervention group vs. control group</p> <p>I-II 103 (50) vs. 112 (50)</p> <p>III-IV 103 (50) vs. 113 (50)</p> <p>median EF%: not given</p> <p>Mean age all = 72 yr (SD 11):</p> <p><60yr: 35 (15%) vs. 32 (14%)</p> <p>60-70 yr: 52 (22%) vs. 55 (24%)</p> <p>70-80 yr: 92 (40%) vs. 86 (37%)</p> <p>>80 yr: 49 (21%) vs. 61 (26%)</p> <p>Ethnicity, n(%):</p> <p>White 195(86) vs. 191(82);</p> <p>Black 13(5) vs. 14(6);</p> <p>American Indian 9(4) vs. 18(8);</p> <p>Hispanic 7(3) vs. 7(3);</p> <p>Asian 4(2) vs. 4(2)</p> <p>Study inclusion criteria: Hospitalised with a provisional diagnosis of heart failure in study hospitals as indicated by new onset or worsening heart failure on the basis of 1) shortness of breath (dyspnoea at rest, orthopnoea or paroxysmal nocturnal dyspnoea)</p> <p>Exclusion criteria:</p> <p>Scheduled for coronary artery bypass surgery or valvular surgery</p> <p>Undergone cardiac surgery in preceding 8 weeks</p> <p>Serum creatinine value > = 5 mg/dl</p> <p>Receiving dialysis</p> <p>Awaiting renal Tx</p> <p>History severe pulmonary disease on home O2</p>

	1 or more additional diagnoses expected to result in death within the year Cognitive mental deficits Substance abuse Severe psychiatric disorders Expected to move from area within 1 year	
Interventions	Duration of intervention: 12 months Intervention: "specialist nurse intervention" <ul style="list-style-type: none">• 1 hour educational session with a nurse in the patient's medical centre• Patient received printed educational materials including methods for self monitoring symptoms, body weight and medications; a dietary management workbook; food frequency questionnaires• Patients viewed a video portraying the treatment process• Patients received instructions on how to access emergency care in case symptoms abruptly worsened• 45 min baseline telephone counselling session within 1 week of randomisation by experienced nurse care manager• Subsequent nurse contacts tailored to meet needs of the patient• Nurse initiated follow up phone calls to patient weekly for 6 weeks, biweekly for 8 weeks, monthly for 3 months, bimonthly for 6 months• Nurse care managers obtained permission from physicians to initiate and regulate pharmacologic therapy for HF according to study protocol• Nurses communicated with physicians about pt's medical status• Nurses coordinated treatment plan with patients and physicians Comparator: usual care (no details given)	
Outcomes	Outcomes (1 year) Primary outcome: time to first hospitalisation HF and all cause secondary outcomes: time to composite outcome of death, readmission or ED visit for cardiac cause or for any cause, The rate of outpatient and ED visits	
Notes	Data source: published data only Generalisability: 2786 patients were screened, of whom 1951 did not meet inclusion criteria and 373 declined to participate. Therefore 462 (16.6% of screened patients and 55% of eligible patients) were randomised and took part in the study	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Research staff who were not associated with delivering the intervention randomly assigned patients to treatment conditions by using sealed assignments. Equal numbers of patients were allocated to the 2 groups in each medical centre using the Efron procedure

De Busk 2004 (Continued)

Allocation concealment (selection bias)	Low risk	Research staff who were not associated with delivering the intervention randomly assigned patients to treatment conditions by using sealed assignments
Selective reporting (reporting bias)	Low risk	Stated outcomes reported clearly
Other bias	Low risk	<p>Risk of care giver performance bias: possible due to unblinded nature</p> <p>Risk of attrition bias: low (ITT analysis used)</p> <p>Risk of detection bias: low: Research staff who were not associated with, and were blinded to, the intervention conditions measured health outcomes at 12 months . . . two cardiologists who were not associated with implementing the intervention reviewed medical records . . .</p>

Del Sindaco 2007

Methods	<p>Open RCT</p> <p>Recruitment: January 2001 to December 2002</p> <p>Duration of follow-up: 24 months</p>
Participants	<p>Country: Italy</p> <p>N Randomised: 184 (control n= 87, intervention n=86)</p> <p><i>NYHA:</i></p> <ul style="list-style-type: none"> • NYHA 1; Control: 0 (0), Intervention: 0 (0) • NYHA 2; Control: 34 (39.1), Intervention: 32 (37.2) • NYHA 3; Control: 49 (56.3), Intervention: 44 (51.2) • NYHA 4; Control: 4 (4.6), Intervention: 10 (11.6) <p><i>LVEF:</i> Control: 32.5 (SD 10), Intervention: 33.5 (SD 11)</p> <p>Age: Control: 77.5 (SD 5.7), Intervention: 77.4 (SD 5.9)</p> <p>Percentage male: Control: 52.8, Intervention: 51.2</p> <p>Ethnicity: not stated</p> <p>Inclusion/exclusion criteria:</p> <p><i>Inclusion:</i></p> <ul style="list-style-type: none"> • 70 years or older • Discharged home after hospitalisation due to heart failure • NYHA III-IV for at least 24 hours requiring IV therapy on admission • Diagnosis determined according to ECS guidelines (Remme et al. Eur H J 2001;22:1527-1560). <p><i>Exclusion:</i></p> <ul style="list-style-type: none"> • Valvular heart disease requiring planned surgical correction • Active substance abuse • Severe gait impairment • Confined to bed

	<ul style="list-style-type: none"> • Severe dementia • Psychiatric disease likely to limit compliance • Co-existent non-cardiac disease likely to reduce life expectancy • Need for long term IV inotropic therapy • Unwillingness to provide informed consent • Living in a nursing home <p>Living outside the area served by the clinical sites.</p>		
Interventions	<p>Duration of intervention: 24 months</p> <p>Intervention: disease management programme (DMP) combining hospital clinic-based and home based care</p> <ul style="list-style-type: none"> • teams included a cardiologist experienced in geriatrics, 2-4 specialised nurses and the patient's primary care physician • components of the programme were; discharge planning, continuing education, therapy optimisation, improved communication with healthcare providers, early attention to signs and symptoms and flexible diuretic regimes. • patients given a written list of recommendations, a weight chart, a contact number available 6h/day, and an education booklet • follow-up via hospital clinic visits, periodical nurse's phone calls • patients attended heart failure clinics within 7 to 14 days of discharge and at 1, 3 and 6 months thereafter for optimisation of treatment and education • primary care physicians assessed adherence to treatment, evaluated adverse effects and co-morbidities, and monitored diet <p>Control: usual care</p> <ul style="list-style-type: none"> • optimised treatment and standard education • all treatments and services ordered by primary care physician and/or cardiologist. • baseline clinical evaluation and therapeutic plan documented 		
Outcomes	<p>Primary:</p> <ul style="list-style-type: none"> • Composite of all cause death and hospital admissions from heart failure at 24 months. <p>Secondary (24 months):</p> <ul style="list-style-type: none"> • All cause and heart failure hospitalisations • Cumulative number of hospitalisations • All cause and heart failure related mortality • QoL • Perceived health status • Functional status and indexes of quality of care (such as % of patients taking beta-blockers) - not recorded here 		
Notes	<p>Data source: published data only</p> <p>Generalisability: Paper does not state how many patients were admitted, screened or eligible for the study, and only gives the number of randomised patients (n=184)</p>		
Risk of bias			
Bias	<table> <tr> <th>Authors' judgement</th><th>Support for judgement</th></tr> </table>	Authors' judgement	Support for judgement
Authors' judgement	Support for judgement		

Random sequence generation (selection bias)	Unclear risk	No details given, just states 'randomised'.
Allocation concealment (selection bias)	High risk	Eligible patients were randomised and informed consent was given on the basis of information relevant to the allocated study group
Selective reporting (reporting bias)	Low risk	All outcomes fully reported on.
Other bias	Low risk	Outcomes were evaluated in a blinded manner by a central endpoint committee composed of three cardiologists, who had no knowledge of the treatment assignment

Doughty 2002

Methods	Cluster RCT, GP as the unit of randomisation (but see note), single centre. Recruitment: during 1997 and 1998. Duration of follow up: 12 months.
Participants	Country: New Zealand Participants: 97 patients (54 males, 56%) in comparison group, 100 (64 males, 64%) in intervention group. Actual age of study subjects: mean 73 years (SD 10.8, range 34 to 92 years). Male sex: 60% Ethnicity: 'NZ European' 79% Severity of heart failure in study subjects: (At index admission) NYHA class, n (%): controls II 24 (25%), III 73 (75%), intervention group II 24 (24%), III 76 (76%). (At baseline) LVEF: control group mean 33.8% (SD 12.7), intervention group 30.6% (SD 12.7) Study inclusion criteria: Patients admitted to general medical wards with a primary diagnosis of heart failure Study exclusion criteria: 1. Surgically remediable cause for heart failure. 2. Consideration for heart transplantation. 3. Terminal cancer. 4. Participation in another trial. 5. Inability to provide informed consent.
Interventions	Duration of intervention: 12 months Intervention: 'integrated heart failure management programme' After discharge: Outpatient review at heart failure clinic within 2/52 of discharge from hospital: clinical status reviewed, pharmacological treatment based on evidence based guidelines, one-to-one education with study nurse, education booklet provided. Patient diary for daily weights, Rx record & clinical notes provided.

	Detailed letter faxed to GP and follow up phone call to GP. GPs encouraged to discuss management with clinic team. Follow up plan aiming at 6 weekly visits alternating between GP and HF clinic. Group education sessions for patients run by cardiologist and study nurse: two sessions offered within 6 weeks of discharge and one at 6 months post d/c. Telephone access to study team for GPs or patients during office hours Group education sessions covered: education about disease; monitoring daily body weight and action plans for weight changes; medication; exercise; diet. Comparison: usual care	
Outcomes	Primary endpoints (12 months): Time to first event i.e. death or hospital readmission. HRQL measured using Minnesota Living With Heart Failure Q at baseline and 12 months Other endpoints (12 months): All cause hospital readmissions. Heart failure related hospital readmissions. All cause hospital bed-days. Also looked at: Medications at 12 months.	
Notes	Data source: published data only Generalisability: does not report how many patients were screened for eligibility to study, nor how many of those deemed eligible agreed to participate	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	”General practitioners were randomly allocated using computer generated random numbers...after consent was obtained the patient was informed of their group allocation based on the randomisation of their current general practitioner.“
Allocation concealment (selection bias)	Unclear risk	not reported. GPs were randomised before participant recruitment - possibility that team were aware of assignment of GP before recruitment of patient into study
Selective reporting (reporting bias)	Low risk	all stated outcomes reported clearly

Other bias	Low risk	Care giver performance bias: unclear; primary care giver performance bias unlikely because to avoid contamination of GPs a cluster RCT design was employed. However, not clear whether hospital staff managed both intervention and control patients. Risk of attrition bias: low Risk of detection bias: possible, no mention of blinding of those assessing endpoints ITT analysis
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Ducharme 2005

Methods	RCT, single centre Recruitment: January 1998- January 2000 Duration of follow-up: 6 months
Participants	Country: Canada Participants: intervention n=115 / control n=115 Mean (SD) age: 68 (10) / 10 (10) % male: 83 (73) / 82 (71) ethnicity: not stated Ejection fraction, % (SD): 34 (14) / 35 (15) NYHA class, n (%) II 8 (7) / 14 (12) III 68 (59) / 63 (55) IV 39 (34) / 38 (33) Inclusion criteria <ul style="list-style-type: none"> • seen at the emergency department of or admitted to the Montreal Heart Institute with a primary diagnosis of congestive heart failure • radiologic confirmation of congestive heart failure or known impaired LVEF (< 45%) Exclusion criteria: <ul style="list-style-type: none"> • a primary diagnosis of acute myocardial infarction • discharge to a chronic care facility, scheduled cardiac surgery • unwillingness to sign informed consent or to attend the outpatient clinic • participation in another research trial • residence in an outlying area
Interventions	Duration of intervention: 6 months Intervention: multi-disciplinary heart failure clinic with phone follow-up from nurses <ul style="list-style-type: none"> • evaluation at clinic within 2 weeks of hospital discharge • heart failure clinic provided rapid access to cardiologists, clinician nurses, dieticians and pharmacists, with access to social workers and other medical specialists as required • clinic allowed observation for up to 5 hours and IV diuretics if required • follow-up phone call from nurse within 72 hours of hospital discharge and then

	<p>monthly, unless a problem necessitated more frequent contact</p> <ul style="list-style-type: none"> • After baseline evaluation, clinic cardiologists individualized treatment plan (including pharmacologic treatment) for patients • One-on-one education of the patient and family with the study nurse initiated at first clinic visit. Individualized advice on the disease process, symptoms and signs of heart failure (changes in symptoms indicative of worsening heart failure), fluid and sodium intake restrictions, the importance of daily monitoring of body weight and action plans to remedy changes in weight, effects of medications and the importance of compliance, and recommendations regarding exercise and diet. • patient diary for daily weight measurement, medication record, clinical notes and appointments, physical activity recommendations, an education booklet and a telephone number for clinic during business hours • individualized dietary assessments by registered dietician at baseline, instructions reinforced by nurse at subsequent visits • pharmacist evaluated medications for each patient and assessed patient's knowledge • individualized follow-up plan included monthly visits with both a cardiologist and nurse at the clinic • study team available for ad hoc consultation during normal working hours. <p>Patients advised to call clinic nurse if symptoms worsened. During calls nurse evaluated signs of clinical deterioration and adverse effects and patients were referred to clinic cardiologist as required</p> <p>Comparator: standard care</p>
Outcomes	<p>primary endpoints: all-cause hospital readmissions and the total number of associated hospital days at 6 months</p> <p>secondary outcomes (at 6 months): number of emergency department visits, quality of life and mortality</p>
Notes	<p>Data source: published data only</p> <p>generalisability: Of 1203 patients admitted, 1019 (84.7%) were eligible for the study. However, of these 789 refused to participate, so only 462 (22.6% of admitted patients, 36.9% of eligible patients) were randomised</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Eligible patients who agreed to participate were randomly assigned to the control group or intervention group using consecutively numbered opaque envelopes that contained a random number generating group assignment."
Allocation concealment (selection bias)	Low risk	see above
Selective reporting (reporting bias)	Low risk	Stated outcomes reported clearly

Ducharme 2005 (Continued)

Other bias	Low risk	Analyses were ITT Blinded personnel administered the quality-of-life questionnaire to both groups at baseline and at 6 months
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Holland 2007

Methods	Multicentre RCT (3 centres) Recruitment: December 2003 and March 2005 Duration of follow up: 6 months
Participants	<p>Country: UK N Randomised: 339 169 allocated to intervention, 170 to control 20 intervention and 26 control patients excluded post-randomisation. Study involved 149 intervention pts and 144 control group pts <i>NYHA</i>:</p> <ul style="list-style-type: none"> • NYHA 1; Control: 11 (7.6), Intervention: 6 (4.0) • NYHA 2; Control: 37 (25.7), Intervention: 43 (28.9) • NYHA 3; Control: 47 (32.6), Intervention: 52 (34.9) • NYHA 4; Control: 49 (34.0), Intervention: 48 (32.2) <p>LVEF: Not stated Age: Control: 77.6 (9.0), Intervention: 76.4 (9.5) Percentage male: Control: 63.8, Intervention: 63.2 Ethnicity: Not stated Inclusion/exclusion criteria: <i>Inclusion</i>:</p> <ul style="list-style-type: none"> • adults (aged over 18 years), admitted as an emergency in which heart failure was an important ongoing clinical condition, i.e. all patients had been hospitalised for HF • prescribed two or more drugs (from any drug class) on discharge <p><i>Exclusion</i>:</p> <ul style="list-style-type: none"> • living in a residential or nursing home • awaiting surgery for ischaemic or valvular heart disease • awaiting heart transplantation • terminal malignancy
Interventions	<p>Duration of intervention: 6-8 weeks Intervention: community pharmacist home visits within two weeks of discharge, where</p> <ul style="list-style-type: none"> • pharmacist provided education to patient and carer on HF, drugs, exercise, diet and smoking cessation, in line with BHF's 'Living with Heart Failure' booklet *which was left with patients • patients encouraged to complete simple sign and symptom monitoring diary card (including weight) • pharmacist fed back recommendations to GP and any need for drug adherence aid to local pharmacist • An additional follow-up visit was made 6-8 weeks after discharge to review progress and reinforce original advice. <p>Control group: usual care</p>

Holland 2007 (Continued)

Outcomes	Primary: <ul style="list-style-type: none">total emergency admissions to hospital in 6 months Secondary: <ul style="list-style-type: none">deaths at 6 monthsquality of life (EQ-5D) and MLWHF at 6 months	
Notes	Data source: published data only Generalisability: 1880 patients were assessed for eligibility. Of these, 555 (18%) were approached and asked to take part in the study. 339 (61%) agreed and were available to be randomised into the study	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"We used third party telephone randomisation based on a computer generated random allocation sequence."
Allocation concealment (selection bias)	Unclear risk	no information in paper
Selective reporting (reporting bias)	Low risk	stated outcomes reported
Other bias	Low risk	ITT analyses reported. No suggestions of other biases, other than those possible due to impracticality of blinding

Jaarsma 2000

Methods	RCT Recruitment: May 1994 to March 1997. Duration of follow up: 9 months.
Participants	Country: the Netherlands Participants (patients enrolled and surviving to discharge): 95 patients in comparison group, 84 in intervention group* Actual age of study subjects: not given for original group, those who remained at 9 months were mean age 72 years (SD 9) at baseline. Male sex: of those who remained at 9 months, 60% Ethnicity: not given Actual severity of heart failure in study subjects at recruitment: not known Study inclusion criteria: 1. Patients admitted to the cardiology unit of one hospital with HF symptoms and diagnosis verified with Boston score. 2. NYHA III or IV. 3. HF diagnosis for longer than 3 months. 4. Age 50 years or older.

	<p>5. Dutch literate.</p> <p>Study exclusion criteria:</p> <ol style="list-style-type: none"> 1. Coexisting, severe, chronic debilitating disease. 2. Discharge to a nursing home. 3. Psychiatric diagnosis. 4. CABG, angioplasty or valve replacement in past 6 months or expected to have such treatment in next 3 months
Interventions	<p>Duration of intervention: up to 10 days after discharge from index admission, on average one week*</p> <p>Intervention: 'Supportive educational intervention'</p> <p>During index admission:</p> <p>Intensive education by study nurse using standard nursing care plan</p> <p>After discharge:</p> <p>Study nurse phoned patient within one week of discharge to assess potential problems and made appointment for home visit.</p> <p>Home visit on average one week after discharge*. At home visit education continued.</p> <p>If required, study nurse wrote to patient's home care nurse about patient's specific needs.</p> <p>Between discharge and home visit patient could contact study nurse if they encountered problems.</p> <p>After home visit patient encouraged to contact their cardiologist, GP or emergency heart centre with any problems.</p> <p>Educational component covered: symptoms of worsening failure, sodium restriction, fluid balance and compliance and individuals' problems, and included education and support to patients' family</p> <p>Comparison: usual care.</p> <p>"A nurse or physician, depending on his or her individual insight into the patients' questions, provided these patients with education about medication and lifestyle". Usual care patients did not receive structured education</p>
Outcomes	<p>Primary endpoints: none specified</p> <p>Measures of QOL:</p> <p>Heart Failure Functional Status Inventory (to assess functional capabilities at baseline, 3 and 9 months).</p> <p>Symptom occurrence (at baseline, 1, 3 and 9 months), severity and distress questionnaire, designed for this study (at 3 and 9 months).</p> <p>Psychosocial Adjustment to Illness Scale (at baseline, 3 and 9 months).</p> <p>Cantril's Ladder of Life (to measure overall well being at baseline, 1, 3 and 9 months)</p> <p>Measures of self-agency and self-care behaviour:</p> <p>The patients' ability to care for themselves using the Appraisal of Self-care Agency Scale (ASE) (at baseline, 3 and 9 months).</p> <p>The patients' self care behaviour using a Heart Failure Self-care Behaviour Scale, designed for this study (at baseline, 1, 3 and 9 months)</p> <p>Healthcare resource use:</p> <p>Patients' report of number and reason for contact with GP, cardiologist, medical specialists, physical therapists, social care providers and alternative health specialists.</p> <p>Hospital readmissions and out patient visits from hospital database.</p> <p>Reasons for readmission from patient charts.</p> <p>Also reported:</p>

	Deaths at 9 months.	
Notes	Data source: published data and author contacted for clarification (indicated by *) Generalisability: * Of 828 admissions to the ward with heart failure; 184 (22%) were readmissions; 66 patients were not screened and 14 died during screening. 564 (68%) patients met inclusion criteria; 352 of these (62%) were excluded; 40 (7% of 564) did not give informed consent, 186 (33% of 564, 22% of the 828 admissions) were randomised of whom 7 died before discharge	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"By drawing from an envelope patients were randomly assigned to receive either care-as-usual or the supportive-education intervention"
Allocation concealment (selection bias)	Unclear risk	no information in paper
Selective reporting (reporting bias)	Low risk	stated outcomes reported
Other bias	Unclear risk	<p>Risk of care giver performance bias: low; "Health care personnel (cardiologists or staff) involved in the care for the patients did not know if the patient was in the intervention or control group."</p> <p>Risk of attrition bias: possible, 186 patients enrolled in to the study and 132 (71%) remained at 9 months. 58/84 (69%) remained in the intervention group whilst 74/95 (78%) in the control group, NS, there was a trend towards more patients with NYHA IV dropping out. Analyses on self-care abilities and behaviour were adjusted in an attempt to compensate for the influence of attrition - this adjustment assumed that those who dropped out did not improve their self-care and self-agency from baseline this assumption may not have adequately adjusted for attrition.</p> <p>Risk of detection bias: high; the two study nurses who delivered the intervention were also involved in the study as data collectors and were aware of the allocation status of the patients</p>

Methods	<p>RCT, 17 centres</p> <p>Recruitment: Oct 23rd 2002 to February 2nd 2005</p> <p>Duration of follow up: 18 months</p>
Participants	<p>Country: Netherlands</p> <p>Total number randomised= 1049 (basic intervention n=348, intensive intervention n=353, control n=348) 26 died before discharge, leaving 1023 in the total group</p> <ul style="list-style-type: none"> • NYHA 1; intensive: 0 (0), basic: 0 (0), control: 0 (0) • NYHA 2; intensive: 165 (48), basic: 171 (51), control: 177 (54) • NYHA 3; intensive: 163 (48), basic: 159 (47), control: 139 (42) • NYHA 4; intensive: 13 (4), basic: 8 (3), control: 13 (4) <p>LVEF: intensive: 33 (SD 15), basic: 34 (SD 14), control: 34 (SD 14)</p> <p>Age: intensive: 70 (SD 12), basic: 71 (SD 11), control: 72 (SD 11)</p> <p>Percentage male: intensive: 61, basic: 66, control: 60</p> <p>Ethnicity: Not stated</p> <p>Inclusion/exclusion criteria:</p> <p><i>Inclusion:</i></p> <ul style="list-style-type: none"> • Patient admitted to hospital with heart failure NYHA functional class II- IV • Aged 18 years or older • Evidence of structural underlying heart disease as shown at cardiovascular imaging • Systolic and diastolic dysfunction (preserved LVEF) • Stable on standard HF medication before discharge <p><i>Exclusion:</i></p> <ul style="list-style-type: none"> • concurrent inclusion in another study or HF clinic • inability to complete the questionnaires • invasive procedure or cardiac surgery intervention performed within the last 6 months • such procedure or intervention planned to be performed within the next 3 months • ongoing evaluation for heart transplantation • inability or unwillingness to give informed consent
Interventions	<p>Duration of intervention: 18 months</p> <p>Intervention: disease management program</p> <p>basic intervention:</p> <ul style="list-style-type: none"> • During index hospital stay: patient (and family) education by HF nurse according to protocol and guidelines, behavioural strategies used to improve adherence • Within 2/52 of d/c telephone call to pt from HF nurse • During regular visits to cardiologist at the outpatient clinic (at 2, 6, 12 and 18 months after d/c) additional visits to HF nurse • additional visits just to the HF nurse at the outpatient clinic at one, 3, 9, & 15 months after d/c. • Telephone access to HF nurse Monday to Friday 9am -5 pm, patients (and families) encouraged to contact their nurse if any change in their condition or any questions. <p>intensive intervention:</p> <ul style="list-style-type: none"> • As for the basic intervention plus: • Home visit by HF nurse within 10 days of d/c to assess coping, CHF health status general health, and medical, health care and social support. Second home visit 11 months after discharge,

	<ul style="list-style-type: none">• Weekly telephone calls by the HF nurse in the first month after discharge then monthly calls.• Out of hours back up to provide 24 hour telephone coverage.• HF nurse to consults multidisciplinary team at least once during both index admission and once during follow up to optimise her advice for each patient. Control: standard management by cardiologist and, subsequently, GP	
Outcomes	Primary (18 months): <ul style="list-style-type: none">• Time to death (all cause) or hospitalisation because of heart failure (composite outcome)• Number of days lost to death or hospitalisation• number of readmissions per patient Secondary (18 months): <ul style="list-style-type: none">• death from any cause• hospitalisation because of HF• QoL• costs	
Notes	Data source: published data only Some differences in number of contacts with the cardiologist in all groups: 33% more cardiologist visits in control group 40% more cardiologist visits and phone calls in basic group 10% more cardiologist visits and phone calls in intensive group Generalisability: 2957 patients were assessed for eligibility, of whom 1131 (38%) met the inclusion criteria and were available for the study. However, 282 refused to take part, so 1049 patients (92.7% of eligible patients and 38% of screened patients) were randomised to the study	
<i>Risk of bias</i>		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	“The computer-generated randomisation scheme used random permuted blocks of 6 patients stratified per centre to ensure balanced assignment of patients to each of the 3 groups in each of the 17 participating centres.”
Allocation concealment (selection bias)	Unclear risk	No information in paper
Selective reporting (reporting bias)	Low risk	All outcomes fully reported on
Other bias	Low risk	“with blinded endpoint evaluation?”

Methods	<p>RCT, two centres</p> <p>Recruitment: December 1996 to December 1998.</p> <p>Duration of follow up: Six months from recruitment (plus additional three months)</p>
Participants	<p>Country: USA</p> <p>Participants: 102 patients (66 males, 65%) in intervention group, 98 (55 males, 56%) in comparison group.</p> <p>Actual age of study subjects at recruitment: median 63.5 years (range 25-88 years)</p> <p>Male sex: 61%</p> <p>Ethnicity: 'white' 64%</p> <p>Actual severity of heart failure in study subjects at baseline:</p> <p>NYHA class, n (%): controls II 33 (34%), III 60 (61%), intervention group II 38 (37%), III 57 (56%).</p> <p>LVEF: control group mean 27.5% (SD 13.9, range 5-60), intervention group 27.1% (SD 13.8, range 10-70)</p> <p>Study inclusion criteria:</p> <ol style="list-style-type: none"> 1. Admitted to one of two hospitals with a primary diagnosis of NYHA class III/IV CHF. 2. English speaking. 3. Permission from patient's 'primary physician' 4. Judged to be at high risk of CHF readmission, i.e. one or more of the following criteria: <ul style="list-style-type: none"> "Age >70 years. "LVEF <35%. "One or more other hospital admission for CHF in previous year. "Ischaemic cardiomyopathy. "Peripheral oedema at hospital discharge. "Less than 3kg weight loss while in the hospital. "Peripheral vascular disease. 5. Or any one of the following during the index admission: <ul style="list-style-type: none"> "Pulmonary capillary wedge pressure >25 mmHg. "Cardiac index <2.0 l/min/m². "SBP >180 mmHg. "DBP >100 mmHg. <p>Study exclusion criteria:</p> <ol style="list-style-type: none"> 1. Valvular heart disease requiring surgery. 2. Active substance abuse. 3. Cardiomyopathy (peripartum, hypertrophic with LV outflow tract obstruction or restrictive). Constrictive pericarditis. 4. Psychiatric disease. 5. Dementia likely to limit compliance. 6. Non-cardiac illness likely to cause repeat hospital admission. 7. Heart transplantation likely to occur within six months. 8. Uncorrected thyroid disease. 9. Serum creatinine => 3.0 mg/dl. 10. Long term home intravenous inotropic therapy. 11. Cardiac surgery or MI during the index admission. 12. Active participation in another research trial. 13. Residence in a nursing home, rehabilitation facility or outside the area served by the

	two hospitals
Interventions	<p>Duration of intervention: 6 months.</p> <p>Intervention Group: 'multidisciplinary program'</p> <p>During index hospitalisation:</p> <p>CHF cardiologist designed an individualised treatment plan for each patient before randomisation which included medication, diet and exercise management</p> <p>After discharge:</p> <p>'Telephone nurse co-coordinator' phoned patients within 72 hours of discharge and then weekly for 1st month, bi-weekly in 2nd month and then monthly. (Content of phone calls: set script with problems pursued as clinically indicated . No medication adjustments over phone.)</p> <p>Monthly follow up with CHF nurses (usually in CHF clinic).</p> <p>'Primary care physicians' (66% internal medicine physicians, 29% cardiologists) received regular updates from CHF nurses and were notified of abnormal lab results.</p> <p>All intervention patients received: pill sorter, list correct medications, list of dietary and exercise recommendations, 24 hour telephone contact number and patient educational material.</p> <p>If required and financial resources limited patients also received: 3g sodium 'Meals on Wheels' diet, weigh scale, medications, transport to the clinic and a phone.</p> <p>CHF cardiologist saw patients at 6 months.</p> <p>Content of CHF nurse follow up:</p> <p>aimed to implement the treatment plan designed by CHF cardiologist by using a pre-specified 55 page algorithm (also designed by the CHF cardiologists) which included initiation and titration of drugs, a low sodium diet and exercise recommendations</p> <p>Comparison group: Usual care.</p> <p>This was care by the patients' primary physicians (73% internal medicine physicians, 26% cardiologists). CHF cardiologist designed treatment plan for each patient "documented in patient's chart without further intervention"</p>
Outcomes	<p>Primary endpoint (6 months):</p> <p>Total number of CHF hospital admissions plus all cause deaths (i.e. composite endpoint)</p> <p>Secondary outcomes (6 months):</p> <p>Death.</p> <p>CHF hospital admissions.</p> <p>All cause hospital admissions.</p> <p>Change in HRQOL (MLHFQ).</p> <p>Change in activity status (Duke Activity Status Index).</p> <p>Process indicators including: proportion of patients with systolic dysfunction receiving ACEI according to published guidelines or appropriate alternative treatment if intolerant of ACEI; percentage patients euvolemic according to defined goal weight; compliance with dietary guidelines using locally developed sodium score and cost data</p>
Notes	<p>Data source: published data and information supplied by author*</p> <p>Generalisability: 1,452 patients with heart failure were screened, (screened patients were not consecutive admissions*); 976 (67% of those screened) met inclusion criteria of whom 686 (70%) had one or more exclusion criteria; of the remaining 290 eligible subjects 90* (31%) refused to participate</p>

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The coordinating centre made treatment assignments by using an automated telephone response system"
Allocation concealment (selection bias)	Low risk	"Random number schedules were prepared before initiation of patient recruitment and were unknown to the clinical investigators"
Selective reporting (reporting bias)	Low risk	All outcomes fully reported on.
Other bias	Low risk	Care giver performance bias: physicians providing usual care were aware of study and knew that their patient had not been allocated to the intervention so possible Hawthorn effect on care received by the usual care group. *Also 10 % of these physicians had other patients allocated to the intervention arm which may also have influenced their usual care. The effect of both of these influences would be to underestimate the effect of the intervention. Risk of attrition bias: low. Risk of detection bias: low for main outcomes.

Kimmelstiel 2004

Methods	Multicentre RCT (6 centres) Recruitment period: 22 months, dates not stated Duration of follow up: 12 months
Participants	Country: USA N Randomised: 200 (control n=97, intervention n=103) NYHA: <ul style="list-style-type: none"> • NYHA 1 (%); Control: (1.9), Intervention: (0) • NYHA 2 (%); Control: (58.3), Intervention: (50.5) • NYHA 3 (%); Control: (35.9), Intervention: (49.5) • NYHA 4 (%); Control: (3.9), Intervention: (0) LVEF: Control: 31 (SD 12), Intervention: 30 (SD 14) Age: Control: 73.9 (SD 10.7), Intervention 70.3 (SD 12.2) Percentage male: Control: 58.3, Intervention: 57.7 Ethnicity: : Not stated Inclusion/exclusion criteria: Inclusion:

	<ul style="list-style-type: none"> Patients were enrolled during an index HF hospitalisation or within 2 weeks of discharge. Patients with HF resulting from ischemic heart disease, dilated cardiomyopathy, valvular heart disease (either surgically treated or deemed inoperable), or hypertensive heart disease. <p><i>Exclusion:</i></p> <ul style="list-style-type: none"> noncardiac debilitating illness such as active malignancy severe liver disease severe renal insufficiency (creatinine ≥ 3.0 mg/dL) dementia obstructive lung disease requiring hospitalisation angina at rest or as the principal cause of activity limitation myocardial infarction or revascularization procedure during the index hospitalisation or within the preceding 30 days planned revascularization or valvular surgery restrictive myopathy pericardial constriction hypertrophic cardiomyopathy
Interventions	<p>Duration of intervention: 90 days, followed by passive surveillance (nurse-manager available for incoming calls but didn't make scheduled calls) for clinically stable patients or continuation for patients with overt clinical instability (class A)</p> <p>Intervention: Specialized Primary and Networked Care in HF (SPAN-CHF)</p> <ul style="list-style-type: none"> Home visit from nurse-manager within 3 days of discharge, focusing on dietary and medical compliance, daily weights, self-monitoring, and early reporting of changes in weight or clinical status. Teaching tool 'Patient and Family Handbook' given to patients during home visit, including sections on HF (definition), medications, low-salt diet, importance of daily weight, and clinical signs and symptoms that should prompt a call to the SPAN-CHF nurse or primary care physician (plus contact phone numbers). During home visit, nurse performed cardiovascular examination and symptom assessment. Weekly or biweekly phone calls from nurse-manager to patients focused on identifying changes in clinical condition and education reinforcement. Patients had 24-hr 7-day telephone access to nurse managers, and were instructed to report changes in clinical status and relevant weight change. Frequent communication between nurse-managers, primary care physicians and HF specialist. <p>Comparator: usual care</p>
Outcomes	<p>Primary:</p> <ul style="list-style-type: none"> hospitalisations for HF during the first 90 days after enrolment <p>Secondary (90 days):</p> <ul style="list-style-type: none"> cardiac hospitalisations and all-cause hospitalisations number of days hospitalised per patient-year of follow-up for HF, cardiac and all-cause hospitalisations at one year
Notes	<p>Data source: published data only</p> <p>Generalisability: the paper does not contain information on the numbers of patients</p>

	screened or eligible for the study, only the number randomised (n=200)	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	“Randomization lists were generated independently for each hospital (in blocks of 4 patients), stratifying patients first by level of care needed.”
Allocation concealment (selection bias)	Unclear risk	no information in paper
Selective reporting (reporting bias)	Unclear risk	All outcomes reported, but not clear whether ITT analysis was used as numbers included in analysis not stated
Other bias	Low risk	“Non-nurse study coordinators, blinded to treatment assignment, performed telephone follow-up in all patients at 3 and 12 months after enrolment to ascertain clinical events. Events were adjudicated by an investigator blinded to treatment group.”

Krumholz 2002

Methods	RCT, single centre Recruitment period: October 1997 to September 1998. Duration of follow up: one year.
Participants	Country: USA Participants: 44 patients (29 males, 66%) in comparison group, 44 (21 males, 48%) in intervention group. Actual age of study subjects: median age 74 years, controls mean age 71.6 (SD 10.3), intervention 75.9 (SD 8.7) Males: 57% Ethnicity: '74% Caucasians' Actual severity of heart failure in study subjects at recruitment: Mean ejection fraction: control group 37% (SD 16), intervention group 38% (SD 17). NYHA: not given Study inclusion criteria: 1. Age 50 or over 2. Needed to have either admission diagnosis of heart failure or radiological signs of heart failure on admission chest x-ray. All patients had been hospitalised for HF 3. Reviewed within three days to verify additional set of criteria derived from NHANES-1 Study exclusion criteria: 1. Patients transferred from other hospitals or nursing homes.

	2. Patients with HF secondary to high output states or non-cardiac disease. 3. Patients with another terminal illness (e.g. expected survival < 6/12)	
Interventions	Duration of intervention: one year Intervention: 'Education and Support' After discharge: Initial hour long face to face consultation with experienced cardiac nurse within two weeks of discharge using a teaching booklet (45% of these consultations took place in patient's home, remainder in hospital clinic). Following this weekly telephone contact for four weeks, bi-weekly for eight weeks then monthly until one year Initial consultation covered five sequential care domains for chronic illness including: patient knowledge of illness; the relation between medication and illness; the relation between health behaviours and illness; knowledge of early signs and symptoms of decompensation, and where and when to obtain assistance. Follow up phone calls reinforced the five care domains but did not modify current regimens or provide recommendations about treatment. However the nurse could recommend that the patient consulted his/her physician when the patient's condition deteriorated sharply or when the patient had problems, in order to help patients to understand when and how to seek and access care Comparison: usual care. All usual care treatments and services ordered by their physicians	
Outcomes	Primary endpoint: readmission or death at 12 months follow up. Secondary endpoints (12 months follow up): All cause admissions. HF related or other CVD related readmissions. Cumulative number of days in hospital. Cost of readmission.	
Notes	Data source: published data and information from author*. Generalisability: 390 consecutive admissions who met clinical criteria for HF screened, 142(36%) eligible and a further 34 eligible but not enrolled, 20 (5%) patient, physician or family refusal to participate, 88 (23% of those screened) enrolled in the study	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	computer generated**
Allocation concealment (selection bias)	Unclear risk	no information in paper
Selective reporting (reporting bias)	Low risk	stated outcomes reported
Other bias	Low risk	Comment on risk of care giver performance bias: low, care givers were not informed of patient's involvement in the study by the

		<p>researchers*.</p> <p>Risk of attrition bias: unclear</p> <p>Risk of detection bias: low, record examinations to confirm events and classify cause done by a clinician masked to patient's intervention allocation</p> <p>ITT analysis</p>
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Kwok 2008

Methods	<p>RCT, 2 centres</p> <p>Recruitment: September 1999 - February 2001</p> <p>Duration of follow-up: 6 months</p>
Participants	<p>Country: China (Hong Kong)</p> <p>N Randomised: 105 (intervention n=49, control n=56)</p> <p>NYHA not stated</p> <p>LVEF <40% : 15 (30%) (control, n=50); 9 (18%) (intervention, n=43)</p> <p>Age (years): Control: 76.8 (SD 7.0), Intervention: 79.5 (SD 6.6)</p> <p>Percentage male: Control: 45, Intervention: 45</p> <p>Ethnicity: not stated</p> <p>Inclusion/exclusion criteria:</p> <p><i>Inclusion:</i></p> <ul style="list-style-type: none"> • hospitalised with a principal diagnosis of CHF • age older than 60 • residing within the region and had at least one hospital admission for CHF in the 12 months prior to the index admission. <p><i>Exclusion:</i></p> <ul style="list-style-type: none"> • communication problems but without caregivers • residing in a nursing home • terminal disease with a life expectancy of less than six months
Interventions	<p>Duration of intervention: 6 months</p> <p>Intervention:community nurse-supported hospital discharge programme</p> <ul style="list-style-type: none"> • community nurse (CN) visited patients prior to discharge, to provide health counselling, information on drug compliance, dietary advice • home visit by CN within 7 days of discharge, then weekly for 4 weeks, then monthly, to check vital signs and signs of poorly controlled CHF (ankle swelling, dyspnoea and basal crepitation on auscultation). Medications checked and dietary/exercise advice given. • home care and day care services arranged if social support insufficient • patients encouraged to contact CN via a telephone hotline during office hours when they developed symptoms • following liaison with geriatrician or cardiologist, CN able to alter medication, arrange appointments and clinical admission as appropriate • CN monitored patients refusing further home visits by telephone <p>Control:usual medical and social care, but with follow-up in the hospital outpatient clinics by the same group of designated geriatricians or cardiologists</p>

Kwok 2008 (Continued)

Outcomes	Primary: <ul style="list-style-type: none">percentage of subjects who ever had unplanned hospital readmissions within six calendar months of discharge Secondary (6 months): <ul style="list-style-type: none">number of unplanned hospital readmissionschanges in six-minute walking testLondon Handicap Scale (LHS) domain scores	
Notes	Data source: published data only Generalisability: the paper does not contain information on the numbers of patients screened or eligible for the study, only the number randomised (n=105)	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The ward nurses then phoned a second research assistant who assigned trial grouping according to a random number table."
Allocation concealment (selection bias)	Low risk	see above
Selective reporting (reporting bias)	Low risk	all outcomes reported on
Other bias	Low risk	"The RN was not aware of the randomisation grouping of the subjects."

Lopez 2006

Methods	<p>RCT, 2 centres</p> <p>Recruitment: September 2000 to August 2002</p> <p>Duration of follow-up: 1 year</p>
Participants	<p>Country: Spain</p> <p>N Randomised: 134 (control n=64, intervention n=70)</p> <p><i>NYHA</i>:</p> <ul style="list-style-type: none"> NYHA 1-2 (%); Control: 54 (87.1), Intervention: 58 (84.1) NYHA 3-4 (%); Control: 8 (12.9), Intervention: 11 (15.9) <p><i>LVEF</i>: Control: 47.4 (SD 17.3), Intervention: 54.5 (SD 14.4)</p> <p>Age: Control: 76.1 (SD 9.4), Intervention: 75.3 (SD 8.4)</p> <p>Percentage male: Control: 46.9, Intervention: 41.4</p> <p>Ethnicity: Not stated</p> <p>Inclusion/exclusion criteria:</p> <p><i>Inclusion</i>:</p> <ul style="list-style-type: none"> patients admitted to the General Hospital of Vic and the Municipal Hospital of Badalona for heart failure (HF) who met 2 major or 1 major and 2 minor Framingham criteria

	<i>Exclusion:</i> <ul style="list-style-type: none">regularly living out of the area of influence of the hospitalregularly living in an old people's homemoved to a social-health centre or to other centres for acute patientssuffering any type of dementia or disabling psychiatric diseaserefusing to participate in the study	
Interventions	Duration of intervention: 12 months Intervention: Active Information Program, carried out by a pharmacist with 2 key components: 1. Information -personal interview on day of discharge, covering information about the disease, diet education, information on drug therapy and the need for compliance 2. Telephone support - patients given pharmacist's name and phone number, and encouraged to contact about any doubts arising during treatment, or questions about the disease. Monthly during the 1st 6 months and every 2 months thereafter, patients received home phone calls (not clear from who) to reinforce the intervention and solve any problems or questions arising Comparison: No details given. Follow-up visits at 2, 6 and 12 months to check compliance, QoL and patient satisfaction	
Outcomes	Primary (2,6 and 12 months): <ul style="list-style-type: none">time to the first readmission for heart failure or for another causepercentage of patients with readmissiontotal number of readmissionstotal of hospital stay days during the study period. Secondary (2,6 and 12 months): <ul style="list-style-type: none">treatment compliance (not reported here)quality of life (EuroQol)patient satisfaction with the care received and death during the follow-up (not reported here)	
Notes	Data source: published data only Generalisability: It is not clear how many of the 339 screened patients were eligible for inclusion into the study, but only 134 (39.5%) were randomised	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The patients were randomised to one of the two groups through a randomisation software. Lists were generated in blocks of 4 to assure a consistent patient distribution in both groups."

Lopez 2006 (Continued)

Allocation concealment (selection bias)	Low risk	“Neither the physician nor the nurse responsible for the patient knew the allocation until the educational intervention, the day of discharge”
Selective reporting (reporting bias)	Low risk	All stated outcomes reported.
Other bias	Unclear risk	Not clear if readmissions reported on an ITT basis.

Mejhert 2004

Methods	RCT, single centre Recruitment: January 1996 and December 1999 Mean (SD) follow up: 1122 (405) days
Participants	Country: Sweden N Randomised: 208 (control n=105, intervention n=103) <i>NYHA</i> : <ul style="list-style-type: none"> • NYHA 2; Control: 69 (66%), Intervention: 60 (58%) • NYHA 3; Control: 34 (32%), Intervention: 43 (42%) • NYHA 4; Control: 2 (2%), Intervention: 0 (0%) <i>LVEF (%)</i> :Control: 35 (SD 11), Intervention: 34 (SD 12) Age: Control: 75.7 (SD 6.6), Intervention: 75.9 (SD 7.7) Percentage male: Control: 59, Intervention: 56 Ethnicity: Not stated Inclusion/exclusion criteria: <i>Inclusion</i> : <ul style="list-style-type: none"> • All patients 60 years of age or older hospitalised with heart failure according to New York Heart Association (NYHA) class II - IV and left ventricular systolic dysfunction by echocardiography <i>Exclusion</i> : <ul style="list-style-type: none"> • acute myocardial infarction or unstable angina pectoris within the previous three months • valvar stenosis • dementia • severe concomitant disease • refusal to participate
Interventions	Duration of intervention: at least 18 months, mean follow up was 1122 (405) days Intervention: “nurse based outpatient management programme” <ul style="list-style-type: none"> • regular visits to the outpatient clinic and patient encouraged to keep contact with nurse (not clear how regular) • nurse checking symptoms and signs of heart failure, blood pressure, heart rate, and weight at each visit • nurses can institute and change medication doses according to standard protocol • patient instructed to check weight regularly and monitor early signs of deterioration

	<ul style="list-style-type: none"> patients with good compliance instructed to change dosing of diuretics on their own. dietary advice recommends restricted sodium, fluid, and alcohol intake information repeated in booklets and computerised educational programmes <p>Control group: treated by GPs according to local health care plan for heart failure. All patients had clinical examinations and detailed control of medication at 6, 12, and 18 months at the Cardiovascular Research Laboratory</p>
Outcomes	<p>Primary:</p> <ul style="list-style-type: none"> QoL (6, 12 and 18 months) <p>Secondary:</p> <ul style="list-style-type: none"> cardiac function (not reported?) medication (6, 12 and 18 months) hospitalisation (18 months) mortality (18 months)
Notes	<p>Data source: published data only</p> <p>Generalisability: 285 patients were screened for eligibility. 250 (73% were eligible for the study, of whom 208 (83.2%) agreed to take part and were available to be randomised</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Paper states "patients were enrolled and underwent random assignment" but gives no further details on method
Allocation concealment (selection bias)	Unclear risk	no information in paper
Selective reporting (reporting bias)	Unclear risk	Cardiac function stated as a secondary outcome, but doesn't appear to be reported
Other bias	Low risk	no other apparent sources of bias

Naylor 2004

Methods	<p>Multicentre RCT (6 centres)</p> <p>Recruitment: February 1997 - January 2001</p> <p>Follow-up: 1 year</p>
Participants	<p>Country: USA</p> <p>Participants: N Randomised = 239 (control n=121, intervention n=118)</p> <p><i>NYHA</i>:</p> <ul style="list-style-type: none"> Not stated <p>Documented ejection fraction, n (%) intervention 88 (72) / control 98 (80)</p> <p><20% 12 (14) / 17 (17) p=0.755</p> <p>20 to <25% 10 (11) / 9 (9) p=0.760</p>

	<p>25 to <35% 28 (32) / 30 (30) p=0.914 35 to <45% 26 (30) / 28 (28) p=0.942 45% or more: 12 (14) / 14 (14) p=1.00 Age: Control: 75.6 (SD 6.5), Intervention: 76.4 (SD 6.9) Percentage male: Control: 44, Intervention: 40 Ethnicity: Control: 62% White, Intervention: 66% White. Remainder of patients African American Inclusion/exclusion criteria: <i>Inclusion:</i></p> <ul style="list-style-type: none"> all patients aged 65 and older admitted to study hospitals from their homes between February 1997 and January 2001 with a diagnosis of heart failure (diagnosis-related group 127 validated at discharge) were screened for participation speak English be alert and oriented be reachable by telephone after discharge reside within a 60-mile radius service area of the admitting hospital <p><i>Exclusion:</i></p> <ul style="list-style-type: none"> end-stage renal disease
Interventions	<p>Duration of intervention: 3 months Intervention: transitional care delivered by 3 advanced practice nurses (APNs), who received standardised training before the study commenced (1) Quality-Cost Model of APN Transitional Care management strategies, including: i) identification of patients' and caregivers' goals; ii) individualized plans of care developed and implemented by APNs in collaboration with patients' physicians; iii) educational and behavioral strategies to address patients' and caregivers learning needs; iv) continuity of care and care coordination across settings (2) evidence-based protocol, guided by national heart failure guidelines, included:</p> <ul style="list-style-type: none"> APN discharge planning initial APN visit within 24 hours of index hospital admission, and at least daily during the index hospitalisation for comprehensive assessment of patients and carers ≥ 8 APN home visits (one within 24 hours of discharge), weekly during the first month then bimonthly during 2nd and 3rd months to check clinical status additional APN visits based on patients' needs APN telephone availability 7 days per week (8 a.m. to 8 p.m., weekdays; 8 a.m. to noon, weekends) if readmission to hospital required during 1st 3 months, APN resumed home visits APNs had email/phone access to multidisciplinary team for consultation of cases as required APNs collaborated with each patient's physician regarding adjustments in medications and other therapies or worked under specific guidance from physician self management of symptoms was promoted by APNs teaching patients and caregivers about early symptom recognition and effective treatment, such as the use of as-needed diuretics taped teaching material was left with patients <p>Comparators: routine care (including site-specific discharge planning and clinical paths) and standard home agency care if referred, consisting of comprehensive skilled home</p>

	health services 7 days a week. On-call registered nurse available 24 hrs/day. 58% of control patients received skilled nursing or physical therapy after index discharge
Outcomes	<p>Primary:</p> <ul style="list-style-type: none"> time to first readmission or death during 52 weeks <p>Secondary (52 weeks follow-up):</p> <ul style="list-style-type: none"> time to first readmission total rehospitalisations quality of life functional status patient satisfaction medical costs cumulative days of rehospitalisation mean readmission LoS no. of unscheduled acute care visits after discharge other treatments and healthcare utilisation cost of post index hospitalisation readmission
Notes	<p>Data source: published data only</p> <p>Generalisability: Of 641 patients screened, 239 (37.3%) were enrolled in the study. It is not clear how many of the screened patients were eligible but did not wish to take part</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"research assistants (RAs) blinded to study aims and groups obtained baseline sociodemographic and health status data and notified the project manager, who assigned patients to study groups using a computer-generated, institution-specific block 1:1 randomisation algorithm."
Allocation concealment (selection bias)	Low risk	as above
Selective reporting (reporting bias)	Low risk	all stated outcomes reported
Other bias	Low risk	ITT analyses, patients similar at baseline and no other apparent sources of bias

Nucifora 2006

Methods	<p>RCT, single centre</p> <p>Recruitment: March 1999 to January 2001</p> <p>Duration of follow up: 6 months</p>
Participants	<p>Country: Italy</p> <p>N Randomised: 200 (control n=101, intervention n=99)</p> <p><i>NYHA:</i></p> <ul style="list-style-type: none"> • NYHA 1; Control: 2 (2), Intervention: 0 (0) • NYHA 2; Control: 37 (37), Intervention: 33 (33) • NYHA 3; Control: 61 (61), Intervention: 63 (64) • NYHA 4; Control: 1 (1), Intervention: 3 (3) <p><i>LVEF:</i>Control: 43 (SD 19), Intervention: 43 (SD 16)</p> <p>Age: Control: 73 (SD 8), Intervention: 73 (SD 9)</p> <p>Percentage male: Control: 62, Intervention: 62</p> <p>Ethnicity: Not stated</p> <p>Inclusion/exclusion criteria:</p> <p><i>Inclusion:</i></p> <ul style="list-style-type: none"> • Aged 85 or younger • admitted to internal medicine department with a diagnosis of HF during recruitment period • HF diagnosed by 2 major or 1 major and 2 minor Frammingham criteria <p><i>Exclusion:</i></p> <ul style="list-style-type: none"> • Chronic cor pulmonale • Terminal illness in addition to HF • Severe dementia or other psychiatric illness • Indication for surgical therapy in the next 6 months • Refusal to participate
Interventions	<p>Duration of intervention: 6 months</p> <p>intervention: "HF management programme"</p> <ul style="list-style-type: none"> • pre discharge intensive education by an experienced cardiovascular research nurse using a teaching booklet, covering causes of HF, recognition of symptoms of worsening HF, the role of sodium restriction and pharmacological therapy, the importance of fluid and weight control, physical activity and complete abstinence from alcohol and smoking. • phone call from nurse 3-5 days post discharge to assess any problems, promote self management and check compliance, weight and lifestyle issues • patients had telephone access from 8.00 to 9.00am, Monday to Friday, and out of hours answering machine • outpatient visits to doctor at 15 days, 1 and 6 months after discharge, to evaluate test results, physical condition and medicine adherence and make any required changes to drug therapy <p>Control:</p> <ul style="list-style-type: none"> • pre-existing routine of post-discharge care; i.e. usual care by primary care physician • outpatient visit to doctor at six months after discharge
Outcomes	<p>Primary:</p> <ul style="list-style-type: none"> • All cause readmissions at 6 months • All cause deaths at 6 months

	Secondary (6 months): <ul style="list-style-type: none">● Event free survival● Days of unplanned readmissions● Number of unplanned outpatient visits● Patients clinical status● Compliance● Adherence to treatment plan● Quality of life	
Notes	Data source: published data only Generalisability: the paper does not contain information on the numbers of patients screened or eligible for the study, only the number randomised (n=200)	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Paper states: Patients were randomly assigned to receive either the study intervention or the usual care“ but gives no details on method of randomisation
Allocation concealment (selection bias)	Unclear risk	no information in paper
Selective reporting (reporting bias)	Low risk	all stated outcomes reported
Other bias	Unclear risk	Statistically significantly more patients in the intervention group were in sinus rhythm compared to control group (73% vs 52%, p=0.06). More patient in control group had previous CABG compared to intervention group (13% vs 5%, p=0.059)

Rainville 1999

Methods	RCT, single centre Recruitment: July 1996 to June 1997 Duration of follow up: 12 months
Participants	Country: USA Participants: 17 patients (9 53% males) in comparison group, 17 (8 males 47%) in intervention group, Actual age of study subjects: control group mean 72.8 years (SD 10.7), intervention group 66.9 (SD 8.7). Male sex: 50% Ethnicity: not given Actual severity of heart failure in study subjects at recruitment: NHYA class, n, (%): control group II 4 (24%), III 11 (65%), IV 2 (10%), intervention

	<p>group II 1 (6%), III 12 (71%), IV 4 (24%).</p> <p>LVEF: not given.</p> <p>Study inclusion criteria:</p> <ol style="list-style-type: none"> 1. All patients with heart failure in their admission diagnoses and with a history of heart failure. 2. Age 50 years or older. <p>Study exclusion criteria:</p> <ol style="list-style-type: none"> 1. "A more significant concomitant disease (e.g. unstable angina, cardiac arrhythmia, COPD). 2. Living in long-term care facility. 3. Significant psychiatric illness. 4. Long term renal dialysis. 5. Life expectancy < 3 months. 6. No home phone. 7. Had a language barrier.
Interventions	<p>Duration of intervention: 90 days</p> <p>Intervention Group: 'pharmacist intervention'</p> <p>During index hospitalisation:</p> <p>"Routine care plus pharmacist and clinical nurse specialist identified patient issues which posed risk for rehospitalisation and determined corrective action."</p> <p>Before discharge the pharmacist reviewed pathology and treatment of HF, weight monitoring and risk modifications with the patient or caregiver.</p> <p>Patient given information brochure, video, weight log and medication organiser.</p> <p>Pharmacist also recommended medication changes to physicians.</p> <p>After discharge:</p> <p>Pharmacist phoned within three days of discharge, and at 7, 30, and 90 days and 12 months to enquire about any readmissions, respond to questions, reinforce information given before discharge.</p> <p>Pharmacist's phone number provided to patients for further support</p> <p>Comparison Group: usual care</p> <p>Routine care and preparation for discharge including: written prescription, physician discharge instructions, nurse review of diet, treatment plans and medications; patients provided with computer generated drug information sheets.</p> <p>At 30, and 90 days and 12 months pharmacist contacted patients to ask about readmissions</p>
Outcomes	<p>Primary endpoint: hospital readmission for heart failure or death (composite endpoint) at 1 year</p>
Notes	<p>Data source: published data and information from author*</p> <p>Generalisability: *Of 377 patients whose admission history included HF, 42 refused consent (11%) and 42 (11%) were eligible and provided informed consent (3 patients then became ineligible during index admission, 1 patient lost to follow up). Data on these four patients were excluded</p>
<i>Risk of bias</i>	
Bias	<p>Authors' judgement</p> <p>Support for judgement</p>

Rainville 1999 (Continued)

Random sequence generation (selection bias)	Low risk	computer generated*
Allocation concealment (selection bias)	Unclear risk	"Information on patient randomisation was concealed from the patient and all care givers except for the pharmacists involved in the study". It is not clear who was responsible for allocation
Selective reporting (reporting bias)	Low risk	all stated outcomes reported
Other bias	Unclear risk	Analysis done on intention to treat basis: No* Risk of care giver performance bias: low* Risk of attrition bias: low Risk of detection bias: high

Stewart 1999a

Methods	RCT, single centre Recruiting: March 1997 to May 1998 Duration of follow up: 6 months
Participants	Country: Australia Participants: 100 patients (59 males) in comparison group, 100 (65 males) in intervention group, Actual age of study subjects: control group mean 76.1 years (SD 9.3), intervention group 75.2 years (SD 7.1) years Male sex: 62% Ethnicity: not given Actual severity of heart failure in study subjects at recruitment: NYHA class, n,: control group II 48, III 43, IV 9, intervention group II 42, III 46, IV 12 LVEF: control group mean 37% (SD 11), intervention group 37% (SD10) Study inclusion criteria: 1. Admitted to tertiary care hospital under cardiologist and at least one previous admission for acute heart failure (pulmonary congestion or oedema evident on CXR with acute dyspnoea at rest). 2. NYHA class II-IV. 3. LVEF =< 55%. 4. Age =>55 years. 5. To be discharged home. 6. Lives within hospital catchment area. Study exclusion criteria: 1. Terminal disease. 2. Valvular disease suitable for surgery. 3. Intended heart transplantation.

	<p>4. Heart failure precipitated by extensive, reversible ischaemia.</p> <p>5. Home address outside hospital catchment area.</p>
Interventions	<p>Duration of intervention: mainly within 2 weeks of discharge but some phone contact throughout study</p> <p>Intervention Group: Usual care plus 'Multidisciplinary, home-based intervention'</p> <p>After discharge:</p> <p>Comprehensive assessment at home by a cardiac nurse 7-14 days after discharge.</p> <p>After home visit nurse sent report to primary care physician and cardiologist.</p> <p>Cardiac nurse arranged a flexible diuretic regimen for patient's weight and symptoms if required.</p> <p>Phone call by cardiac nurse to patient contact at 3 and 6 months.</p> <p>Patients encouraged to contact the nurse if any problems arose.</p> <p>Home visits repeated if a patient had two or more unplanned readmissions within 6 months of index admission</p> <p>Home visit included:</p> <p>assessment of clinical status, physical activity, adherence to medication, understanding of disease, psychosocial support and use of community resources.</p> <p>Followed by (as appropriate):</p> <p>'remedial counselling' to patients and their families,</p> <p>strategies to improve adherence,</p> <p>simple exercise regimen,</p> <p>incremental monitoring by family/carers,</p> <p>urgent referral to 10 care physician.</p> <p>(Median duration of visit = 2 hr (range 1-3.5hr)).</p> <p>Comparison Group: usual care</p> <p>All study patients could be referred to cardiac rehab nurse, dietician, social worker , pharmacist and community nurse as appropriate. All patients had appointment with their primary care physician and/or cardiology outpatient service within 2 weeks of discharge. Regular outpatient review by the cardiologist was undertaken throughout the follow up period</p>
Outcomes	<p>Primary endpoint:</p> <p>Frequency of unplanned readmissions plus all cause out-of-hospital deaths (i.e. composite endpoint) during 6 months follow up</p> <p>Other endpoints (6 months):</p> <p>Time to first primary endpoint (event-free survival).</p> <p>Frequency of unplanned readmissions.</p> <p>Days of unplanned readmissions.</p> <p>All cause deaths.</p> <p>Out of hospital deaths.</p> <p>Cost of hospital and community based health care sample of patients only)</p> <p>Random sample of patients only: Minnesota living with heart failure questionnaire and Australian version of SF-36 at baseline, 3 & 6 months</p>
Notes	<p>Data source: published data only</p> <p>Generalisability: Of 4055 cardiology inpatients screened over 14 month period only 285 (7%) were clinically eligible, 200 (70%, 5% of 4055) participated, 59 (21%) met at least one exclusion criteria and 26 (11%) refused consent or died before discharge</p>

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Telephone call to an investigator who was unaware of the patient's demographic and clinical profile, who then allocated the individual [to group] via a computer generated protocol."
Allocation concealment (selection bias)	Low risk	See above.
Selective reporting (reporting bias)	Low risk	All stated outcomes reported.
Other bias	Unclear risk	<p>"The two groups were well matched for all but number of admissions for acute heart failure and creatinine concentration at hospital discharge."</p> <p>Risk of care giver performance bias: high, as part of the intervention patient's primary care physician and cardiologist received a report on the patients' home assessment and any actions taken or recommended.</p> <p>Risk of attrition bias: low, all analyses ITT</p> <p>Risk of detection bias: low - all data collection and analysis was done "with masking maintained" assume means they were masked to patients' intervention/usual care group status</p>

Stromberg 2003

Methods	<p>Multicentre RCT (3 centres)</p> <p>Recruitment: June 1997 to December 1999</p> <p>Follow up: 12 months</p>
Participants	<p>Country: Sweden</p> <p>N Randomised: 106 (control n= 54, intervention n=52)</p> <p>NYHA:</p> <ul style="list-style-type: none"> • NYHA 1; Control: 0 (0), Intervention: 0 (0) • NYHA 2; Control: 12 (22), Intervention: 7 (13) • NYHA 3; Control: 36 (67), Intervention: 39 (75) • NYHA 4; Control: 6 (11), Intervention: 6 (12) <p>LVEF: Not stated</p> <p>Age: Control: 78 (SD 6), Intervention: 77 (SD 7)</p> <p>Percentage male: Control: 32/54 (59%), Intervention: 33/52 (63%)</p> <p>Ethnicity: Not stated</p>

	<p><i>Inclusion:</i></p> <ul style="list-style-type: none"> • Diagnosed heart failure, either by echocardiography, radiographic evidence of pulmonary congestion or typical symptoms and signs of heart failure. • All patients had been hospitalised for HF. <p><i>Exclusion:</i></p> <ul style="list-style-type: none"> • severe chronic pulmonary disease • dementia or other psychiatric illness • short anticipated survival • discharge to a geriatric clinic or home care • already receiving follow-up at the nurse-led heart failure clinic
Interventions	<p>Duration of intervention: not clear</p> <p>Intervention: nurse led HF clinic</p> <ul style="list-style-type: none"> • 1st visit 2-3 weeks after discharge, nurses evaluated status, assessed treatment and provided education about HF and social support • individualised education included both written and verbal information, and was based on guidelines. It included information on HF, treatment, dietary advice, individually adjusted energy intake advice, lifestyle advice (including exercise), and promoted self-management • nurses contactable by phone during office hours, Monday-Friday, and nurses called patients to provide psychosocial support and evaluate drug changes required • heart failure nurses called patients in order to provide psychosocial support, evaluate drug changes or other actions • extra appointments to attend HF clinic scheduled for patients unstable with symptoms of worsening heart failure or if further education was needed • patients referred back to primary health care once they were stable and well informed <p>Control: conventional follow-up in primary health care. Some patients got a scheduled visit after discharge, but most were encouraged to phone primary health care if they had problems due to heart failure</p>
Outcomes	<p>Primary:</p> <ul style="list-style-type: none"> • all-cause mortality or all-cause hospital admission after 12 months. <p>Secondary (12 months):</p> <ul style="list-style-type: none"> • mortality due to CV disease or other • number of readmissions for any reason • number of days in hospital • self-care behaviour
Notes	<p>Data source: published data only</p> <p>Generalisability: 1964 patients were assessed for eligibility, of whom only 161 (5.4%) were eligible. 106 (65.8%) of eligible patients were randomised. The authors attribute the low eligibility rate to procedural changes at the participating hospitals that meant that many patients already received follow-up at the nurse-led heart failure clinic or were discharged to the geriatric clinic or home care. Other limitations were that many patients were over 75 years old, in an end-stage of heart failure, or had other severe disease or cognitive dysfunction</p>
<i>Risk of bias</i>	

Stromberg 2003 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The randomisation was blinded with the use of a computer-generated list of random numbers and sealed envelopes
Allocation concealment (selection bias)	Low risk	as above
Selective reporting (reporting bias)	Low risk	all stated outcomes reported
Other bias	Unclear risk	"There were significantly more patients with hypertension in the intervention group, 26 vs 16 ($p<0.05$). There were more patients with diabetes in the control group, 17 vs eight ($p=0.05$)."

Thompson 2005

Methods	2 centre cluster RCT Recruitment: 20 months, dates not specified Follow-up: 6 months
Participants	Country: UK N Randomised: 106 (control n=48, Intervention n=58) NYHA: <ul style="list-style-type: none"> NYHA 1-2; Control: 13 (27), Intervention: 14 (24) NYHA 3-4; Control: 35 (73), Intervention: 44 (76) LVEF: Control: 29 (SD 11), Intervention: 31 (SD 8) Age: Control: 72 (SD 12), Intervention: 73 (SD 14) Percentage male: Control: 73, Intervention: 72 Ethnicity: not stated Inclusion/exclusion criteria: <i>Inclusion:</i> <ul style="list-style-type: none"> Acute admission to hospital with a diagnosis of CHF. Objective evidence (e.g. echocardiography or coronary angiography) of impaired left ventricular systolic function as evidenced by a left ventricular ejection fraction (LVEF) of at least 45% immediately prior to study recruitment. Discharged to home. <i>Exclusion:</i> <ul style="list-style-type: none"> awaiting an elective cardiac procedure with the intent to reverse the cause of underlying heart failure (e.g. coronary artery bypass surgery for coronary artery stenosis) terminal illness other than CHF
Interventions	Duration of intervention: 6 months Intervention: "clinic plus home-based intervention" <ul style="list-style-type: none"> appointment with specialist nurse prior to discharge, to receive information on HF and medications

	<ul style="list-style-type: none">● office-hours contact number for nurse specialist● home visit with 10 days of hospital discharge, for education on symptom management and lifestyle, and clinical examination● monthly nurse-led outpatient heart failure clinic for 6 months post-discharge, including education, clinical examination and indices monitoring, and starting of new therapeutic drugs where appropriate Control group: standard care (i.e. explanation of condition, prescribed medications by the ward nurse and referral to appropriate post-discharge support as required). Patients given an outpatient department appointment 6-8 weeks post discharge	
Outcomes	Primary: <ul style="list-style-type: none">● event-free survival from either death or recurrent hospitalisation for any reason during the 6-month follow-up Secondary (6 months): <ul style="list-style-type: none">● rate of recurrent hospital stay● treatment adherence (not reported here)● health related quality of life	
Notes	Data source: published data only Generalisability: Of 5746 patients screened, only 119 (1.84%) were eligible for the study. the authors attribute this to difficulty in obtaining objective evidence of left ventricular systolic dysfunction, and estimate that 642 otherwise eligible patients (12%) were lost to the study for this reason. Of the 119 eligible patients, 106 (89%) agreed to take part and were available for randomisation	
<i>Risk of bias</i>		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	“a random number allocation was used to allocate equal numbers of small and large clinics to either post discharge HBI+C or UC.”
Allocation concealment (selection bias)	Unclear risk	no information in paper
Selective reporting (reporting bias)	Low risk	all stated outcomes reported
Other bias	Low risk	“Data on recurrent hospital stay and/or death were also collated (in a blinded manner) via the local area hospital record system and death registry.”

Methods	Multicentre 2-stage RCT (only second stage randomised) recruitment dates: September 1999 to April 2000 Follow-up: 6 months
Participants	<p>Country: Canada N Randomised: 276 (usual care n=136, intervention n=140) NYHA (%):</p> <ul style="list-style-type: none"> • NYHA 1; Control: (14), Intervention: (12) • NYHA 2; Control: (52), Intervention: (48) • NYHA 3; Control: (30), Intervention: (35) • NYHA 4; Control: (3), Intervention: (5) <p>Age: Control: 72 (SD 12), Intervention: 71 (SD 12) Percentage male: Control: 58, Intervention: 58 Ethnicity: Not stated Inclusion/exclusion criteria: <i>Inclusion:</i></p> <ul style="list-style-type: none"> • Consecutive patients older than age 18 years, admitted to a hospital with a most responsible, primary, secondary, or complicating diagnosis of HF were eligible to participate in the study. <p><i>Exclusion:</i></p> <ul style="list-style-type: none"> • known secondary causes of HF (i.e., correctable causes as anaemia or hyperthyroidism) • preserved systolic function • were taking an angiotensin-II antagonist because of known intolerance or contraindication to ACE inhibitors • had a terminal illness with a life expectancy less than 6 months • cognitive impairment • were unable to communicate because of language barriers, • were attending a specialized HF clinic for medical management, • were participating in a HF clinical trial • absolute contraindication to ACE inhibitors • patients residing outside the region of the participating hospital • those discharged to a setting where patients were not responsible for own medication administration
Interventions	<p>Duration of intervention: 6 months Intervention: patient support program:</p> <ul style="list-style-type: none"> • 5 key areas: salt and fluid restriction, daily weighing, exercise alternating with rest periods, proper medication use, and early recognition of worsening symptoms • 1-1 education with research coordinator prior to discharge using written educational package covering information on HF (definition, causes, symptoms), nondrug treatment, medication information (with special emphasis on proven benefits of therapies), and self-monitoring • adherence aids provided prior to discharge (medication organizer, medication administration schedule, and daily weight log) • patients encouraged to contact coordinator for ongoing community support • community follow up to reinforce education and adherence: telephone contact by the local research coordinator at 2 weeks, 4 weeks, and monthly thereafter for up to 6 months post discharge (i.e. 7 calls)

	<ul style="list-style-type: none"> monthly newsletter "Living with Congestive HF", featuring articles on 5 key components, patient success stories, salt content of foods, low-salt recipes, and compliance tips research coordinator could also recommend that patient consult physician for ACE inhibitor dosage titration as appropriate, or if a problem arose which required further investigation <p>Usual care:</p> <ul style="list-style-type: none"> Patients received a general heart disease pamphlet before discharge, but no formal counselling beyond routine hospital procedure. Monthly telephone contact to check for clinical events.
Outcomes	<p>Primary (6 months):</p> <ul style="list-style-type: none"> medication adherence, as measured by pharmacy records <p>Secondary (6 months):</p> <ul style="list-style-type: none"> clinical events
Notes	<p>Data source: published data only</p> <p>Generalisability: 2310 patients were assessed for eligibility, and of these 766 (12%) were eligible for the study. However, only 276 (36%) were randomised - of the remaining 490 patients, 58% were unwilling to take part and 30% were not responsible for their own medications so were unable to take part</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization was conducted by a computer-generated sequence using block randomisation (block size of 4), stratified by study site (hospital)."
Allocation concealment (selection bias)	Unclear risk	No information in paper.
Selective reporting (reporting bias)	Low risk	Stated outcomes reported.
Other bias	Low risk	No other apparent sources of bias, although monthly follow-up calls to 'usual care' group could have provided more contact than would otherwise be expected, which could affect the generalisability of results

CHF = chronic heart failure, HF = heart failure, LOS = length of stay, HRQL = health related quality of life, NYHA = New York Heart Association functional class, PVD = peripheral vascular disease, LVEF = left ventricular ejection fraction, LV = left ventricle, Tx = transplantation, i/v = intravenous, Rx = therapy, MI = myocardial infarction, Q = questionnaire, ACEI= angiotensin converting enzyme inhibitor, GP = general practitioner

* = information obtained from personal communication with author

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Aiken 2006	Not HF disease specific - pts had HF or COPD (palliative care programme)
Akosah 2002	Non-randomised study.
Akosah 2004	Non-randomised study.
Artinian 2003	Non-randomised study.
Austin 2007	Described as cardiac rehab. Hospital admission for heart failure not an inclusion criterion
Azad 2008	Hospital admission for heart failure not an inclusion criterion
Azevedo 2002	Non-randomised study.
Barth 2001	Very small RCT, limited data presented, statistical analyses appear incorrect
Benatar 2003	RCT both arms received an intervention.
Blaha 2000	Paper discusses methodology of the intervention and is not a study or trial
Bondmass 2007	secondary analysis of data from a previously excluded study
Bouvy 2003	Hospital admission for heart failure not an inclusion criterion
Bucci 2003	Hospital admission for heart failure not an inclusion criterion, and intervention is heart failure clinic with pharmacy intervention for some
Cleland 2005	Pure telemonitoring intervention
Cordisco 1999	Non-randomised study.
Costantini 2001	Mixed before and after and parallel group study.
de la Porte 2007	Hospital admission for heart failure not an inclusion criterion
de Lusignan 1999	Hospital admission for heart failure not an inclusion criterion
Dewalt 2006	Hospital admission for heart failure not an inclusion criterion
Discher 2003	Non- randomised study.
Duffy 2005	Description of development of telephone mediated intervention - no evaluative data
Ekman 1998	Less than 6 months follow up.

(Continued)

Evans 1993	"Generic intervention" (i.e. not exclusively designed for, or directed at, patients with CHF)
Farag 1967	Non-randomised study.
Feldman 2004	Hospital admission for heart failure not an inclusion criterion. Nurse-based CRT
Fitzgerald 1994	"Generic" intervention.
Flynn 2005	Not an RCT.
Foley 2008	Comment on an included study.
Fonarow 2004	Editorial.
Galbreath 2004	Hospital admission for heart failure not an inclusion criterion
Gattis 1999	Hospital admission for heart failure not an inclusion criterion.
GESICA 2005	Phone based
Goldberg 2003	Purely telemonitoring intervention.
Goodyer 1995	Hospital admission for heart failure not an inclusion criterion
Grancelli 2003	Hospital admission for heart failure not an inclusion criterion
Gregory 2006	Cost data from included study by Kimmelstiel et al.
Hanchett 1967	Hospital admission for heart failure not an inclusion criterion
Hansen 1992	"Generic" intervention
Harrison 2002	Less than 6 months follow up,
Heidenreich 1999	Non-randomised study.
Hughes 2000	"Generic" intervention,
Inglis 2006	Long term follow up of 2 Stewart RCTs, only 1 of which was included in this review Combined data from the 2 studies presented, so not possible to separate out data from the included and excluded studies
Jaarsma 2004	Methodology paper, no outcome data.
Jain 2005	Not an RCT.

(Continued)

Jerant 2001	Small RCT with three arms: 13 patients receiving home tele care; 12 patients received telephone care; 12 received usual care. An interesting paper but excluded from this review because the presentation and analyses of these data do not allow either of the two interventions to be compared with the control treatment
Johnson 2000	"Generic" intervention.
Karlsson 2005	No relevant outcome data.
Khunti 2007	Not all patients had a previous hospital admission for heart failure
Laramée 2003	Less than 6 months follow up.
Ledwidge 2003	Cost study of patients in the included study by McDonald et al
Lin 2001	Non-randomised study.
Linden 2005	Non-randomised study.
Martensson 2005	Hospital admission for heart failure not an inclusion criterion
McCoy 2007	Non-randomised study.
McDonald 2002	Less than 6 months follow up.
Murray 2007	Hospital admission for heart failure not an inclusion criterion
Naylor 1994	"Generic" intervention.
Naylor 1999	"Generic" intervention.
Nguyen 2007	Hospital admission for heart failure not an inclusion criterion
Ojeda 2005	Non-randomised study. Contacted author for clarification, who clarified that this is a non-randomised follow up of subgroup of patients from the PRICE RCT by Atienza et al
Palmer 2003	Narrative review
Panella 2005	Not an RCT of the appropriate intervention.
Patel 2008	Hospital admission for heart failure not an inclusion criterion
Peters-Klimm 2007	Hospital admission for heart failure not an inclusion criterion
Philbin 2000	RCT, unit of randomisation was the hospital, analyses of outcome at hospital level only
Powell 2008	No usual care comparison group. Hospital admission for heart failure not an inclusion criterion

(Continued)

Quinn 2006	Non-randomised study.
Ramachandran 2007	Hospital admission for heart failure not an inclusion criterion. Contact with author indicated some may have only been clinic outpatients
Rao 2007	Hospital admission for heart failure not an inclusion criterion
Rich 1993	Less than 6 months follow up.
Rich 1995	Less than 6 months follow up.
Riegel 2000	Non-randomised study.
Riegel 2002	Purely telemonitoring intervention.
Rondinini 2008	Non-randomised study.
Rubin 1992	"Generic" intervention.
Schneider 1993	Non-randomised study.
Serxner 1998	Purely educational intervention.
Shively 2005	Hospital admission for heart failure not an inclusion criterion
Sisk 2006	Hospital admission for heart failure not an inclusion criterion
Smeulders 2006	Hospital admission for heart failure not an inclusion criterion
Smith 2005	Hospital admission for heart failure not an inclusion criterion
Stewart 1998a	"Generic" intervention.
Stewart 1998b	Subgroup from a "generic" study.
Stewart 1999b	Subgroup from a "generic" study.
Stewart 2002b	Follow up data at 4.2 years combining data from included study (Stewart 1999 Lancet) and excluded study (Stewart 1998 JAGS). Data on included study not presented separately
Topp 1998	Non-randomised study.
Townsend 1988	"Generic" intervention.
Trochu 2003	Not an RCT
van Rossum 1993	"Generic" intervention.

(Continued)

Weinberger 1996	"Generic" intervention.
Williams 1994	"Generic" intervention.
Wongpiriyayothar 2008	1. Majority of patients had valvular heart disease. 2. not clear if all hospitalised for HF
Wright 2003	Further analysis of included Doughty paper - no new data.

Characteristics of studies awaiting assessment *[ordered by study ID]*

Alcides2004

Methods	Unable to ascertain
Participants	Unable to ascertain
Interventions	Unable to ascertain
Outcomes	Unable to ascertain
Notes	

Anguita 2005

Methods	Unable to ascertain
Participants	Unable to ascertain
Interventions	Unable to ascertain
Outcomes	Unable to ascertain
Notes	

Brotons 2005

Methods	Unable to ascertain
Participants	Unable to ascertain
Interventions	Unable to ascertain
Outcomes	Unable to ascertain
Notes	

Fabbri 2007

Methods	Unable to ascertain
Participants	Unable to ascertain
Interventions	Unable to ascertain
Outcomes	Unable to ascertain
Notes	

Jaarsma 2003

Methods	Unable to ascertain
Participants	Unable to ascertain
Interventions	Unable to ascertain
Outcomes	Unable to ascertain
Notes	

Valle 2004

Methods	Unable to ascertain
Participants	
Interventions	
Outcomes	
Notes	

Wierchowicki 2006a

Methods	Unable to ascertain
Participants	Unable to ascertain
Interventions	Unable to ascertain
Outcomes	Unable to ascertain
Notes	

Wierchowicki 2006b

Methods	Unable to ascertain
Participants	Unable to ascertain
Interventions	Unable to ascertain
Outcomes	Unable to ascertain
Notes	

Woodend

Methods	Unable to ascertain
Participants	Unable to ascertain
Interventions	Unable to ascertain
Outcomes	Unable to ascertain
Notes	

Characteristics of ongoing studies [ordered by study ID]**Hardman S**

Trial name or title	The evaluation of a nurse-led intervention to improve self-management for patients admitted to hospital with a diagnosis of heart failure (due to left ventricular systolic dysfunction)
Methods	
Participants	250 patients (125 in intervention arm, 125 in control arm)
Interventions	The intervention is designed to enhance patients' sense of self efficacy (confidence) in their ability to adhere to medication and other aspects of their treatment regime including fluid restriction, diet exercise and self monitoring for signs of deteriorating heart failure, using a problem solving approach
Outcomes	Primary endpoints: All cause hospital readmissions and heart failure related hospital readmissions during the first three months after discharge. Numerous secondary endpoints including mortality and 12 month data
Starting date	NA, study likely to be completed in 2005.
Contact information	Dr. Suzanna Hardman Consultant Cardiologist with an interest in Community Cardiology, The Whittington & UCL Hospitals, Clinical & Academic Department of Cardiovascular Medicine, St Mary's Wing, Whittington Hospital, Highgate Hill, London N19 5NF, UK

Hardman S (Continued)

Notes	Contacted author July 2010, publication expected soon.
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Massie 2001

Trial name or title	A controlled trial of heart failure management programs.
Methods	
Participants	147 patients with symptomatic CHF at 5 VA facilities.
Interventions	Three groups: usual care, nurse manager, home monitoring also in two sites patients randomised to HF clinic
Outcomes	Death or hospitalisation for a cardiac cause
Starting date	NA
Contact information	NA
Notes	Poster abstract only. Author contacted, full trial not published yet

Moser 2000

Trial name or title	Community case management decreases rehospitalisation rates and costs and improves quality of life in heart failure patients with preserved and non-preserved left ventricular function: a randomised controlled trial
Methods	
Participants	136 patients.
Interventions	Community case management: a home visit and weekly phone calls for one month followed by monthly phone calls from a HF nurse aimed at patient assessment, comprehensive education and counselling
Outcomes	Hospitalisations, health care costs, LOS in hospital, QOL.
Starting date	NA
Contact information	Prof. Debra Moser, College of Nursing, Ohio State University, Columbus, Ohio USA
Notes	

Pugh 1999

Trial name or title	Nursing case management for elderly heart failure patients.
Methods	
Participants	200 patients aged 65 years or older hospitalised at one centre for the treatment of CHF
Interventions	Intervention group receive enhanced discharge planning, and are taught to manage their CHF within parameters set by their physician using a workbook for guidance. In addition they receive patient-specific printed material and ongoing assessment and follow up by a nurse for a 6 month period through phone calls and visits
Outcomes	Morbidity, mortality, quality of life and functional status at 6 months and one year after discharge
Starting date	NA, in July 1998 57 patients had been recruited.
Contact information	NA
Notes	no publications identified

DATA AND ANALYSES

Comparison 1. All interventions

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All cause mortality	24	5671	Odds Ratio (M-H, Random, 95% CI)	0.74 [0.60, 0.90]
2 HF readmissions	12	3135	Odds Ratio (M-H, Random, 95% CI)	0.57 [0.43, 0.75]
3 Unplanned readmissions	3	502	Odds Ratio (M-H, Random, 95% CI)	0.68 [0.38, 1.22]

Comparison 2. Case management vs usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 HF mortality	3	1423	Odds Ratio (M-H, Random, 95% CI)	0.87 [0.64, 1.17]
2 Mortality at 6 months follow up	7	1454	Odds Ratio (M-H, Random, 95% CI)	0.85 [0.54, 1.32]
3 Mortality at more than 6 months follow up	11	2801	Odds Ratio (M-H, Random, 95% CI)	0.66 [0.47, 0.91]
4 Mortality at follow up (studies where allocation concealment confirmed)	8	1784	Odds Ratio (M-H, Random, 95% CI)	0.60 [0.43, 0.84]
5 Readmissions for HF at 6 months follow up	3	655	Odds Ratio (M-H, Random, 95% CI)	0.64 [0.46, 0.88]
6 Readmissions for HF beyond 6 months follow up	7	1726	Odds Ratio (M-H, Random, 95% CI)	0.47 [0.30, 0.76]
7 HF readmissions (studies where allocation concealment confirmed)	3	604	Odds Ratio (M-H, Random, 95% CI)	0.42 [0.29, 0.62]
8 All cause readmissions 6 months follow up	4	694	Odds Ratio (M-H, Random, 95% CI)	0.77 [0.50, 1.20]
9 All cause readmissions more than 6 months follow up	7	2199	Odds Ratio (M-H, Random, 95% CI)	0.75 [0.57, 0.99]

Comparison 3. Clinic vs. usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality at follow up	6	1486	Odds Ratio (M-H, Random, 95% CI)	0.74 [0.51, 1.09]
2 HF readmissions	2	869	Odds Ratio (M-H, Random, 95% CI)	1.02 [0.75, 1.38]
3 All cause readmissions	4	1129	Odds Ratio (M-H, Random, 95% CI)	0.78 [0.48, 1.26]

Comparison 4. Multidisciplinary vs. usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality	2	403	Odds Ratio (M-H, Random, 95% CI)	0.70 [0.43, 1.14]
2 HF readmissions	2	403	Odds Ratio (M-H, Random, 95% CI)	0.45 [0.28, 0.72]
3 All cause readmissions	2	403	Odds Ratio (M-H, Random, 95% CI)	0.46 [0.30, 0.69]

Comparison 5. Level of intensity (agreed by authors)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality intensive intervention	7	1671	Odds Ratio (M-H, Random, 95% CI)	0.65 [0.48, 0.88]
2 Mortality moderately intensive intervention	11	3067	Odds Ratio (M-H, Random, 95% CI)	0.74 [0.59, 0.94]
3 Mortality low intensity intervention	4	869	Odds Ratio (M-H, Random, 95% CI)	1.08 [0.69, 1.70]
4 HF readmissions intensive intervention	6	1657	Odds Ratio (M-H, Random, 95% CI)	0.59 [0.36, 0.96]
5 HF Readmissions moderately intensive intervention	4	1335	Odds Ratio (M-H, Random, 95% CI)	0.57 [0.32, 1.02]
6 HF Readmissions low intensity intervention	3	489	Odds Ratio (M-H, Random, 95% CI)	0.56 [0.39, 0.81]

Comparison 6. Professional delivering intervention

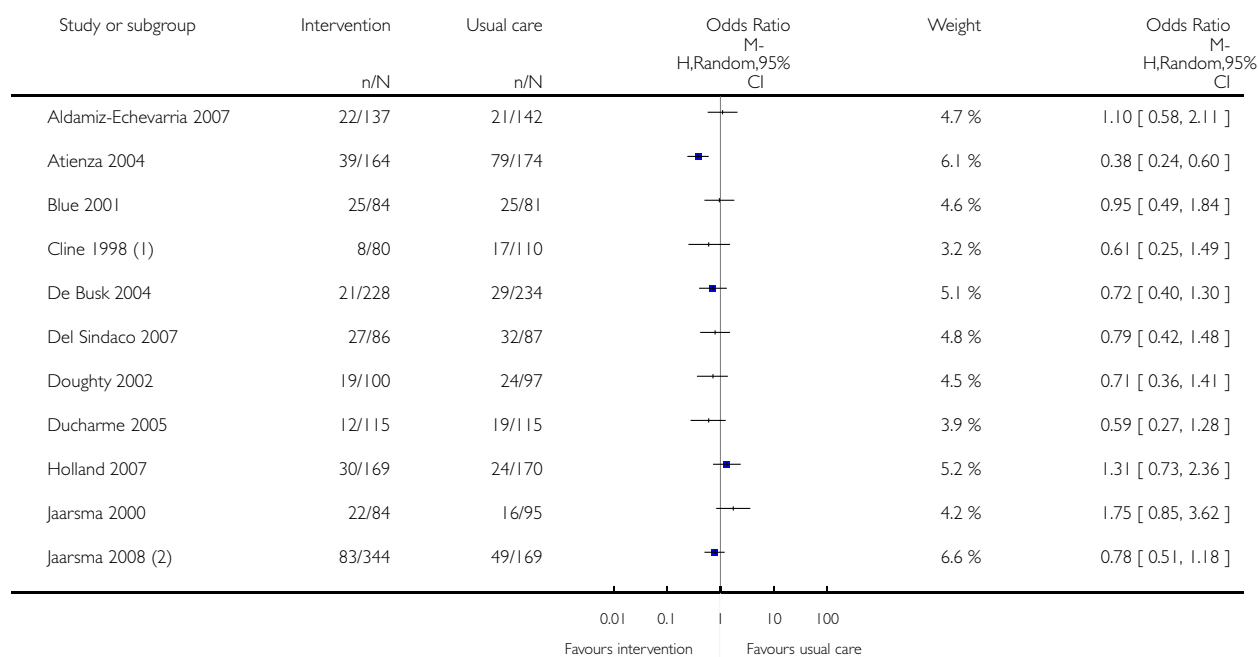
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 mortality- specialist nurse	12	2387	Odds Ratio (M-H, Random, 95% CI)	0.72 [0.52, 1.00]
2 mortality - nurse/community nurse	4	1054	Odds Ratio (M-H, Random, 95% CI)	0.97 [0.69, 1.37]
3 mortality - pharmacist / community pharmacist	3	507	Odds Ratio (M-H, Random, 95% CI)	0.58 [0.18, 1.83]
4 HF readmissions - nurse/community nurse	1	208	Odds Ratio (M-H, Random, 95% CI)	1.06 [0.60, 1.88]
5 HF readmissions - specialist nurse	6	1381	Odds Ratio (M-H, Random, 95% CI)	0.55 [0.37, 0.81]
6 mortality - multidisciplinary	4	1109	Odds Ratio (M-H, Random, 95% CI)	0.79 [0.59, 1.04]
7 HF readmissions - multidisciplinary	3	883	Odds Ratio (M-H, Random, 95% CI)	0.80 [0.41, 1.55]

Analysis 1.1. Comparison 1 All interventions, Outcome 1 All cause mortality.

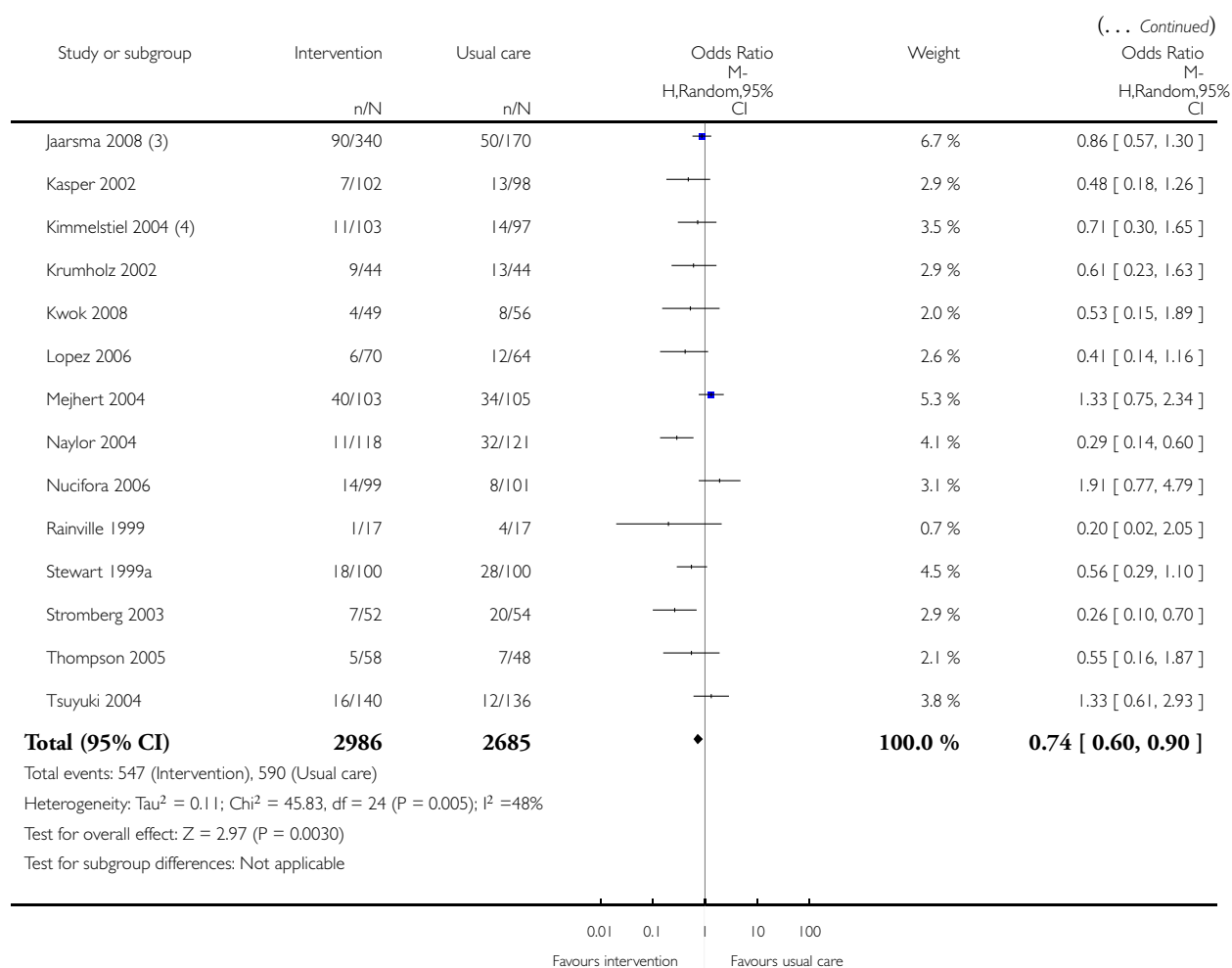
Review: Clinical service organisation for heart failure

Comparison: 1 All interventions

Outcome: 1 All cause mortality



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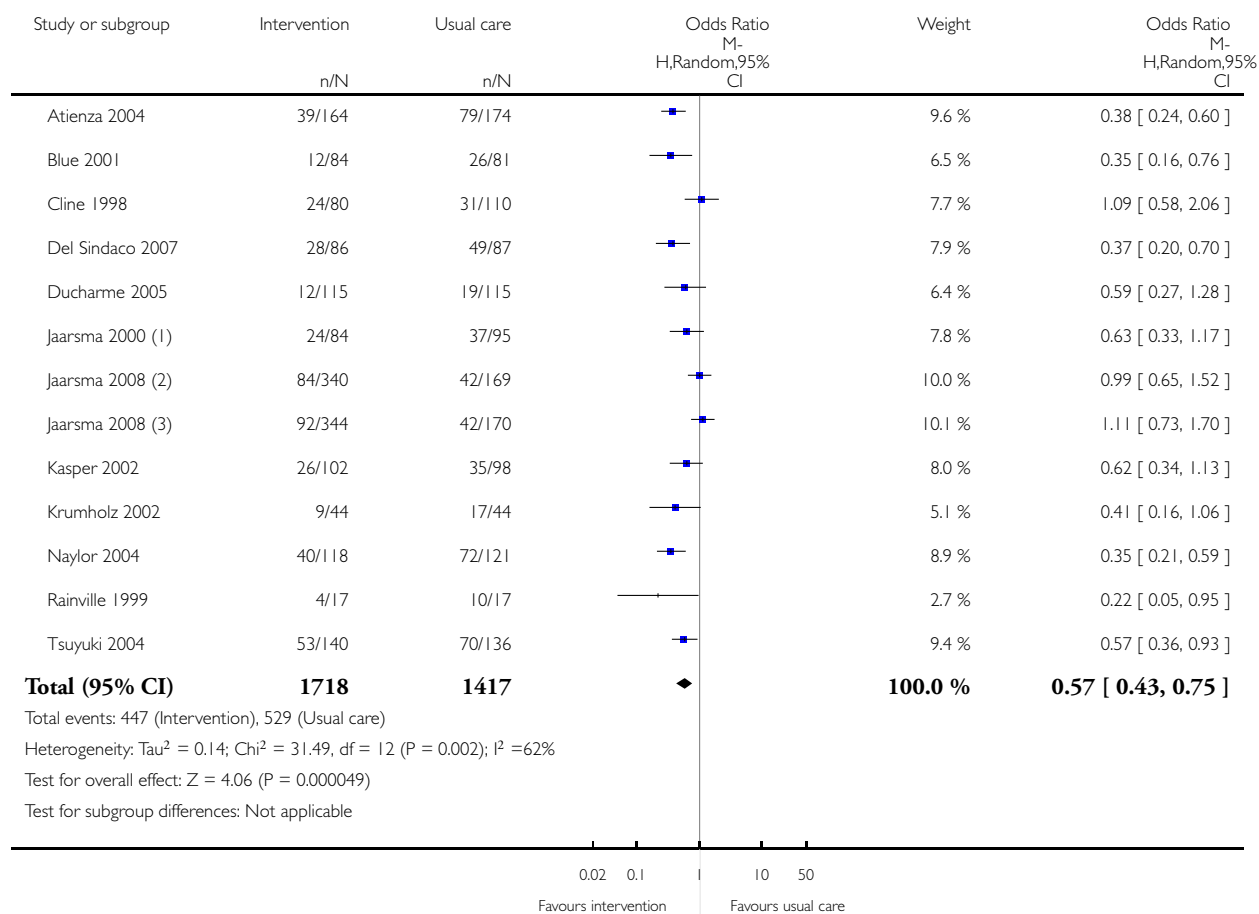
- (1) 90 days
- (2) intensive intervention
- (3) basic intervention
- (4) 1 year data

Analysis 1.2. Comparison 1 All interventions, Outcome 2 HF readmissions.

Review: Clinical service organisation for heart failure

Comparison: 1 All interventions

Outcome: 2 HF readmissions



(1) 9 month follow up

(2) basic intervention

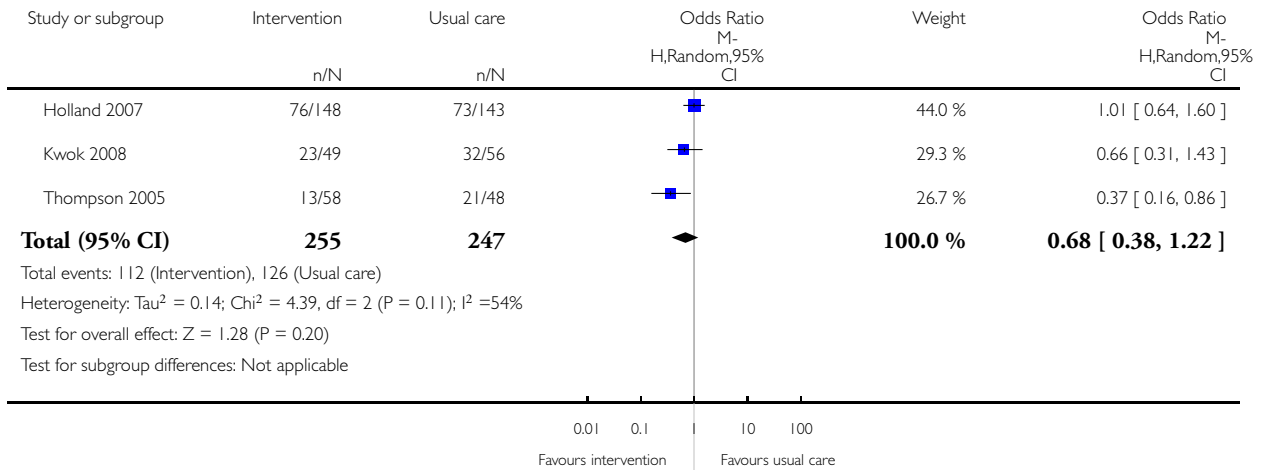
(3) intensive intervention

Analysis 1.3. Comparison 1 All interventions, Outcome 3 Unplanned readmissions.

Review: Clinical service organisation for heart failure

Comparison: 1 All interventions

Outcome: 3 Unplanned readmissions

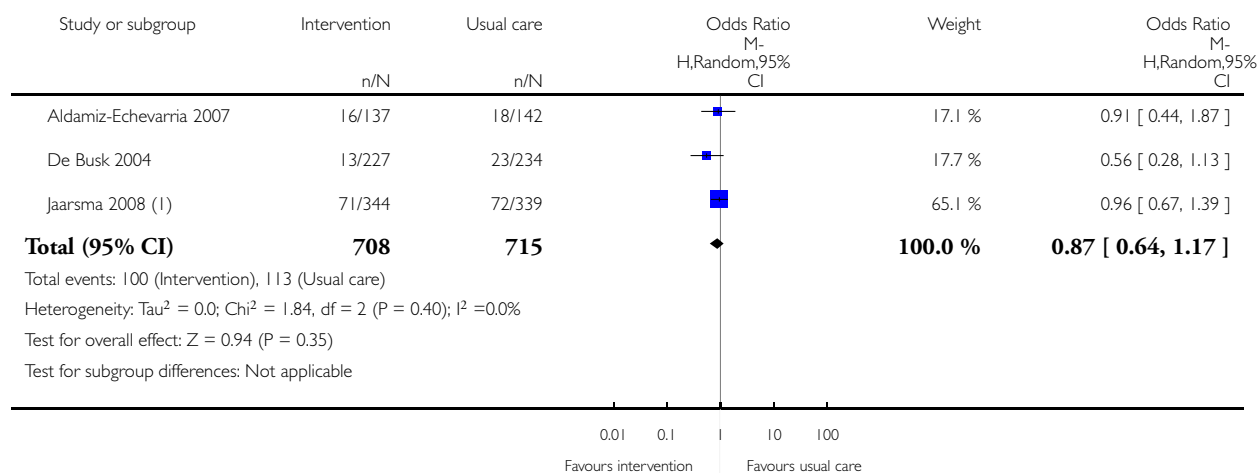


Analysis 2.1. Comparison 2 Case management vs usual care, Outcome 1 HF mortality.

Review: Clinical service organisation for heart failure

Comparison: 2 Case management vs usual care

Outcome: 1 HF mortality



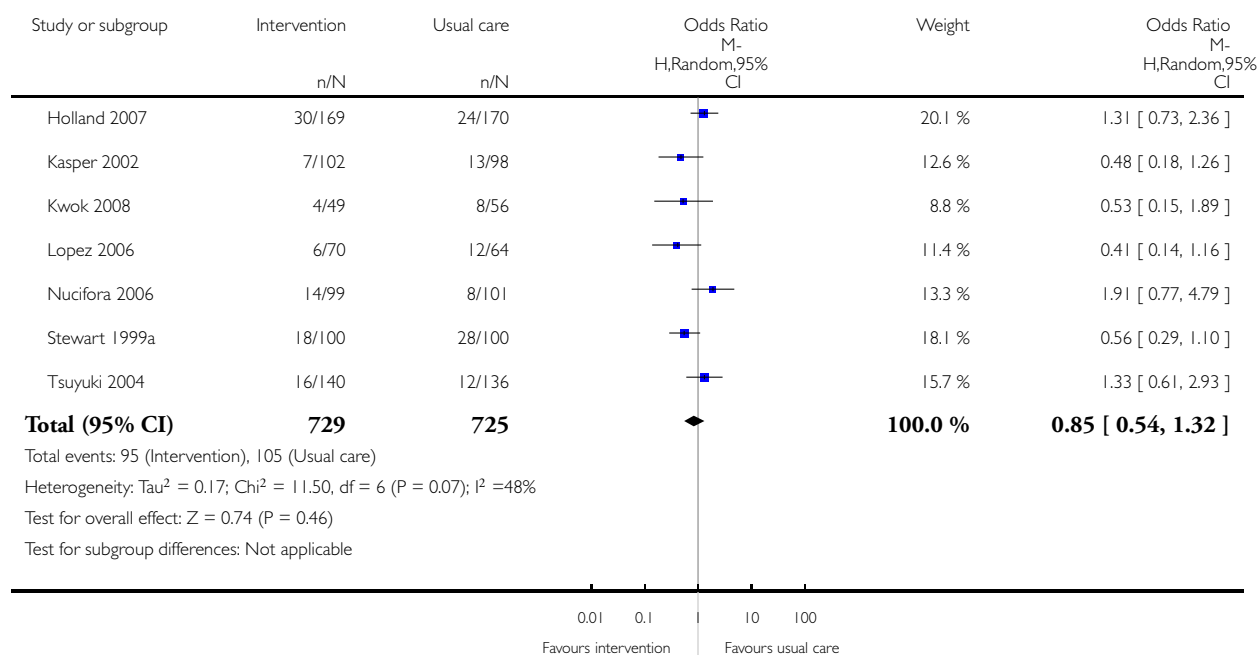
(I) intensive intervention

Analysis 2.2. Comparison 2 Case management vs usual care, Outcome 2 Mortality at 6 months follow up.

Review: Clinical service organisation for heart failure

Comparison: 2 Case management vs usual care

Outcome: 2 Mortality at 6 months follow up

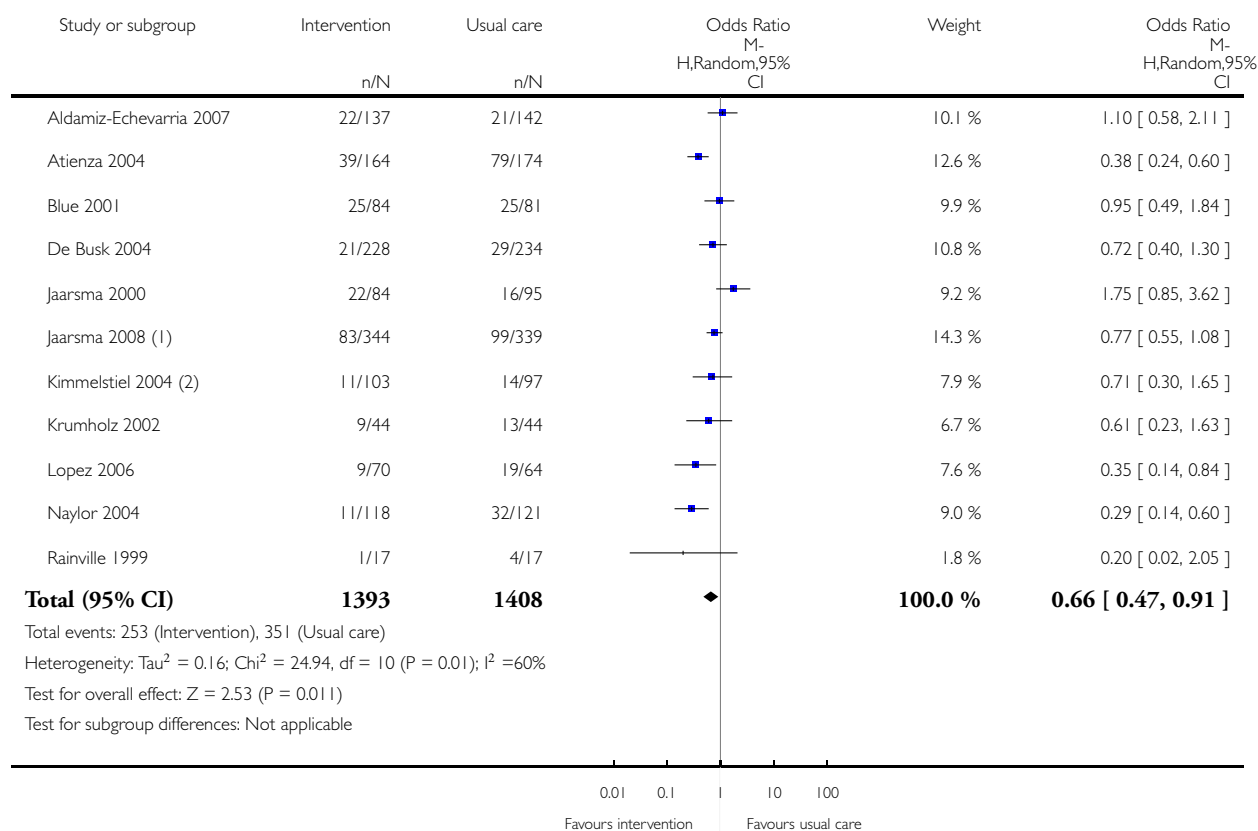


Analysis 2.3. Comparison 2 Case management vs usual care, Outcome 3 Mortality at more than 6 months follow up.

Review: Clinical service organisation for heart failure

Comparison: 2 Case management vs usual care

Outcome: 3 Mortality at more than 6 months follow up



(1) intensive intervention

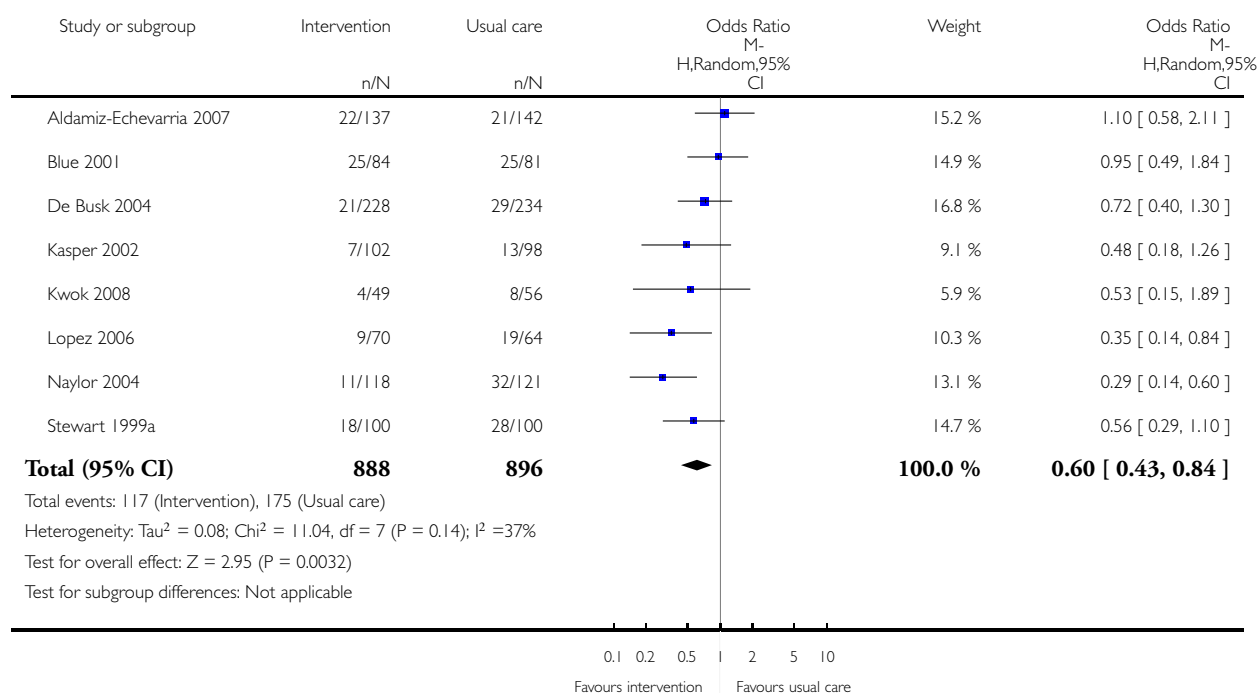
(2) 1 year data

Analysis 2.4. Comparison 2 Case management vs usual care, Outcome 4 Mortality at follow up (studies where allocation concealment confirmed).

Review: Clinical service organisation for heart failure

Comparison: 2 Case management vs usual care

Outcome: 4 Mortality at follow up (studies where allocation concealment confirmed)

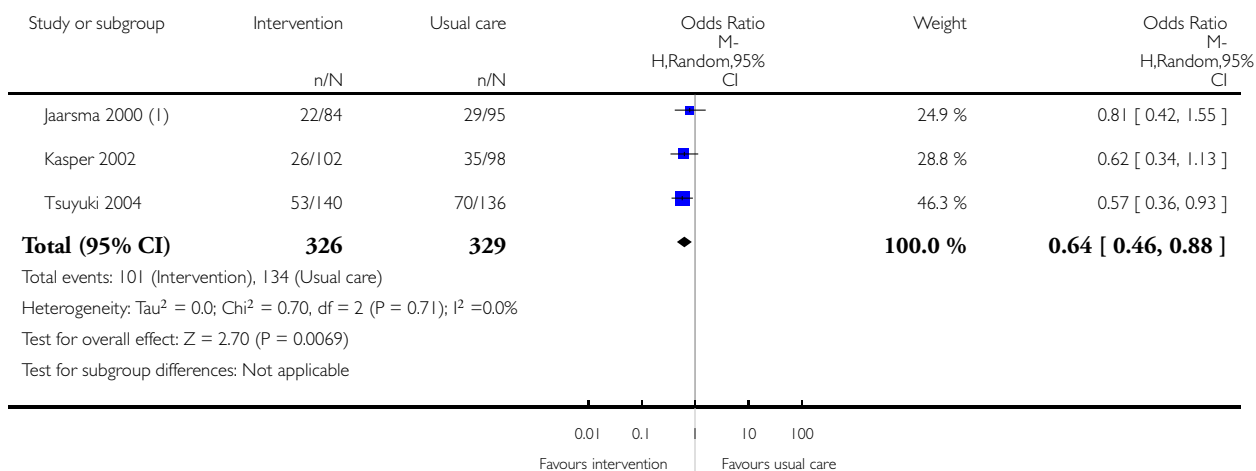


Analysis 2.5. Comparison 2 Case management vs usual care, Outcome 5 Readmissions for HF at 6 months follow up.

Review: Clinical service organisation for heart failure

Comparison: 2 Case management vs usual care

Outcome: 5 Readmissions for HF at 6 months follow up



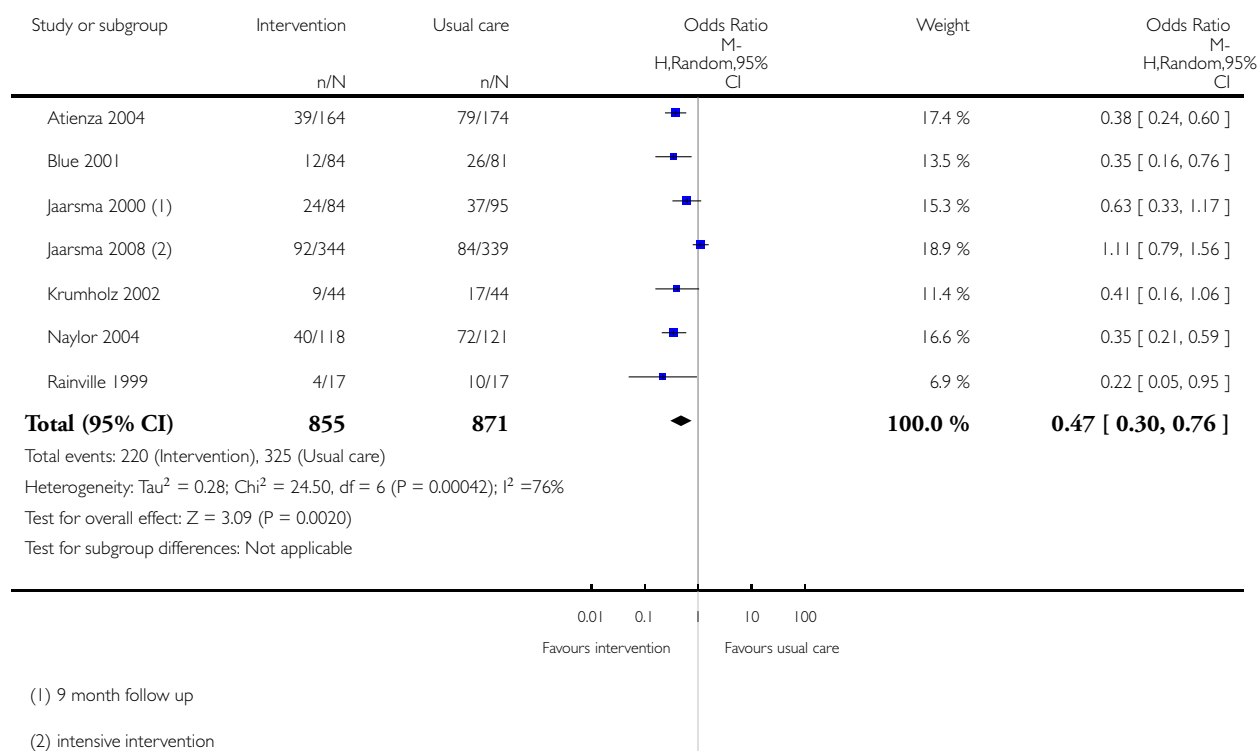
(1) 3 month follow up data

Analysis 2.6. Comparison 2 Case management vs usual care, Outcome 6 Readmissions for HF beyond 6 months follow up.

Review: Clinical service organisation for heart failure

Comparison: 2 Case management vs usual care

Outcome: 6 Readmissions for HF beyond 6 months follow up

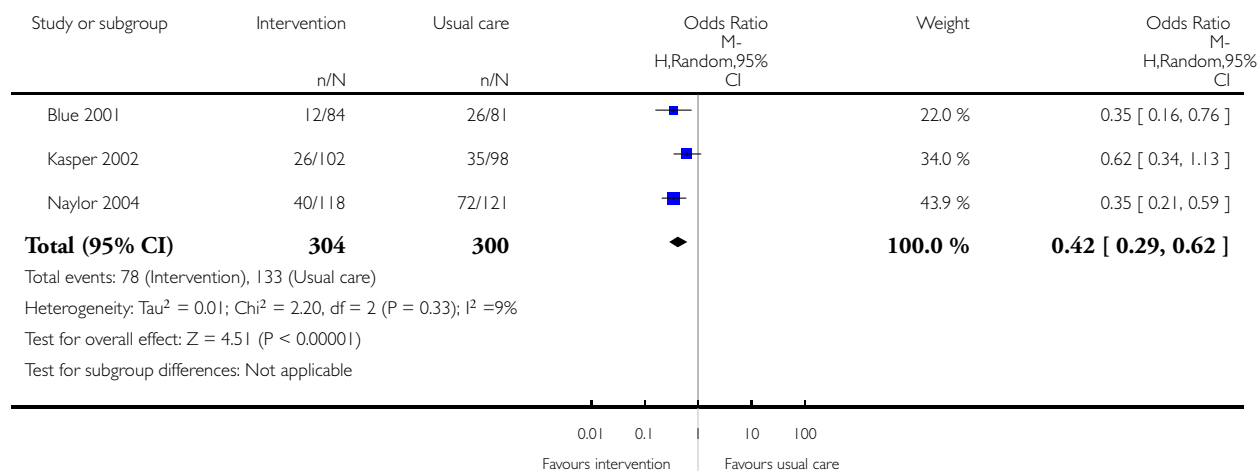


Analysis 2.7. Comparison 2 Case management vs usual care, Outcome 7 HF readmissions (studies where allocation concealment confirmed).

Review: Clinical service organisation for heart failure

Comparison: 2 Case management vs usual care

Outcome: 7 HF readmissions (studies where allocation concealment confirmed)

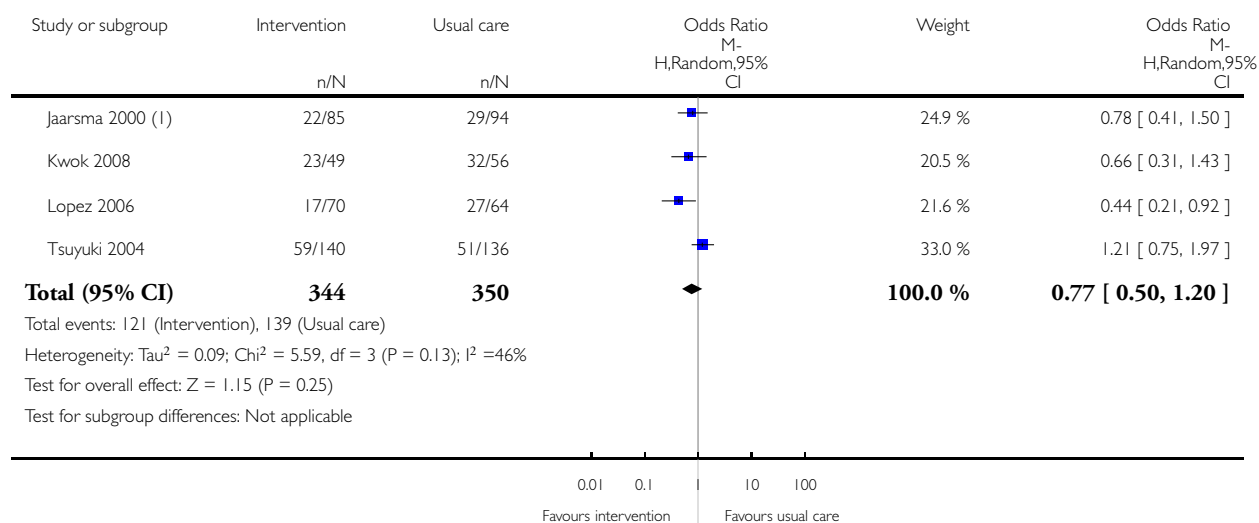


Analysis 2.8. Comparison 2 Case management vs usual care, Outcome 8 All cause readmissions 6 months follow up.

Review: Clinical service organisation for heart failure

Comparison: 2 Case management vs usual care

Outcome: 8 All cause readmissions 6 months follow up











(1) 3 months follow up

Analysis 2.9. Comparison 2 Case management vs usual care, Outcome 9 All cause readmissions more than 6 months follow up.

Review: Clinical service organisation for heart failure

Comparison: 2 Case management vs usual care

Outcome: 9 All cause readmissions more than 6 months follow up

Study or subgroup	Intervention n/N	Usual care n/N	Odds Ratio M- H,Random,95% CI	Weight	Odds Ratio M- H,Random,95% CI
Atienza 2004	68/164	101/174		15.9 %	0.51 [0.33, 0.79]
Blue 2001	47/84	49/81		11.2 %	0.83 [0.45, 1.54]
De Busk 2004	116/227	117/234		17.9 %	1.05 [0.73, 1.51]
Jaarsma 2000 (1)	31/85	47/94		11.7 %	0.57 [0.32, 1.04]
Jaarsma 2008 (2)	194/344	181/339		19.8 %	1.13 [0.84, 1.53]
Lopez 2006	23/70	31/64		9.7 %	0.52 [0.26, 1.05]
Naylor 2004	53/118	67/121		13.8 %	0.66 [0.39, 1.09]
Total (95% CI)	1092	1107		100.0 %	0.75 [0.57, 0.99]

Total events: 532 (Intervention), 593 (Usual care)

Heterogeneity: $\tau^2 = 0.08$; $\chi^2 = 14.27$, $df = 6$ ($P = 0.03$); $I^2 = 58\%$

Test for overall effect: $Z = 2.00$ ($P = 0.045$)

Test for subgroup differences: Not applicable

0.01 0.1 10 100
Favours intervention Favours usual care

(1) 9 months follow up

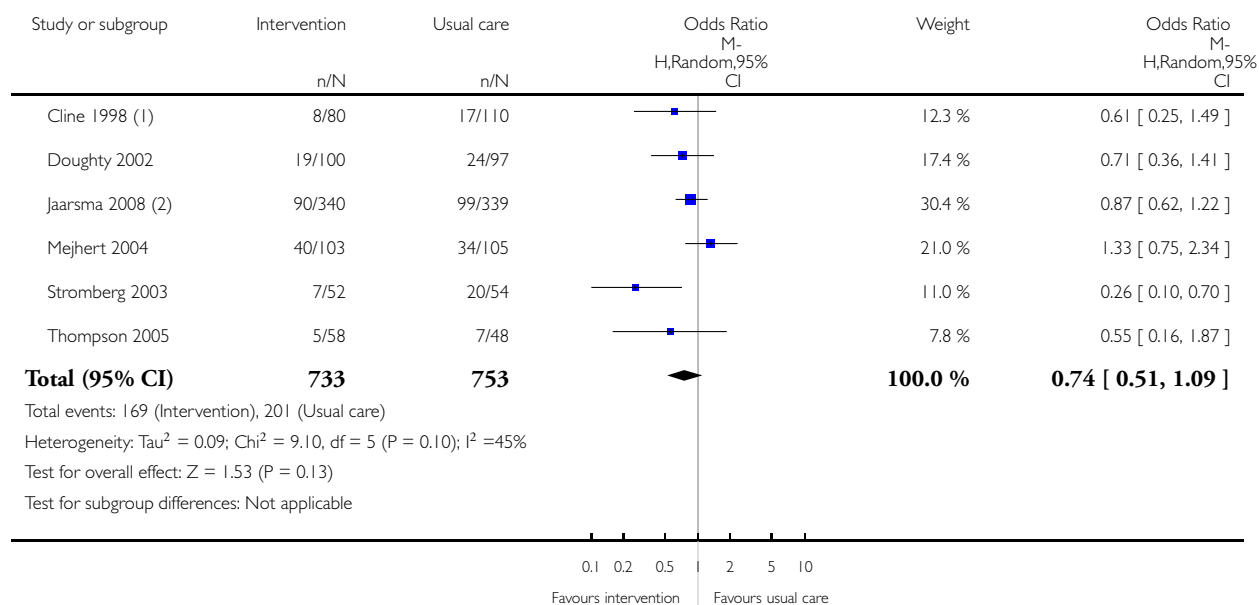
(2) intensive intervention

Analysis 3.1. Comparison 3 Clinic vs. usual care, Outcome 1 Mortality at follow up.

Review: Clinical service organisation for heart failure

Comparison: 3 Clinic vs. usual care

Outcome: 1 Mortality at follow up



(1) 90 days

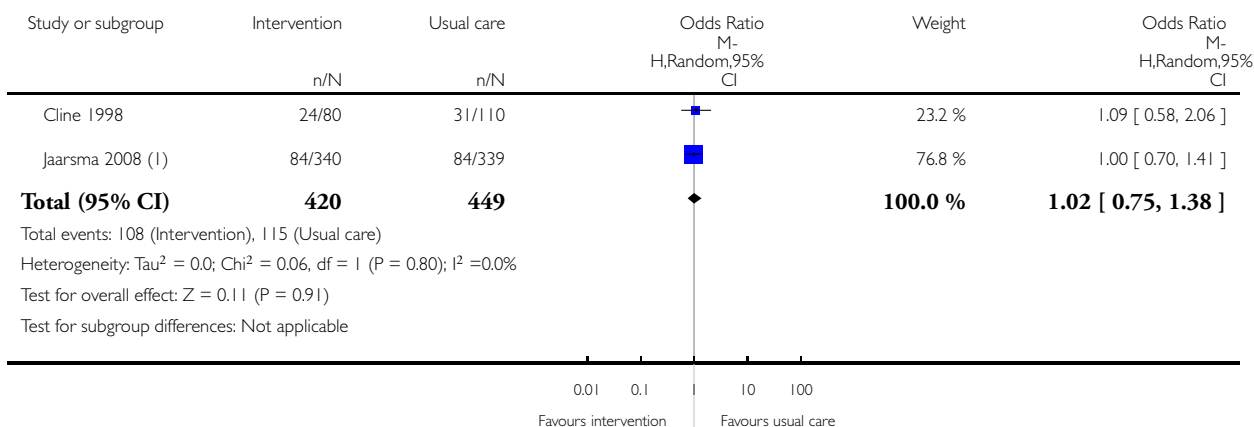
(2) basic intervention

Analysis 3.2. Comparison 3 Clinic vs. usual care, Outcome 2 HF readmissions.

Review: Clinical service organisation for heart failure

Comparison: 3 Clinic vs. usual care

Outcome: 2 HF readmissions



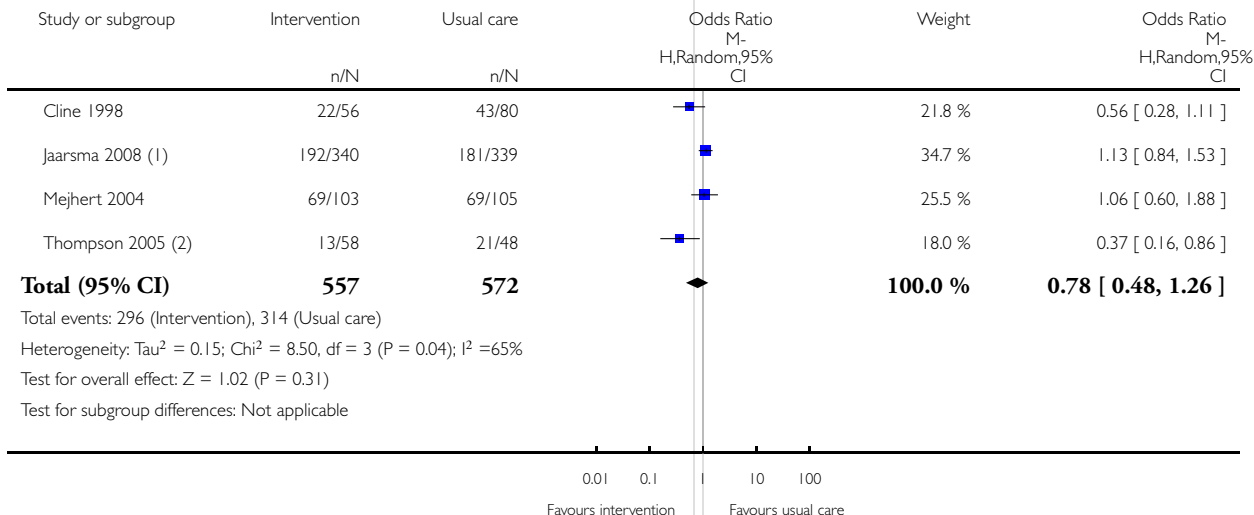
(1) basic intervention

Analysis 3.3. Comparison 3 Clinic vs. usual care, Outcome 3 All cause readmissions.

Review: Clinical service organisation for heart failure

Comparison: 3 Clinic vs. usual care

Outcome: 3 All cause readmissions



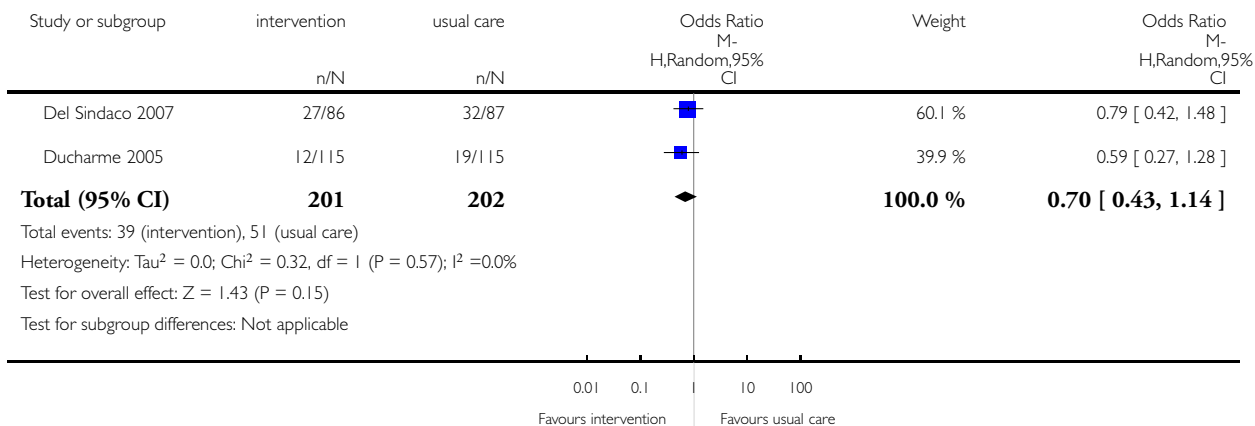
- (1) basic intervention
- (2) 6 months follow up

Analysis 4.1. Comparison 4 Multidisciplinary vs. usual care, Outcome 1 Mortality.

Review: Clinical service organisation for heart failure

Comparison: 4 Multidisciplinary vs. usual care

Outcome: 1 Mortality

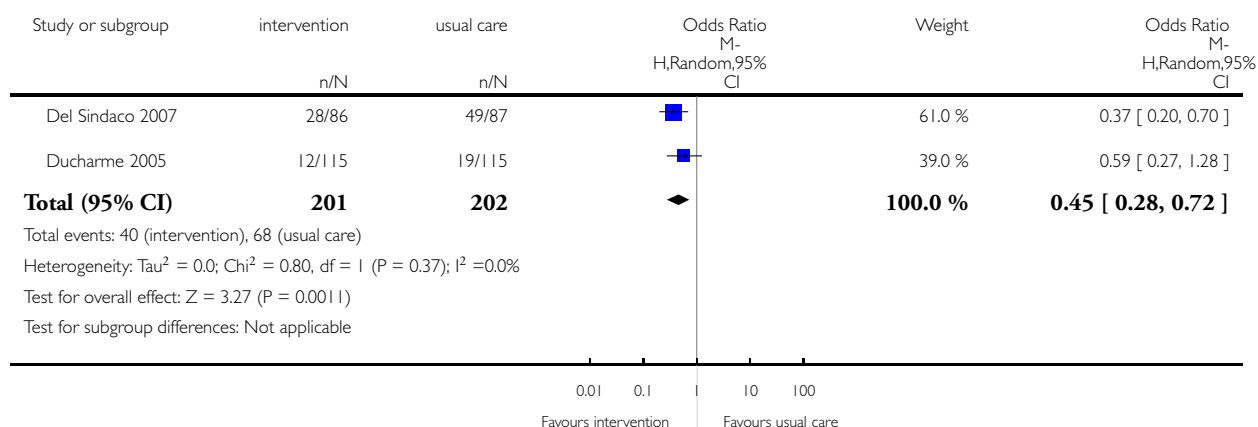


Analysis 4.2. Comparison 4 Multidisciplinary vs. usual care, Outcome 2 HF readmissions.

Review: Clinical service organisation for heart failure

Comparison: 4 Multidisciplinary vs. usual care

Outcome: 2 HF readmissions

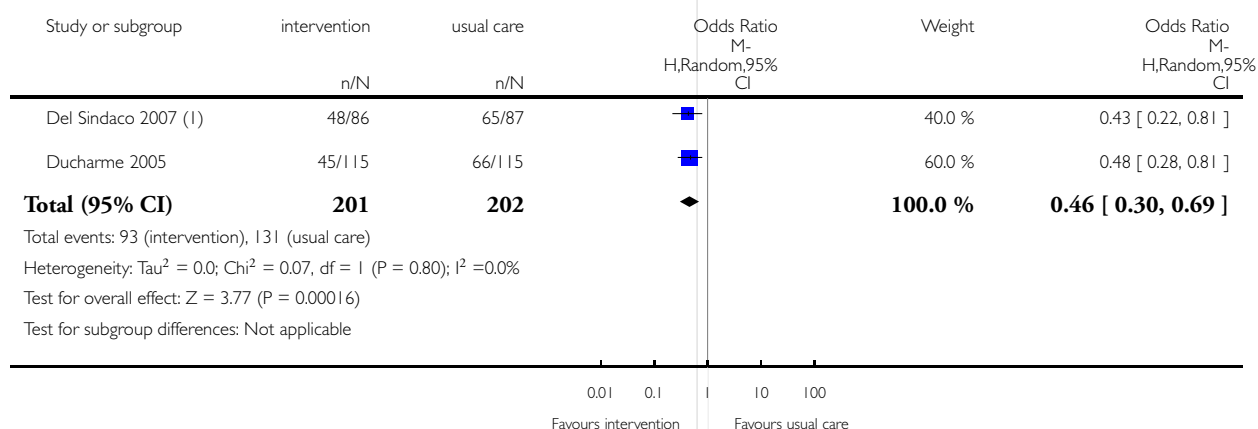


Analysis 4.3. Comparison 4 Multidisciplinary vs. usual care, Outcome 3 All cause readmissions.

Review: Clinical service organisation for heart failure

Comparison: 4 Multidisciplinary vs. usual care

Outcome: 3 All cause readmissions



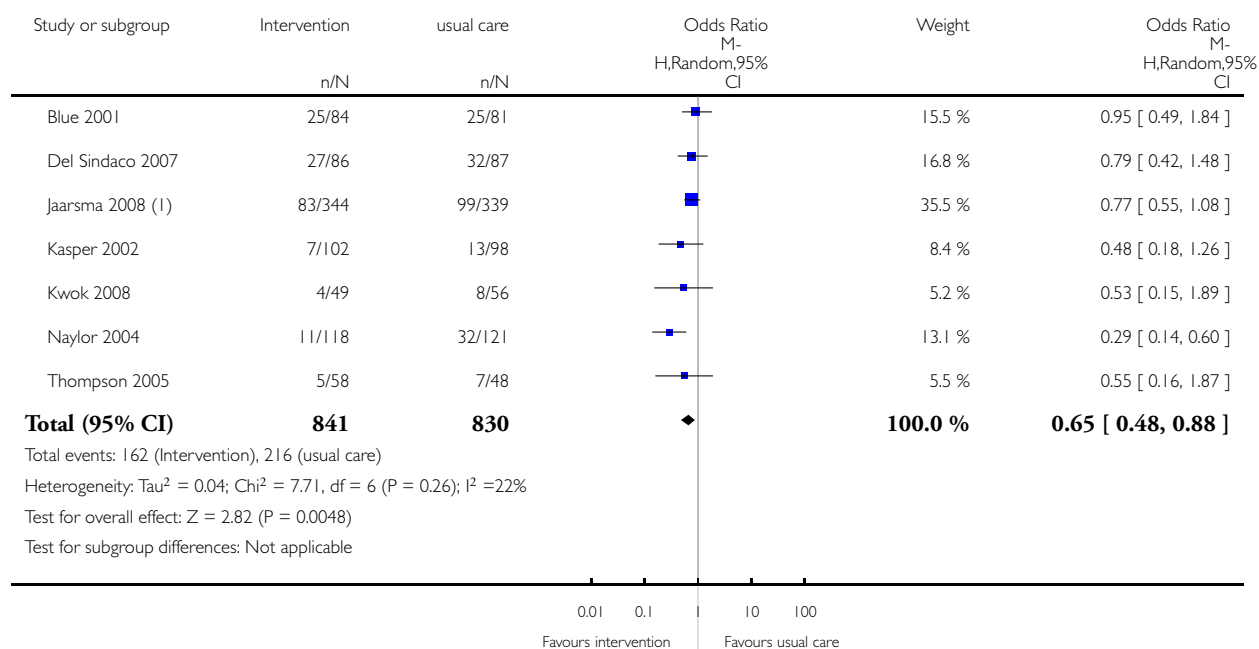
(I) 24 months follow up

Analysis 5.1. Comparison 5 Level of intensity (agreed by authors), Outcome 1 Mortality intensive intervention.

Review: Clinical service organisation for heart failure

Comparison: 5 Level of intensity (agreed by authors)

Outcome: 1 Mortality intensive intervention



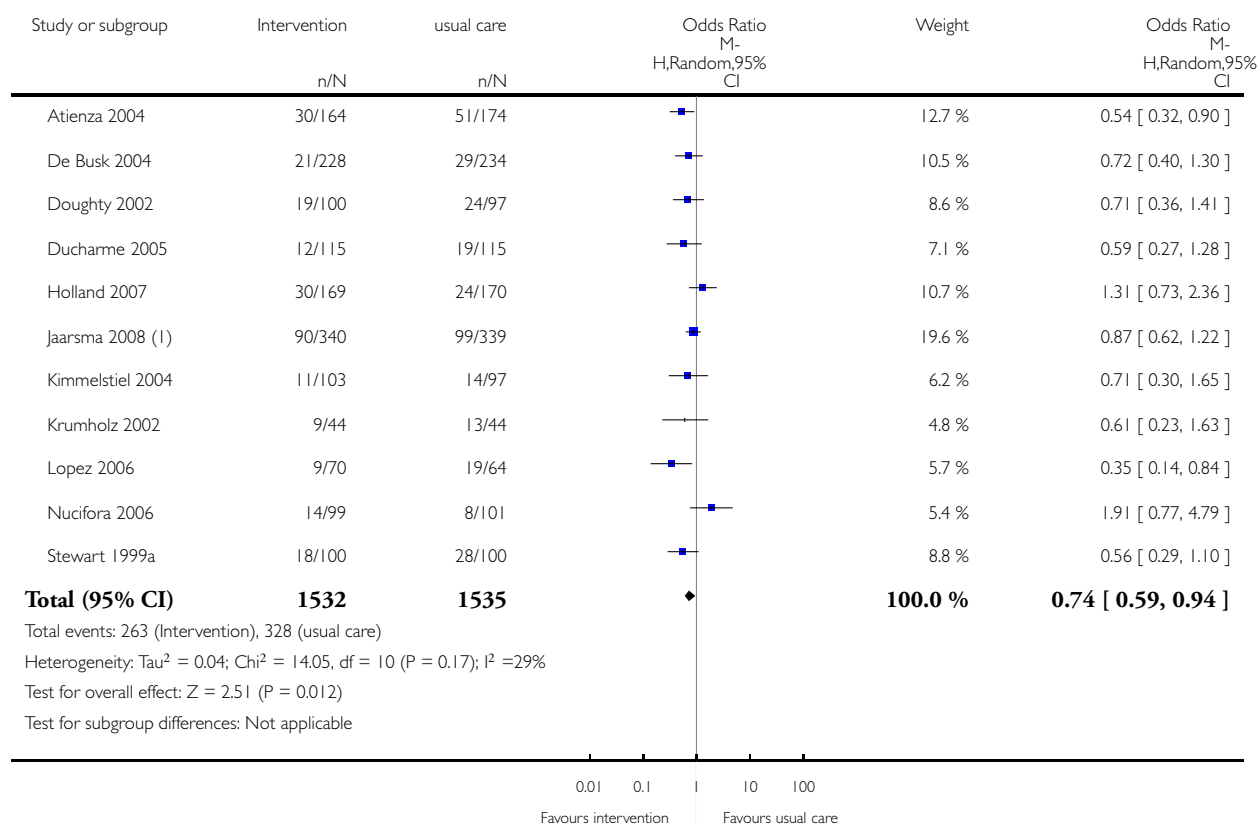
(I) intensive intervention

Analysis 5.2. Comparison 5 Level of intensity (agreed by authors), Outcome 2 Mortality moderately intensive intervention.

Review: Clinical service organisation for heart failure

Comparison: 5 Level of intensity (agreed by authors)

Outcome: 2 Mortality moderately intensive intervention



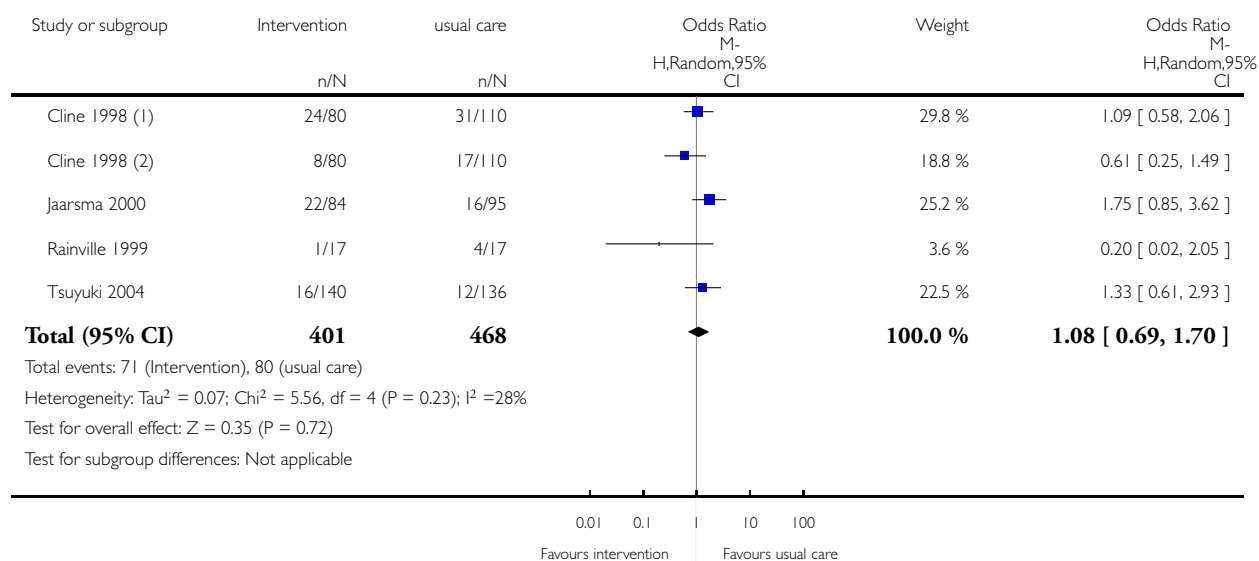
(1) basic intervention

Analysis 5.3. Comparison 5 Level of intensity (agreed by authors), Outcome 3 Mortality low intensity intervention.

Review: Clinical service organisation for heart failure

Comparison: 5 Level of intensity (agreed by authors)

Outcome: 3 Mortality low intensity intervention



(1) one year

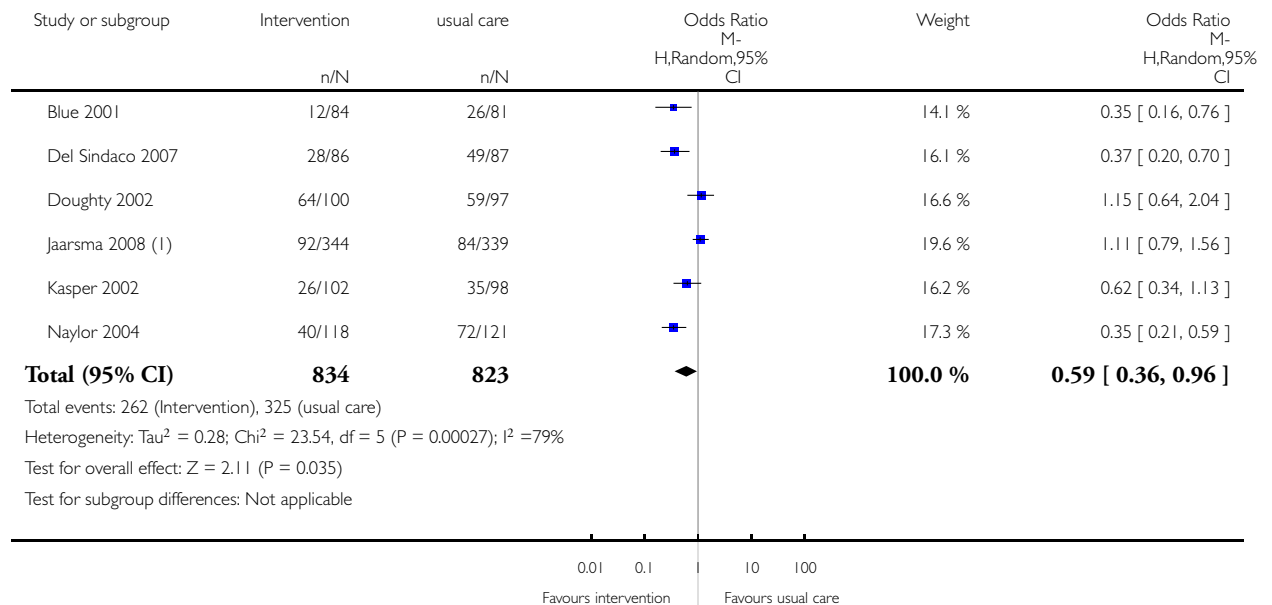
(2) 90 day data from Cline 2001

Analysis 5.4. Comparison 5 Level of intensity (agreed by authors), Outcome 4 HF readmissions intensive intervention.

Review: Clinical service organisation for heart failure

Comparison: 5 Level of intensity (agreed by authors)

Outcome: 4 HF readmissions intensive intervention



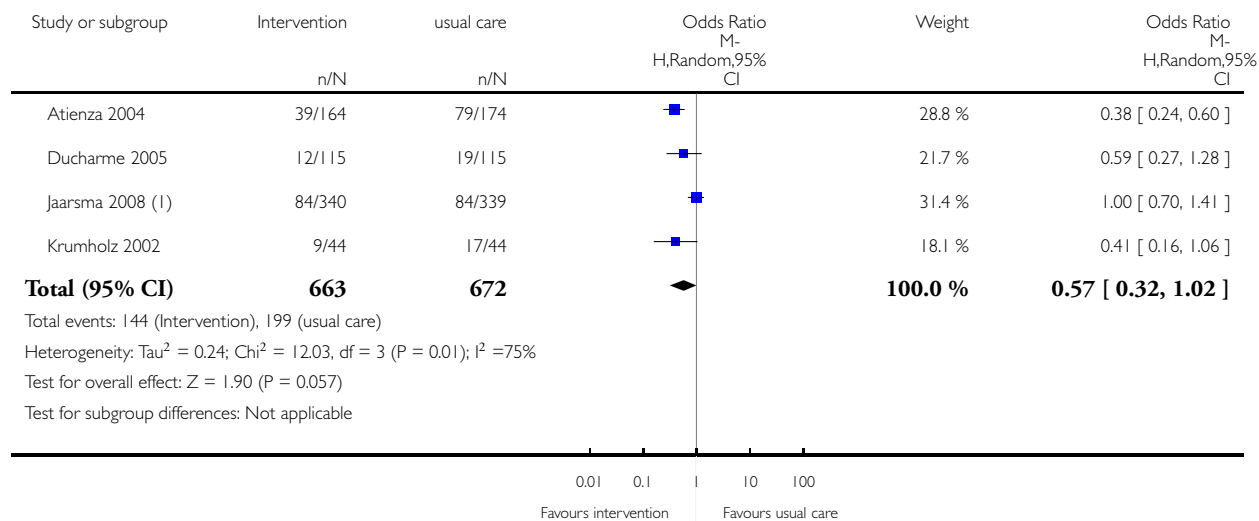
(I) intensive

Analysis 5.5. Comparison 5 Level of intensity (agreed by authors), Outcome 5 HF Readmissions moderately intensive intervention.

Review: Clinical service organisation for heart failure

Comparison: 5 Level of intensity (agreed by authors)

Outcome: 5 HF Readmissions moderately intensive intervention



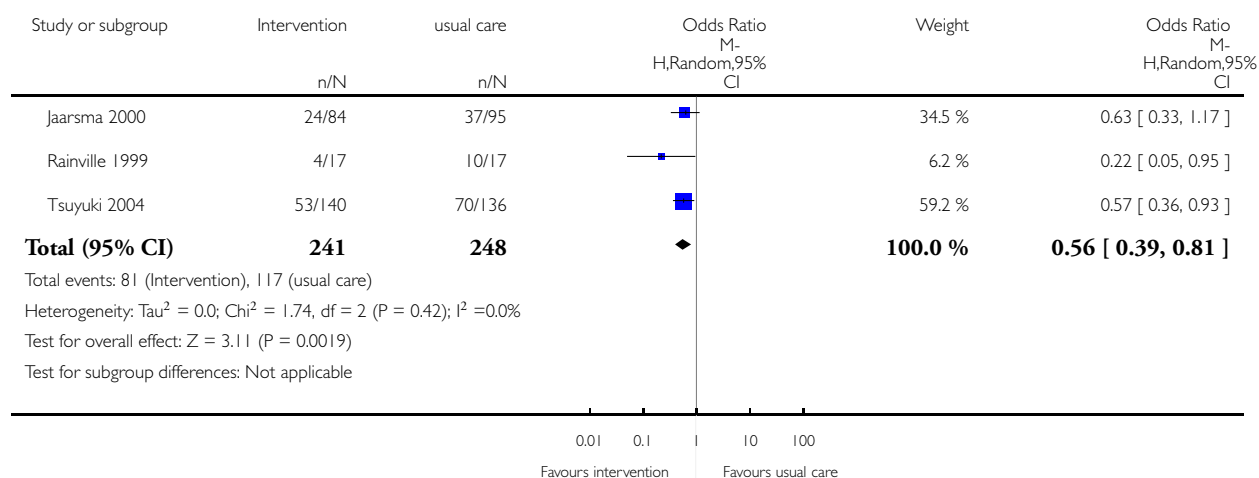
(1) basic intervention

Analysis 5.6. Comparison 5 Level of intensity (agreed by authors), Outcome 6 HF Readmissions low intensity intervention.

Review: Clinical service organisation for heart failure

Comparison: 5 Level of intensity (agreed by authors)

Outcome: 6 HF Readmissions low intensity intervention

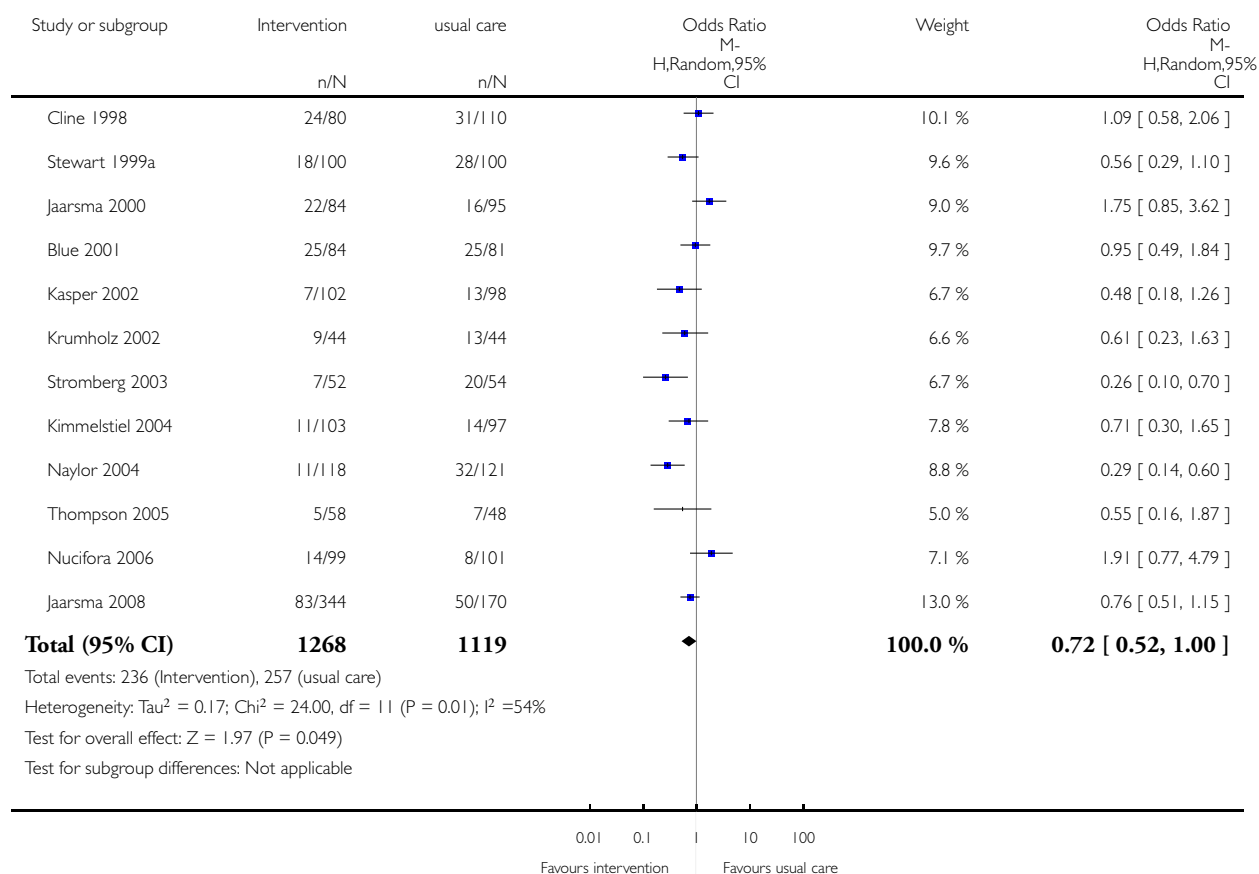


Analysis 6.1. Comparison 6 Professional delivering intervention, Outcome 1 mortality- specialist nurse.

Review: Clinical service organisation for heart failure

Comparison: 6 Professional delivering intervention

Outcome: 1 mortality- specialist nurse

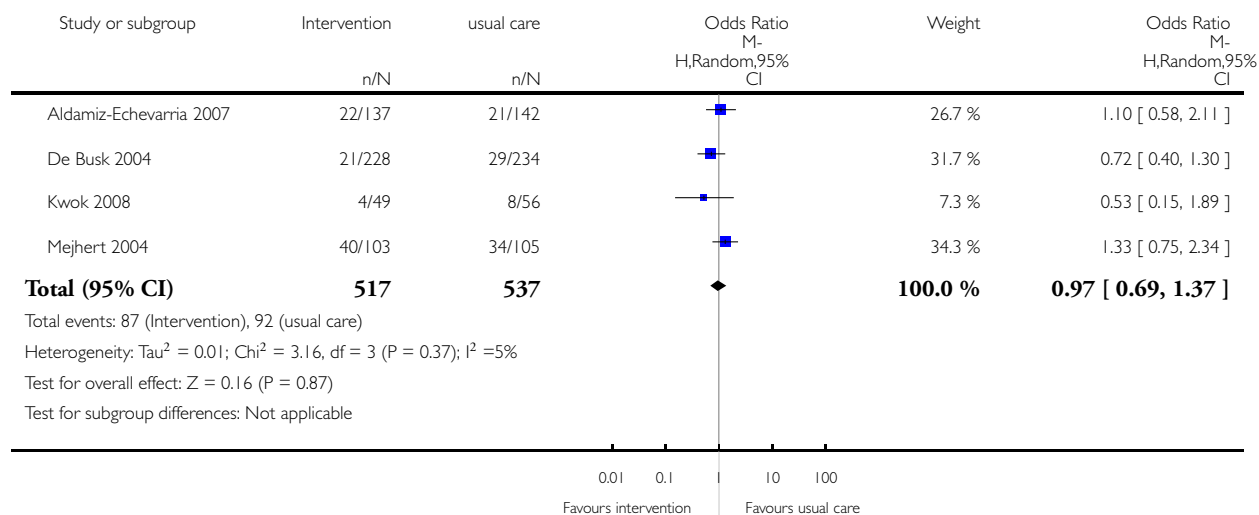


Analysis 6.2. Comparison 6 Professional delivering intervention, Outcome 2 mortality - nurse/community nurse.

Review: Clinical service organisation for heart failure

Comparison: 6 Professional delivering intervention

Outcome: 2 mortality - nurse/community nurse

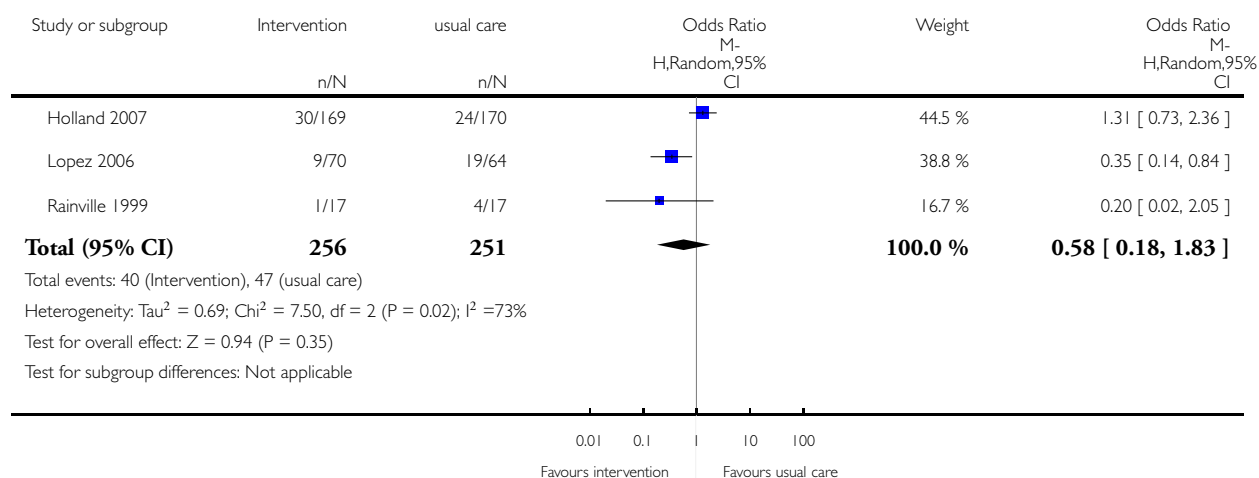


Analysis 6.3. Comparison 6 Professional delivering intervention, Outcome 3 mortality - pharmacist / community pharmacist.

Review: Clinical service organisation for heart failure

Comparison: 6 Professional delivering intervention

Outcome: 3 mortality - pharmacist / community pharmacist

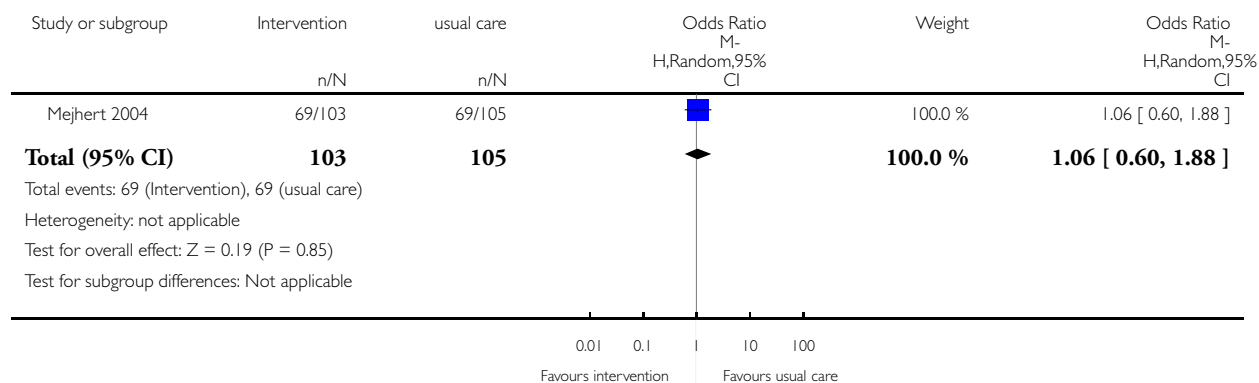


Analysis 6.4. Comparison 6 Professional delivering intervention, Outcome 4 HF readmissions - nurse/community nurse.

Review: Clinical service organisation for heart failure

Comparison: 6 Professional delivering intervention

Outcome: 4 HF readmissions - nurse/community nurse

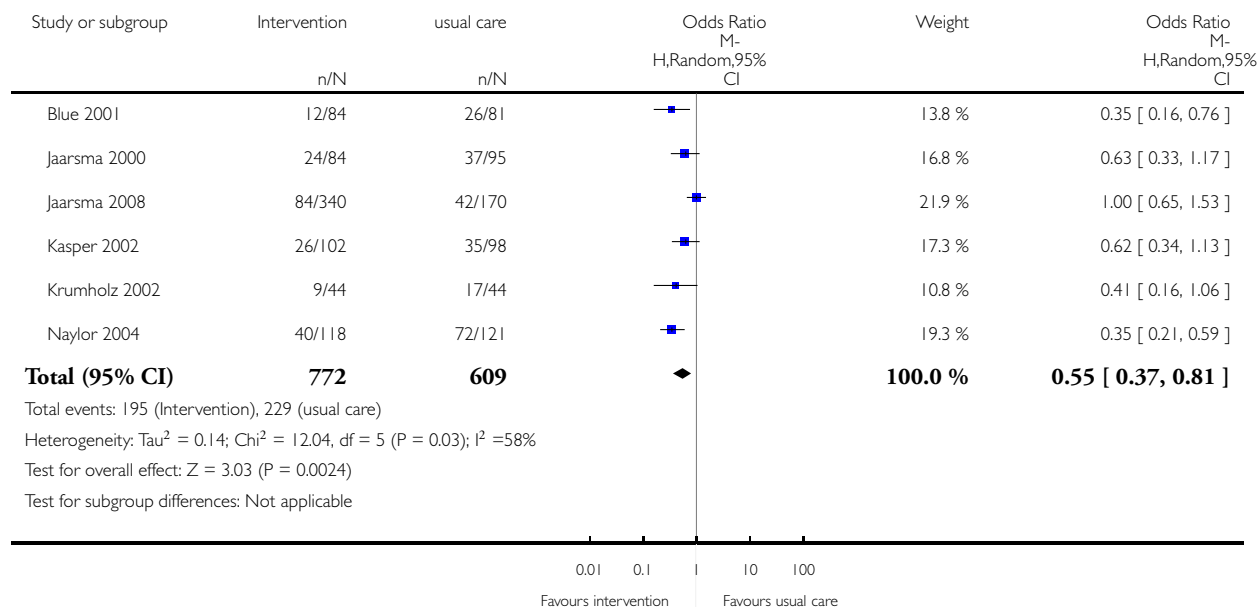


Analysis 6.5. Comparison 6 Professional delivering intervention, Outcome 5 HF readmissions - specialist nurse.

Review: Clinical service organisation for heart failure

Comparison: 6 Professional delivering intervention

Outcome: 5 HF readmissions - specialist nurse

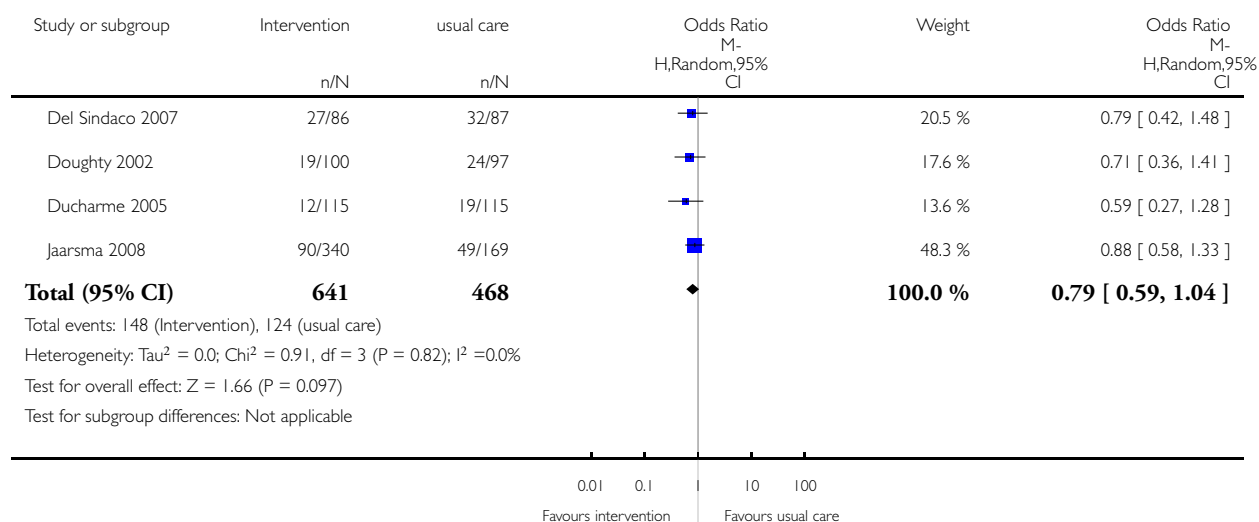


Analysis 6.6. Comparison 6 Professional delivering intervention, Outcome 6 mortality - multidisciplinary.

Review: Clinical service organisation for heart failure

Comparison: 6 Professional delivering intervention

Outcome: 6 mortality - multidisciplinary

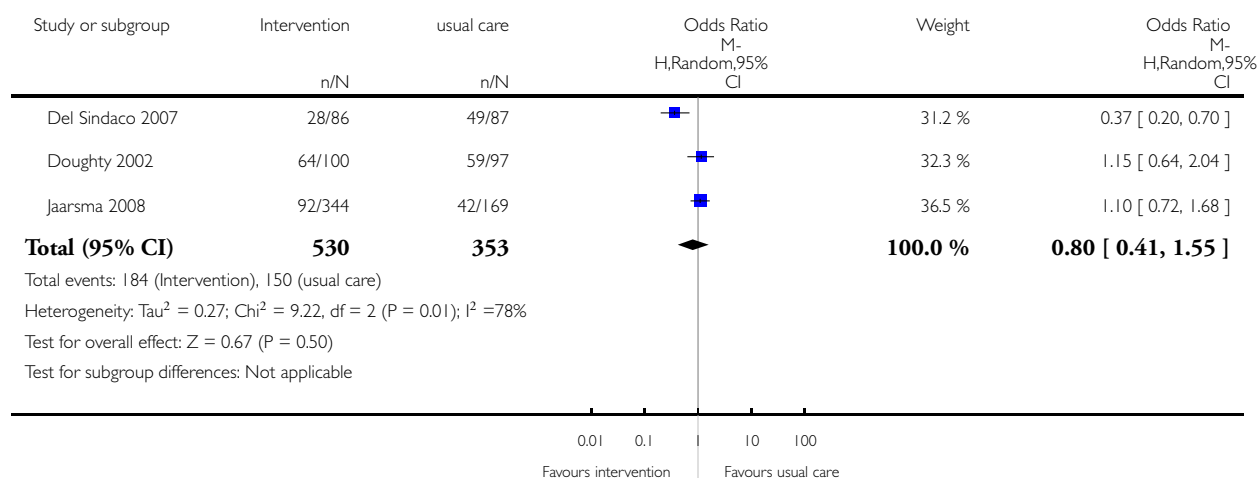


Analysis 6.7. Comparison 6 Professional delivering intervention, Outcome 7 HF readmissions - multidisciplinary.

Review: Clinical service organisation for heart failure

Comparison: 6 Professional delivering intervention

Outcome: 7 HF readmissions - multidisciplinary



ADDITIONAL TABLES

Table 1. Study components (as indicated in published reports)

Study	Phone follow up	Largely Educational	Self management	Weight monitoring	Dietary advice	Exercise promotion	Medication review	Social/psych. sup.	Duration
Cline 1998		Y	Y	Y					12 months
Rainville 1999	Y			Y			Y		3 months
Stewart 1999a	Y					Y			Intervention concentrated in first 2 weeks but some phone

Table 1. Study components (as indicated in published reports) *(Continued)*

									contact up to end of follow up (6 months)
Jaarsma 2000	Y (one call)	Y							Around one week
Blue 2001	Y	Y	Y					Y	Up to 12 months
Capomolla 2002		Y	Y	Y	Y	Y		Y	Not clear
Doughty 2002		Y	Y	Y	Y	Y			12 months
Kasper 2002	Y			Y	Y	Y			6 months
Krumholz 2002	Y	Y							12 months
Stromberg 2003	Y	Y	Y	Y?	Y	Y	Y	Y	unclear
Atienza 2004	Y	Y	Y		Y	Y	Y		Median duration 509 days
De Busk 2004	Y	Y	Y	Y	Y		Y		1 year
Kimmelstiel 2004	Y	Y		Y	Y		Y		90 days + longer for unstable patients
Mejhert 2004			Y	Y	Y		Y		18 months
Naylor 2004	Y	Y	Y		Y	Y	Y		3 months intervention, 1 year follow up
Tsuyuki 2004	Y	Y	Y	Y	Y	Y			6 months

Table 1. Study components (as indicated in published reports) *(Continued)*

Ducharme 2005	Y			Y	Y		Y		6 months
Thompson 2005		Y	Y	Y					6 months
Lopez 2006	Y	Y			Y				12 months
Nucifora 2006	Y		Y				Y		6 months
Aldamiz-Echevarria 2007	Y	Y	Y		Y		Y		15 days
Del Sindaco 2007	Y						Y		24 months
Holland 2007		Y		Y	Y	Y			6-8 weeks
Jaarsma 2008	Y			Y*	Y*				18 months * for intensive intervention only
Kwok 2008	Y				Y	Y	Y	Y	6 months

Table 2. Delphi quality criteria table

Study	Ran-domised?	Allocation concealed	Similar at baseline?	Eligibility specifd.	Assessor masked?	Point estimates etc?	Intention to treat?	Notes
Cline 1998	Y	U	Y(a)	Y	U	N	U	(a) Mean LVEF significantly lower in intervention group.
Rainville 1999	Y	U	N	Y	N	N	N	

Table 2. Delphi quality criteria table (Continued)

Stewart 1999a	Y	Y	Y	Y	Y	Y	Y	
Jaarsma 2000	Y	U	U(b)	Y	N	N	N	(b) Considerable attrition of study subjects but only those who remained in the study at 9 months are compared at baseline
Blue 2001	Y	Y	Y	Y	Y	Y	U	
Capomolla 2002	U(c)	U	Y	Y(d)	N	Y	U	(c) Method of randomisation not specified (d) apparently no exclusion criteria
Doughty 2002	Y	U	Y	Y	U	N	Y	
Kasper 2002	Y	Y	U(e)	Y	Y	N	Y	(e) Information on presence of all risk factors identified by authors not supplied
Krumholz 2002	Y	N	Y(f)	Y	Y	Y	U	(f) Intervention group significantly older with lower incidence of prior CABG and fewer pre-scribed cal-

Table 2. Delphi quality criteria table (Continued)

								cium chan- nel blockers
Stromberg 2003	Y	Y	N (g)	Y	Y	U	Y	g) There were significantly more patients with hypertension in the intervention group, 26 vs 16 ($p<0.05$). There were more patients with diabetes in the control group, 17 vs eight ($p=0.05$).
Atienza 2004	Y	U	Y(h)	Y	U	Y	Y	(h) More control patients had valvular heart disease (47/174 compared with 31/164) and fewer were on a beta blocker 20/174 compared with 31/164).
De Busk 2004	Y	Y	Y	Y	Y	Y	Y	
Kimmelstiel 2004	Y	U	U (i)	Y	Y	Y	U(j)	(i) Control group patients' mean age slightly older, $p<0.5$. Authors state results not adjusted

Table 2. Delphi quality criteria table (Continued)

								for this because "patient age was not related to any of the outcomes examined" (j) Numbers included in analysis not reported
Mejhert 2004	Y	U	Y	Y	U	N	Y	
Naylor 2004	Y	Y	Y	Y	Y	Y	Y	
Tsuyuki 2004	Y	U	U(k)	Y	U	Y	Y	(k) 65% of the intervention group had an ischemic etiology compared with only 51% in the usual care group (P=0.03)
Ducharme 2005	Y	Y	U (l)	Y	U	Y	Y	l) intervention group had slightly higher baseline medication use
Thompson 2005	Y	U	Y	Y	Y	U	Y	
Lopez 2006	Y	Y	N(m)	Y	U	Y	U(n)	(m) groups generally comparable, but intervention group had higher ejection fraction

Table 2. Delphi quality criteria table (Continued)

								than controls (p<0.05) (n) States cost analysis based on intention to treat, but 3 patients were excluded due to missing data on out-patient appointments
Nucifora 2006	U	U	U(o)	Y	N	Y	Y	(o) Statistically significantly more patients in the intervention group were in sinus rhythm compared to control group (73% vs 52%, p=0.06). More patient in control group had previous CABG compared to intervention group (13% vs 5%, p=0.059)
Aldamiz-Echevarria 2007	Y	Y	Y	Y	U	Y	U	
Del Sindaco 2007	U	N(p)	Y	Y	Y	Y	Y	(p) eligible patients randomised prior to in-

Table 2. Delphi quality criteria table (Continued)

								formed consent which was given on the basis of information relevant to allocated study group
Holland 2007	Y	Y	Y(q)	Y	U	Y	Y	(q)fewer intervention participants were from non-manual social classes (44% v 55%) and intervention participants more often used some form of drug adherence aid (27% v 16%)
Jaarsma 2008	Y	U	Y	Y	Y	Y	Y	
Kwok 2008	Y	Y	Y(r)	Y	Y	Y	Y	(r)The intervention group subjects were more likely to be recipients of CSSA and were at greater economical disadvantage

CABG=coronary artery bypass graft

Table 3. Results of Included Studies

Study ID	Results	Notes
Cline 1998	<p>(All reported as intervention gp. vs. control gp.)</p> <p>"Main outcomes" (primary endpoint not specified) :</p> <p>Mean days to readmission in survivors at one year: 141 (87) vs. 106 (101), $P < 0.05$ (see comment below).</p> <p>Mean days in hospital in survivors at one year: 4.2 (7.8) vs. 8.2 (14.7) NS, $P = 0.07$ (unequal variance) .</p> <p>Also looked at:</p> <p>Deaths at one year: 24 (31%) vs. 31 (28%), NS, (test statistic not given)</p> <p>Deaths at 90 days (Cline 2001): 8/80 vs. 17/110, P given as <0.001, erroneous, our estimation $P = 0.3$</p> <p>Death or at least one readmission to hospital (composite end point) at 12 months: 56 (70%) patients vs. 79 (72%) patients, NS, (test statistic not given)</p> <p>Death or at least one readmission to hospital (composite end point) at 90 days: At three months 53 (66%) vs. 61(56%) NS</p> <p>Number of patients surviving to one year who were readmitted: 22 (39%) vs. 43 (54%) NS, $P = 0.08$</p> <p>Mean no. of hospitalisations per patients surviving to one year: 0.7 (SD 1.1) v 1.1 (SD 1.8) NS , $P = 0.08$</p> <p>Outpatient visits (not clear how defined): 3.6 (3.2) vs. 4.0 (3.4) NS</p> <p>Treatment at one year, % on ACEI: 41 (75%) vs. 41 (52%) $P < 0.05$</p> <p>Treatment at one year, % on all other HF drugs: all differences NS</p> <p>The quality of life in heart failure questionnaire, Nottingham health profile and patients' global self</p>	<p>Comment on statistical analyses:</p> <p>No sample size calculation given, but our post hoc calculations suggest that this study had adequate power.</p> <p>We note an apparent error on page 444, the text says that says 56/79 patients died or were readmitted, Table 2 says 56/79 patients survived some with readmission. Elsewhere the text suggests 46/74 died or were readmitted.</p> <p>The mean time to readmission in patients who survived to one year was longer in the intervention than in the control group (mean days to readmission 141 (SD 87) vs. 106 (100) is given as having $P < 0.05$, but this result is contradicted by the non-significant result of the robust log-rank test which tests the outcome time to death or readmission.</p> <p>Outcome data on readmissions, days in hospital and costs all on survivors at one year not on whole group.</p> <p>Study had some before and after analyses that are not reported here</p>

Table 3. Results of Included Studies (Continued)

	assessment: all differences NS at one year, (test statistics not given)	
Rainville 1999	<p>(All reported as intervention group. vs. control group.)</p> <p>Primary endpoint: Number of patients who died (all causes) or were readmitted with HF at one year: 5 vs. 14, $P < 0.01$ probably Chi squared test (NB See statistical comment below.)</p> <p>Time to readmission for HF or patient death: Significantly longer in intervention group, $P < 0.01$ log rank test.</p> <p>Also reported: Number of patients readmitted with HF at one year : 4 vs. 10, $P 0.05$ probably Chi squared test (NB See statistical comment below.)</p> <p>Deaths (all cause) at one year: 1 v 4 (test statistic not given)</p> <p>Total no. of readmissions at one year : 20 v 26 NS, (test statistic not given)</p> <p>Change in functional health assessment score (Dartmouth COOP charts): no significant change at 30 or 90 days for either group (no test results given)</p>	<p>Comment on statistical analyses: Very small sample size. Inappropriate statistical tests used with small sample sizes. (Chi-square test should not be used here, the correct test is Fisher's exact test.)</p>
Stewart 1999a	<p>(All reported as intervention gp. vs. control gp.)</p> <p>Primary endpoint: Frequency of unplanned readmissions plus all cause out-of-hospital deaths during 6 months follow up: 77 primary events vs. 129 primary events, event rates per month 0.20 (95% CI 0.14-0.26) vs. 0.40 (0.24-0.56), $P = 0.02$ (test not clear) (NB see statistical comment).</p> <p>Other endpoints: Frequency of unplanned readmissions alone at 6 months: 68 vs. 118, event rates per month 0.14 (95% CI 0.10-0.18) vs. 0.34 (0.19-0.49), $P = 0.03$ (NB see statistical comment).</p> <p>Out of hospital deaths at 6 months: 9 v. 11, NS</p>	<p>Comment on statistical analyses: A rationale for the sample size was provided and the sample size appears to have been adequate. The primary end-point is unusual and does not correspond to any well known statistical test. The statistical tests used to analyse multiple events are unclear and it is not certain which test they used to analyse their primary endpoint. Other points: Not clear how readmission was determined to be unplanned or planned.</p> <p>Frequency distribution of unplanned readmissions in the two groups suggests that the difference in unplanned admissions was predominantly amongst those relatively few patients who had three or more admissions in the 6 month follow up period - most</p>

Table 3. Results of Included Studies (Continued)

<p>All cause deaths at 6 months: 18 vs. 28, $P = 0.098$</p> <p>Number of patients remaining event free (i.e. death or readmission) at 6 months: 51 vs. 38, $P = 0.04$</p> <p>Total unplanned days in hospital at 6 months: 460 v. 1174, event rates per month 0.9 (0.6-1.2) vs. 2.9 (1.9-3.9), $P = 0.01$ (NB see statistical comment).</p> <p>Change in Minnesota living with heart failure questionnaire between baseline and 3 & 6 months (random sample of 68 patients): intervention group significantly bigger fall in score than control group at 3 months (higher scores indicate impaired QOL but clinical significance of change seen not clear), no significant difference in scores of survivors at 6 months.</p> <p>Change in Australian version SF-36 between baseline and 3 & 6 months (random sample of 68 patients): no differences seen in mental health scores, change in physical health scores at 3 months significantly higher in intervention group (clinical significance not clear) but no difference in survivors at 6 months.</p> <p>Also looked at: Difference in probability of survival at 18 months: $P = 0.1$</p> <p>Frequency of unplanned readmissions alone at 'the end of follow up' (around 18 months): 118 vs. 156, event rates per month 0.15 (0.11-0.19) vs. 0.37 (0.19-0.55), $P = 0.053$</p> <p>Total elective days in hospital at 6 months: 87 vs. 25, $P = 0.13$</p> <p>Total unplanned days in hospital at 'the end of follow up' (around 18 months): 875 vs. 1476, event rates per month 1.1 (0.8-1.4) vs. 2.7 (1.6-3.7), $P = 0.04$</p> <p>Regression analysis showed that assignment to intervention group was a borderline, independent predictor of survival, $P = 0.046$, Cox proportional hazards model</p>	<p>of these were in the control group.</p> <p>Intervention group patients accumulated more elective days in hospital (87 vs. 25 $P = 0.13$) the majority for surgical procedures delayed whilst patient clinically unstable. However, similar proportions of unplanned readmissions associated with a primary diagnosis of heart failure in each group: 34 (50%) intervention vs. 58 (49%) controls.</p> <p>88/100 intervention patients received intervention 2 died and 10 withdrew after initial consent.</p> <p>After initial home visit immediate review by primary care physician or cardiologist was requested for 33 patients, 42 intervention patients had a flexible diuretic regimen introduced, 19 patients had greater pharmacy contact arranged and 23 patients had new or increased home support services arranged</p>
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Table 3. Results of Included Studies (Continued)

Jaarsma 2000	<p>(All reported as intervention gp. vs. control gp.)</p> <p>Please note: The authors of this study make adjustments to their findings both for attrition and multiple testing. For clarity mean scores, SDs and P values for the different scales are not shown in this table unless the authors have stated by that the findings are significant.</p> <p>Measures of QOL Heart Failure Functional Status Inventory: difference NS at 3 months and at 9 months</p> <p>Symptom occurrence: difference NS at 1, 3 and 9 months</p> <p>Change in symptom severity and distress from baseline: considerable attrition at both 3 and 9 months (e.g. for symptom severity only 26/58 responses in intervention group, 42/74 in control group at 9 months), differences NS at 3 months and NS at 9 months after attempt to adjust for attrition by attributing change score of zero to missing values.</p> <p>Psychosocial Adjustment to Illness Scale: differences NS at 3 and 9 months.</p> <p>Cantril's Ladder of Life: Patients often stated that they had difficulty with this scale resulting in several missing values, differences NS at 1 month (results for 3 and 9 months not given because patients had such difficulty using the scale*).</p> <p>Measures of self-agency and self care behaviour Self care abilities, Appraisal of Self-Care Agency Scale: differences NS at baseline, 3 and 9 months follow up.</p> <p>Self care behaviours: difference NS at baseline and 9 months follow up. At 1 month: 13.8 (SD 3.4) vs. 12.2 (2.9) $P < 0.001$, at 3 months: 11.6 (SD 3.1) vs. 10.2 (3.3) $P < 0.005$.</p> <p>Health care resource use Hospital readmissions (on all patients i.e. 84 intervention and 95 control patients), average days in hospital per patient at 9 months follow up: 9 vs. 9,</p>	<p>Comment on statistical analyses: Rationale for sample size given. The exact statistical tests used in the final analysis were unclear.</p> <p>Other points: 186 patients were enrolled in the study, 7 died before discharge from the index admission, by 9 months 47 (26%) of the remaining 179 had died or dropped out, the data for those who remained had a large number of missing values. Differences in self care behaviour scores significantly better at 1 and 3 months in intervention group but mean differences very small and clinical significance unclear</p>
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Table 3. Results of Included Studies (Continued)

	<p>NS, P value and test not given.</p> <p>Patients with at least one hospital readmission at 9 months follow up: 31 (37%) vs. 47 (50%), P = 0.06, Chi squared test</p> <p>Cardiac readmissions at 9 months follow up, mean days per patient: 5.1 days (SD 11) vs. 7.1 days (SD 15), NS, P value and test not given</p> <p>Patients with at least one cardiac hospital readmission at 9 months follow up: 24 (29%) vs. 37 (39%), P = 0.1, Chi squared test</p> <p>Patients with at least one hospital readmission at 1 month follow up: no significant differences between the two groups</p> <p>Hospital readmissions, average days in hospital per patient at 3 months follow up: 5.1 vs. 5.1, NS, P value and test not given.</p> <p>Patients with at least one hospital readmission at 3 months follow up: 22 (26%) vs. 29 (31%), NS, P value and test not given.</p> <p>Cardiac readmissions at 3 months follow up, mean days per patient: 18 (21%) vs. 23 (24%) NS, P value and test not given.</p> <p>Hospital readmissions, average days in hospital for cardiac readmission per patient at 3 months follow up: 3.0 vs. 4.1, NS, P value and test not given.</p> <p>Also reported: Deaths during 9 months follow up : 22 vs. 16 NS</p>	
Blue 2001	<p>(All reported as intervention gp. vs. control gp.)</p> <p>Primary endpoint at around 12 months: Number of patients with death from all causes or hospital admission for heart failure: 31 vs. 43, hazard ratio = 0.61 (95% CI 0.38 to 0.96), P = 0.03</p> <p>Secondary endpoints at around 12 months: Death: 25 v. 25 NS</p> <p>Number of patients with death from all causes or all cause hospital readmission: 52 vs. 61, hazard ratio</p>	<p>Comment on statistical analyses: The size of the study was only just adequate for statistical power based on a calculation for 12 months follow up. Some of the statistical results are presented in an ambiguous way. The study might have benefited from a further exploration of the data with some sensitivity analyses. For example, the primary endpoint includes deaths that occurred in hospital after randomisation. As it happens there were more deaths in the control group than in the intervention group (6 vs. 1), if the</p>

Table 3. Results of Included Studies (Continued)

	<p>= 0.72 (95% CI 0.49 to 1.40) NS, P = 0.075</p> <p>Number of patients with hospital readmission (all causes): 47 vs. 49, P = 0.27, NS</p> <p>Number of patients with hospital readmission for worsening HF: 12 vs. 26, P = 0.004</p> <p>Also looked at (at around 12 months):</p> <p>Number of admissions per patient per month (all causes): 0.124 vs. 0.174, hazard ratio = 0.71 (95% CI 0.54 to 0.94) P = 0.018</p> <p>Number of admissions per patient per month (worsening HF): 0.027 vs. 0.069, hazard ratio = 0.40 (95% CI 0.23 to 0.71) P = 0.0004</p> <p>Mean days spent in hospital (all causes): 10.3 (SD 19.0) vs. 16.7 (24.1), P = 0.08</p> <p>Mean days spent in hospital (worsening HF): 3.43 (12.2) vs. 7.46 (16.6), P = 0.005</p>	<p>analysis is re-done excluding these in pre-discharge hospital deaths the primary endpoint is no longer significant</p>
Capomolla 2002	<p>(All reported as intervention group vs. control group.)</p> <p>Primary outcomes:</p> <p>Relative risk of cardiac death or urgent heart transplantation: RR 0.17, favouring intervention, (95% CI 0.06, 0.66)</p> <p>Deaths from cardiac causes: 3/112 (3%) vs. 21/122 (17%), P 0.0007</p> <p>Total number of hospital readmissions at mean 12 (SD3) months follow up: 13 vs. 78, P<0.00001 (NB not clear if these readmissions are because of haemodynamic instability as stated earlier in the paper.)</p> <p>Total number of patients with at least one rehospitalisation during follow up: 8 vs. 35 P <0.05</p> <p>Secondary outcomes:</p> <p>QOL (time trade off method): 0.72 (SD 0.17) vs. 0.63 (SD 0.22) P < 0.008. (i.e. intervention patients were willing to trade 10 years of their present health for 7.2 years of excellent health, whereas control patients were willing to trade 6.3 years of their present health. (NB only change within the two groups reported.)</p>	<p>Comment on statistical analyses:</p> <p>No sample size provided but study appears to have adequate power and the statistical tests employed are appropriate.</p> <p>There is a serious error in Table 3 on page 1263: NYHA classifications are given on 112/112 usual care patients at one year and on 113/112 day hospital patients at one year despite the fact that we are told that cardiac death occurred in 21/122 patients in the community group and 3 patients in the day hospital group.</p> <p>Other points:</p> <p>Not stated how deaths from cardiac causes were identified.</p> <p>Not stated how readmissions because of haemodynamic instability were identified.</p> <p>Total number of deaths in each group not given.</p> <p>Not clear if QOL was same at baseline for both groups.</p> <p>Not all the 112 patients in the intervention received all the components of the intervention: 76% received education and physical training; 47% received cardiovascular risk stratification; 45% received tailored therapy; 19% received multidisciplinary intervention.</p>

Table 3. Results of Included Studies (Continued)

	<p>NYHA functional class: only reported as before and after findings and error in table showing the results of NYHA functional class at one year see below.</p> <p>Also looked at: Urgent heart transplant during follow up: 1 vs. 0.</p>	<p>There were 49 'open access interventions' in the intervention group, these included interventions which would have required admission in the control group</p>
Doughty 2002	<p>(All reported as intervention gp. vs. control gp.)</p> <p>Primary endpoints: Event free survival, time to first hospital admissions or all cause death: $P = 0.33$ (NS), Kaplan-Meier</p> <p>HRQL, Change in MLHFQ total score from baseline to 12 months between the two groups: $P = 0.1$ (NS) (change in physical score -11.1 vs. -5.8, $P = 0.015$, change in emotional score -3.3 both groups, $P = 0.97$, NS)</p> <p>Secondary endpoints: All cause hospital readmission rates at 12 months: 1.37 readmissions per patient per year vs. 1.84 (method of calculation not given), rate difference = 0.47 per patient per year (95% CI 0.16, 0.78) .</p> <p>All cause total hospital bed days at 12 months: 1074 vs. 1170 NS, test statistic not given, 12.3 bed days per patient per year vs. 13.9, mean difference in bed days per patient = 1.6 (95% CI 0.51, 2.7) (method not given)</p> <p>readmissions for heart failure at 12 months: 36 vs. 65 NS</p> <p>Also reported: All cause deaths at one year: 19 (19%) vs. 24 (25%)</p> <p>Medication: trend ($P = 0.052$) for intervention group to be on higher ACEI dose at 12 months, no other significant differences</p> <p>Mean time to 1st hospital readmission: 102 (SD 104) vs. 122 (SD 116) $P = 0.4$, NS. (method not given)</p> <p>Total all cause readmissions at 12 months: 120 vs. 154 NS, P value not given (method not given)</p>	<p>Comment on statistical analyses: Trial terminated early apparently because inadequate power to detect difference in primary endpoint. An accompanying editorial article states: "The study was actually prematurely stopped. A provisional estimate of 180 patients per group was made but the final sample size was calculated after 100 patients had been followed for 6 months. The event rate was found to be higher than expected but there was no difference between the two groups for the combined primary endpoint of death or readmission. Projection of the observed effect size suggested that an order of magnitude of more patients would have been required to achieve a result reaching statistical significance, but even this would probably have had little clinical significance. The follow-up of patients already recruited was completed to allow data for total admissions and quality of life to be analysed" (Cunningham 2001).</p> <p>The explanation of the statistical analysis for the analysis of multiple admissions lacks clarity. Some of the data is continuous but since admissions and bed days are likely to be highly skewed the t test, whose use is mentioned in the paper, would be inappropriate. Also the use of Fisher's exact test to compare subsequent readmissions does not seem appropriate since this test cannot be used to analyse multiple events.</p> <p>Other comments: Baseline values of MLHFQ not given. 60% of the intervention group attended the first group educational session, 40% attended the six month educational session</p>

Table 3. Results of Included Studies (Continued)

	<p>First all cause readmissions at 12 months: 64 vs. 59 NS, P value not given (method not given)</p> <p>Subsequent all cause readmissions 56 vs. 95, P = 0.015 (Fishers exact test - test inappropriate)</p> <p>All cause hospital bed days first readmissions: 546 vs. 444 (no statistical test result given)</p> <p>All cause bed days during subsequent readmissions: 528 vs. 726 P = 0.0001 (test method not given)</p> <p>First heart failure related readmissions at 12 months: 21 vs. 23 NS, test statistic not given</p> <p>Subsequent heart failure related readmissions at 12 months: 15 vs. 42 P <0.05 (Fishers exact test - test inappropriate)</p> <p>Total hospital bed days for heart failure related readmissions at 12 months: 358 vs. 561 NS, test statistic not given</p> <p>Hospital bed days for first heart failure related readmission at 12 months: 219 vs. 195 NS, test statistic not given</p> <p>Hospital bed days for subsequent heart failure related readmission at 12 months: 139 vs. 366 P = 0.0001 (test method not given)</p>	
Kasper 2002	<p>(All reported as intervention gp. vs. control gp.)</p> <p>Primary endpoint: Total number of CHF hospital admissions plus all cause deaths: 50 in 102 patients vs. 72 in 98 patients, P = 0.09 (NS) log transformed t test, P = 0.03 Poisson model comparison (see comment below).</p> <p>Secondary endpoints: Deaths at 6 months: 7 in 102 patients vs. 13 in 98 patients P = 0.14 (NS) log-rank test</p> <p>readmissions for CHF: 43 admissions in 26 patients vs. 59 admissions in 35 patients, P = 0.09 (NS) log transformed t test, P = 0.03 Poisson model comparison.</p>	<p>Comment on statistical analyses: Poisson model analyses suggested by the Oversight, Data and Safety Monitoring Committee before patient enrolment. However the Poisson model does not hold for these data. This is because the results are over dispersed. This means that there are a few patients with higher numbers of readmissions than would be expected using a Poisson model, so if the data are analysed using Poisson model then an incorrectly small SP results. If the results are analysed using a Poisson model where the over dispersion is accounted for then the SP is 0.11, very near the value from the log-rank test of 0.13</p>

Table 3. Results of Included Studies (Continued)

	<p>All cause hospital admissions plus all cause deaths: 84 in 102 patients vs. 109 in 98 patients, $P = 0.13$ (NS) log transformed t test, $P = 0.04$ Poisson model comparison.</p> <p>Event free survival (death or readmission at 6 months): P for difference = 0.12 (NS)</p> <p>QOL: change in Minnesota Living with Heart Failure Q (MLHFQ) total score at 6/12 from baseline, mean, median -28.3, -28 vs. -15.7, -15, $P = 0.001$ Wilcoxon test (lower MLHFQ score = better)</p> <p>Functional status: change in Duke Activity Status Score at 6/12 from baseline, 1.1, 1 (mean, median) vs. 0.8, 1 v, $P = 0.44$ (NS) Wilcoxon test. (Duke Activity Status Index also NS).</p> <p>Process measures at 6 months: Proportion of patients with systolic dysfunction receiving target vasodilators: 74/80 vs. 43/7, $P < 0.001$</p> <p>Dietary compliance "good" or "average": 65/94 vs. 38/85, $P = 0.002$ At goal weight: 47/94 vs. 17/85, $P = 0.001$.</p> <p>Medication compliance: NS difference.</p>	
Krumholz 2002	<p>(All reported as intervention gp. vs. control gp.)</p> <p>Primary outcome: Death or all cause readmission at one year : 25 vs. 36, RR 0.69, 95% CI 0.52, 0.92, $P = 0.01$</p> <p>Risk of HF or other CVD readmission, or death (intervention vs. control): HR 0.51, 95% CI 0.29, 0.90, $P=0.02$ (Cox proportional hazards model adjusted for age; sex; history of HF and admission serum creatinine)</p> <p>Secondary outcomes: Deaths: 9/44 (20%) vs. 13/44 (30%) RR 0.69 (95% CI 0.33 to 1.45), $P=0.33$, NS.</p> <p>Total readmissions in one year: 49 vs. 80, $P=0.06$, test not given.</p>	<p>Comment on statistical analyses: The sample size was small and no power calculation was supplied. The statistical analysis seems appropriate, although it is not clear which tests were used for multiple admissions</p>

Table 3. Results of Included Studies (Continued)

	<p>Total HF readmissions: 22 vs. 42, P=0.07, NS, test not given.</p> <p>Multiple readmissions 12/44 (27%) vs. 21/44 (48%) RR 0.57 (95% CI 0.33 to 0.99) P=0.05.</p> <p>Risk of HF readmission or death (intervention vs. control): HR 0.52, 95% CI 0.28, 0.98, P=0.04 (Cox proportional hazards model adjusted for age; sex; history of HF and admission serum creatinine)</p> <p>.</p> <p>Number of patients experiencing HF or other CVD readmission or death: 22/44 (50%) vs. 35/44 (80%) . RR 0.63, 95%CI 0.46, 0.86, P=0.004.</p> <p>Number of patients with at least one heart failure readmission or death: 18/44 (41%) vs. 30/44 (68%) RR 0.6 95% CI 0.41,0.89, P=0.01.</p> <p>All cause hospital days readmitted, mean (SD): 10.2 (S 16.8) vs. 15.2 (SD 17.5), P=0.09 test not given.</p> <p>HF or other CVD hospital readmission days, mean (SD): 6.3 (SD 9.2) vs. 12.3 (SD 14.3), P=0.03 test not given.</p> <p>HF hospital days readmitted, mean (SD): 4.1 (SD 6.4) vs. 7.6 (12.1), P=0.1 NS, test not given</p>	
Stromberg 2003	<p>intervention (n=52) vs. control (n=54), results at 12 months</p> <p>no. of deaths: 7 vs. 20; p=0.005 (5 vs. 18 of which were for cardiovascular disease)</p> <p>no. all cause admissions; 82 vs. 92; p=0.31</p> <p>admissions/patient/months (after 12 months): 0.18 vs 0.40; p=0.06</p> <p>no. pts with events: 29 vs. 40; p=0.03</p> <p>days in hospital: 688 vs 976; p=0.13</p> <p>days in hospital/patient/months: 1.4 vs. 3.9; p=0.02</p> <p>cumulative risk of death (Kaplan-Meier analysis) after 12 months was 13% in the intervention group and 37% in the control group; p=0.005</p>	<p>At 1 year, 6 of 17 patients with diabetes had died in the control group compared to 0 of 8 in the intervention group (p=0.16)</p> <p>When 12 months data were adjusted for time of survival (to take account of mortality rate 3x higher in control group), the intervention group had significantly lower days in hospital and tended towards fewer readmissions</p>
Atienza 2004	<p><i>All reported as intervention (n=164) vs. control (n=174)</i></p> <p>Primary outcome:</p>	<p>At one year, probability of remaining event free was 0.62 (95%CI 0.55-0.69) for intervention patients compared with 0.40 (95% CI:0.33-0.48), p <0.001</p>

Table 3. Results of Included Studies (Continued)

	<p>Event-free survival 156 events (30 deaths and 126 readmissions) vs. 250 events (51 deaths and 199 readmissions) event rates per year: 0.7 vs. 1.17 (70 per 100 patients in intervention group and 117 per 100 patients in control group) <i>This represents a statistically significant difference of 0.47 (95%CI: 0.29-0.65, $p<0.001$)</i></p> <p>Secondary outcomes: hospital admissions (all cause): total admissions 126 vs. 199 rates per year: 0.56 vs. 0.93; $p<0.01$ <i>This represents a statistically significant reduction of 37% per year (95%CI 0.21-0.53, $P<0.001$).</i> hospital admissions (HF): rates per year 0.18 vs. 0.37 <i>This represents a statistically significant reduction of 19% per year (95%CI 0.09-0.29, $P<0.001$).</i> as a proportion of all readmissions: 61/126 vs. 122/199 rates per year: 0.27 vs 0.57 <i>This represents a statistically significant reduction of 30% per year (95%CI:0.18-0.42, $p<0.001$)</i></p> <p>Additional outcomes: proportion of patients readmitted (all cause): 68/164 vs. 101/174 proportion of patients readmitted for HF: 39/164 vs. 79/174 Mortality rate: 30/164 vs. 51/174 Death rate per year: 0.14 vs. 0.24 Probability of remaining free of events at 1 year: 0.62(95% CI: 0.55-0.69) vs. 0.40 (95% CI: 0.33-0.48); $P < 0.001$ Probability of not being readmitted by 1 year: 0.66 (95% CI: 0.59-0.73) vs. 0.45 (95% CI: 0.38-0.53) ; $P < 0.001$</p>	<p>QOL: States that values similar at baseline, and intervention group had significantly higher scores over study period, however unclear how many patients in each group completed follow up QOL and data are only represented graphically</p>
De Busk 2004	<p>Int. v control</p> <p>Primary outcome: Time to first rehospitalisation for heart failure did not statistically significantly differ between patients receiving care management and usual care: proportional hazard 0.84 (95%CI 0.56-1.25) $P>0.2$</p> <p>NNT to prevent 1 hospitalisation for HF by 1 year = 34.4 (95% CI 9.7- ?)</p> <p>Time to first rehospitalisation for any cause did not</p>	

Table 3. Results of Included Studies (Continued)

	<p>statistically significantly differ between patients receiving care management and usual care: proportional hazard (=HR?) 0.98 (95%CI 0.76-1.27) P>0.2</p> <p>secondary outcomes: time to composite outcome of death, readmission or ED visit for cardiac cause or for any cause,</p> <p>The rate of combined endpoints cardiac proportional hazard 0.85 (95% CI 0.64 to 1.14) P>0.2 The rate of combined all cause endpoints proportional hazard 0.87 (95% CI 0.69 to 1.08) P>0.2</p> <p>No. re-admitted in 1st year: 116 (51%) v. 117 (50%) Mean (median) no of rehospitalisations / patients during 1st year: 1.04 (1.0) v. 0.99 (1.0) Mean no. ED visits at 1 year 3.2 (median 22.0) v. 3.5 (median 2.0) Deaths (all cause) at 12 months : 21 (9%) v. 29 (12%) Deaths (cardiac) at 12 months : 13 v. 23</p>	
Kimmelstiel 2004	<p>90-day outcomes (intervention vs. control) hospitalisations (mean±SE per patient-year), n HF: 0.55±0.15 vs. 1.14±0.22, RR 0.48, p=0.027 cardiac: 0.81±0.19 vs. 1.43±0.24, RR 0.57, p=0.043 all-cause: 1.49±0.25 vs. 1.68±0.26, RR 0.89, p=0.61 stay in hospital (mean±SE per patient-year), d HF: 4.3±0.4 vs. 7.8±0.6, RR0.54, p<0.001 cardiac: 6.6±0.5 vs. 10.4±0.7, RR 0.64, p<0.001 all-cause: 10.6±0.7 vs. 11.5±0.7, RR=0.92, p=0.34 mortality: 4 (4.1%) vs. 5 (4.9%)</p> <p>1 year follow-up (intervention vs. control) hospitalisations (mean±SE per patient-year), n HF: 0.74±0.10 vs. 0.73±0.10, RR 1.02, p=0.93 cardiac: 0.94±0.11 vs. 1.19±0.12, RR 0.79, p=0.13 all-cause: 1.48±0.14 vs. 1.40±0.13, RR 1.05, p=0.70 stay in hospital (mean±SE per patient-year), d HF: 4.3±0.24 vs. 4.9±0.25, RR 0.87, p=0.07 cardiac: 5.6±0.27 vs. 6.4±0.29, RR 0.88, p=0.048 all-cause: 9.2±0.35 vs. 8.70±0.33, RR=1.06, p=0.31 mortality: 11 (11.3%) vs. 14 (13.6%)</p>	

Table 3. Results of Included Studies (Continued)

Mejhert 2004	<p>intervention vs. control</p> <p>Primary outcome: Quality of life</p> <p>total mean (SD) score at baseline 162 (115) vs. 150 (119)</p> <p>total mean (SD) score at 18 months: 134 (11*) vs. 130 (125)</p> <p>secondary outcomes:</p> <p>all cause mortality at a mean (SD) of 423 (391) days 40 vs. 34 (p=ns)</p> <p>patients readmitted within 18 months: 69 vs. 69 (p=ns)</p> <p>patients readmitted within follow up 85 vs. 86 (p=ns)</p> <p>readmissions/patient during follow-up 4.4 vs. 4.9 (p=ns)</p> <p>time to 1st readmission (all cause), d: 246 vs. 294 (p=ns)</p> <p>length of stay, 1st readmission, all cause, d: 3.7 vs. 4.1 (p=ns)</p>	<p>* paper states SD=11, possibly a typographic error, as total (SD) score at 12 months is 136 (107). QoL improved from baseline in the entire population (p=.0032), with no differences between the intervention and control group</p> <p>QoL measured using Nottingham Health Profile</p>
Naylor 2004	<p>intervention vs. control</p> <p>primary outcome:</p> <p>time to 1st readmission or death: KM log rank $\chi^2=5.0$, p=0.026</p> <p>rehospitalisation or death at 52 weeks: 56/118 (47.5%) vs. 74/121 (61.2%), p=0.01</p> <p>pts readmitted to hospital: 53 (44.9%) vs. 67 (55.4%); p<0.12, relative risk (95% CI): 1.24 (0.95-1.60)</p> <p>readmissions, all cause, n: 104 vs. 162, p<0.047</p> <p>readmissions for HF, n: 40 vs. 72; p<0.184</p> <p>QoL, mean \pm SD (total n):</p> <p>12 weeks: 3.2 \pm 1.5 (n=89) vs. 2.7 \pm 1.5 (n=100); p<0.05</p> <p>26 weeks: 2.9 (SD 1.6) (n=86) vs. 2.6 (SD1.6) (n=92) p=ns</p> <p>52 weeks: 2.8 \pm 1.8 (n=75) vs. 2.6 \pm 1.7 (n=74)</p> <p>mortality at 52 weeks: 11 vs 32, p=0.830</p>	<p>unadjusted incidence density/ratio control vs. intervention time to death or readmission= 1.48 (95% CI 1.05-2.09); p=0.03</p> <p>adjusted ratio= 1.65 (95% CI 1.13-2.4); p=0.001</p> <p>QoL measured on MLWHF</p>
Tsuyuki 2004	<p>intervention vs. control</p> <p>primary outcome: <i>adherence (not relevant to this review)</i></p> <p>secondary outcomes:</p> <p>all cause</p> <p>hospital readmissions, n: 95 vs. 98 (p=0.635)</p> <p>total length of hospital stay, days: 627 vs. 1082; p<0.001</p> <p>pts with at least 1 readmission, n(%): 59 (42.1) vs. 51 (37.5)</p>	

Table 3. Results of Included Studies (Continued)

	<p>Cardiovascular-related: hospital readmissions, n: 53 vs. 70, p=0.60 total length of hospital stay, days: 341 vs. 812; p=0.003 average length of hospital stay, days \pm SD: 6.4 \pm 6.0 vs. 11.6 \pm 10.3; p=0.003 pts with at least 1 readmission, n(%):37 (26.4) vs. 38 (27.9); p=0.79 mortality: 16/140 vs. 12/136</p>	
Ducharme 2005	<p>Unplanned readmissions (all cause): 72 (63%) vs. 69 (60%); HR =0.99 95% CI 0.70-1.40 proportion of patients readmitted (all cause): 45 (39%) vs. 66 (57%) Hazard Ratio 0.59 95% CI 0.38-0.92 Total days spent in hospital during readmissions (all cause): 514 days vs. 815 days; adjusted HR 0.59, 95% CI 0.38-0.92 All-cause mortality: 12/115 vs. 19/115 HR 0.61, 95% CI 0.24-1.54 Minnesota Living with Heart Failure Questionnaire: substantial improvement in both emotional and physical quality of life scores for intervention vs. control (P<0.001)</p>	
Thompson 2005	<p>intervention vs. control primary outcome: death or readmission: 15 (26%) vs. 21 (44%); (p=0.08) secondary outcomes: mortality: 5 (9%) vs. 7 (15%); p=ns pts with readmissions (all causes): 13/58 (22%) vs. 21/48 (44%); p=0.019, OR 1.95 95% CI 1.10-3.48) no. of readmissions: 15 vs 45; p<0.01 total days in hospital by all readmitted patients: 108 vs. 459; p<0.01 HRQoL, change in scores at 6 months in surviving patients: MLWHF: -14.2 vs. -13.7 (but note that only 46/106 patients completed a questionnaire)</p>	<p>event free survival curves favoured the intervention group, but the difference was not statistically significant (p=0.08) Intervention was associated with a 45% reduction in risk of death (RR 0.55, 95% CI 0.28-1.08, P=0.08) For no. of readmissions and total hospital days for readmissions, p<0.01 when adjusting for the number of events per patient per month of follow up for MLWHE, negative change denotes improvement</p>
Lopez 2006	<p>all outcomes are intervention vs. control 6 months: patients readmitted: 17 (24.3% vs. 27 (42.2%), p=ns no. of readmissions</p>	<p>A multivariate analysis was performed, adjusting the model for ejection fraction (since this was not the same in both groups), age and sex. Probability of hospital readmission was lower in the intervention group (HR: 0.56; 95% CI: 0.32-0.97)</p>

Table 3. Results of Included Studies (Continued)

	<p>total: 25 vs 54, p= not given per patient: 0.36 (SD 0.72) vs. 0.84 (SD 1.45), p= 0.023 hospital stay days total: 299 vs. 435, p not given per patient: 4.3 (SD 13.1) vs. 6.8 (SD 12.5), p=0.020 all cause mortality: 6 (8.6%) vs. 12 (18.8%), p=ns at hospital: 3 (50.0%) vs. 11 (91.7%), p=ns without readmission: 3 (50.0%) vs. 1 (8.3%), p not given EUROQOL score, mean (SD): 62.9 (14.9) vs. 62.8 (14.1), p=ns 12 months: patients readmitted: 23 (32.9%) vs. 31 (48.4%), p= ns no. of readmissions total: 39 vs 72, p= not given per patient: 0.56 (SD 0.93) vs. 1.13 (SD 1.94), p= ns hospital stay days total: 410 vs. 611, p not given per patient: 5.9 (SD 14.1) vs. 9.6 (SD 18.5), p=ns all cause mortality: 9 (12.9%) vs. 19 (29.7%), p= 0.017 at hospital: 6 (66.7%) vs. 15 (78.9%), p=ns without readmission: 3 (33.3%) vs. 4 (21.1%), p not given EUROQOL score, mean (SD): 64.0 (15.4) vs. 60.6 (17.8), p=ns</p>	
Nucifora 2006	<p>intervention (n=99) vs. control (n=101) mean (SD) or n(%), 6 months follow-up no. readmissions: 81 (50%, vs. 82 (50%); p=ns readmissions per patient: 0.8 (1.2) vs. 0.8 (1.2); p= ns LoS (days): 15 (15) vs. 20 (24); p=ns time to readmission (days): 68 (52), 68 (55); p=ns mortality: 14 (14%) vs. 8 (8%); p=ns no. pts dead or readmitted: 53 (54%) vs. 46 (46%) ; p=ns event free survival, days: 68(48) vs. 68(53); p=ns unplanned outpatient visits (n=138): 39 (28%) vs. 99 (72%); p<0.001 unplanned visits/patient: 0.4(0.90 vs. 1(1.3); p<0.001</p>	
Aldamiz-Echevarria 2007	<p>Cumulative incidence of outcomes at 1 year (intervention vs. control) Primary outcome:</p>	

Table 3. Results of Included Studies (Continued)

	<p>readmission or death 45.3 vs. 52.8; Relative risk = 0.86 [95% CI 0.67-1.09]; p=0.232</p> <p>Secondary outcomes:</p> <p>readmission 43.1 vs. 50.0; Relative risk = 0.86 [95% CI 0.67-1.11]; p=0.280</p> <p>Death 16.1 vs. 14.8; Relative risk = 1.08 [95% CI 0.63-1.88]; p=0.769</p> <p>Number of unplanned readmissions (NB total, not pts): 125 vs. 118</p> <p>Due to HF: 55 vs. 57</p> <p>Mean (SD) LoS (all cause unplanned re adm): 8.4 (7.7) vs. 9.6 (13.0)</p> <p>Mean (SD) LoS (HF unplanned re adm): 8.6 (7.2) vs. 10.1 (12.9)</p> <p>Actual mortality: 22/137 vs 21/142 pts</p> <p>Due to CV disease: 16 vs. 18</p> <p>Cumulative incidence of outcomes at 6 months (intervention vs. control)</p> <p>Primary outcome:</p> <p>readmission or death 32.1 vs. 38.0; Relative risk = 0.85 [95% CI 0.61-1.16]; p=0.318</p> <p>Secondary outcomes:</p> <p>readmission 30.7 vs. 35.9; Relative risk = 0.85 [95% CI 0.61-1.19]; p=0.376</p> <p>Death 5.8 vs. 9.9; Relative risk = 0.59 [95% CI 0.26-1.37]; p=0.260</p>	
Del Sindaco 2007	<p><i>All reported as intervention (n=86) vs. control (n=87)</i></p> <p><i>; RRR = relative risk reduction</i></p> <p>Primary outcome:</p> <p>Death or heart failure admission: 40 (46.5%) vs. 56 (64.4%); RRR=0.360; 95% CI 0.167-0.509; P<0.001</p> <p>Secondary outcomes:</p> <p>heart failure admission: 28 (32.5%) vs. 49 (40.3%); RRR=0.422; 95% CI 0.175 - 0.595; p=0.003</p> <p>Hospital admission (all cause): 48 (55.8%) vs. 65 (74.72%); RRR=0.253; 95% CI 0.065- 0.403; p=0.014</p> <p>Death (all cause): 27 (31.4%) vs. 32 (36.8%); RRR=0.146; 95% CI -0.295-0.437; p=ns</p> <p>cardiovascular death: 21 (24.4%) vs. 25 (28.7%); RRR=0.150; 95% CI -0.398-0.483; p=ns</p>	
Holland 2007	<p>intervention vs. control</p> <p>primary outcome</p> <p>no. of emergency hospital readmissions within 6 meths: 134 vs. 112 (p=0.28)</p>	<p>person years of follow up 67.18 vs. 64.58</p> <p>For EQ-5D, high scores imply better health</p> <p>For MLHFQ, low scores imply better health</p> <p>NB large attrition for QoL results</p>

Table 3. Results of Included Studies (Continued)

	<p>no. of readmissions: 0: 72 vs. 70; 1: 42 vs. 49; 2: 18 vs. 13; 3: 12 vs. 9; 4: 1 vs. 1; 5: 0 vs. 2; 6: 1 vs. 1 15% increase in intervention group's readmission rate: rate ratio=1.15, 95% CI 0.89 to 1.48; P=0.28 secondary outcomes mortality: 30 vs. 24. hazard ratio 1.18 (95% CI 0. 69-2.03; p=0.54) EQ -5D, mean (SD) scores, 108 vs. 104 patients: adjusted mean difference (95% CI) between groups at 6 months: 0.07 (-0.01 to 0.14); p=0.08 MLHFQ, mean (SD) scores 78 vs. 80 patients:ad- justed mean difference (95% CI) between groups at 6 months: 3.73 (-3.67 to 11.13); p=0.32</p>	
Jaarsma 2008	<p>all results are reported as no. (%) for intensive in- tervention (N=344) / basic intervention (N=340) / control (N=339) Primary outcomes death or hospitalisation due to HF: 132 (38) / 138 (41) / 141 (42) no. days lost in 18 months: 34268 / 33731 / 39960 no. days lost per patient, median (25th and 75th percentiles: 7.5 (0.0-86.5) / 9.0 (0.0-88.0) / 12.0 (0.0-173.0) intensive vs. control p=0.81; basic vs. control p=0.49 HR time to 1st event: 0.93 (0.73-1.17, p=0.53) (intensive vs. control) 0.96 (0.76-1.21, p=0.73) (basic vs. control) Other outcomes hospitalisations (%all cause): 194 (56) / 192 (57) / 181 (53) hospitalisation (cardiovascular disease): 147 (43) / 143 (42) / 143 (42) hospitalisation (HF): 92 (27%) / 84 (25%) / 84 (25%) no. of hospitalisations (all causes): 408 / 377 / 376 no. of hospitalisations (cardiovascular disease): 255 / 236 / 255 no. of hospitalisations (HF): 134 / 121 / 120 death (all causes): 83 (24) / 90 (27) / 99 (29) HR for mortality: Intensive vs. control: 0.81 (0.60-1.08); p=0.15 basic vs. control: 0.88 (0.66-1.18); p=0.39 death (cardiovascular disease): 71 (21) / 76 (22) / 72 (21) death (non cardiovascular disease): 9 (3) / 10 (5) / 19 (6) death (unknown cause): 3 (1) / 4 (1) / 8 (2)</p>	

Table 3. Results of Included Studies (Continued)

	duration of hospitalisation due to HF, median (25th and 75th percentiles), d: 9.5 (5.0-17.0) / 8.0 (4.0-14.0) / 12.0 (5.0-19.5)	
Kwok 2008	primary outcome: unplanned 6mth readmission rate: 46% vs 57%; p=0.233 secondary outcomes: mortality: 4 vs. 8 median no. unplanned readmissions: 0 [IQ range 0, 1] vs. 1 [0.2]; p=0.057 no significant between group difference in primary cause of readmission	
	gp = group patient, U&E = urea and electrolyte levels, * information from personal communication with author	

APPENDICES

Appendix I. Search strategies as run for the original review

Appendix 1 Electronic Searches for previous version of review

The following electronic databases were searched (searches given below) :

Cochrane CENTAL Register of Controlled Trials (CENTRAL), *The Cochrane Library*, Issue 2 2003;
 MEDLINE January 1966 to July 2003;
 EMBASE January 1980 to July 2003;
 CINAHL (Cumulative Index to Nursing and Allied Health Literature) January 1982 to July 2003;
 AMED (Allied and Alternative Medicine Database, covers occupational therapy, physiotherapy and complementary medicine) January 1985 to July 2003;
 Science Citation Index Expanded searched January 1981 to March 2001
 SIGLE Jan 1980 to July 2003;
 Database of Abstracts of Reviews of Effects (DARE) to July 2003;
 National Research Register to July 2003;
 NHS Economic Evaluations Database to March 2001;
 Cardio-Vascular Disease (CVD) Trials Registry at McMaster University (entire database searched on 7/2/2001);
 Chartered Society of Physiotherapy (CSP) Library Catalogue to June 2001 (searched for us by their librarian)

Cochrane Register of Controlled Trials (CENTRAL/ CCTR) and DARE

HEART-FAILURE-CONGESTIVE*:ME
 (HEART near FAILURE)
 (CARDIAC near FAILURE)
 ((#1 or #2) or #3)

PATIENT-CARE-MANAGEMENT*:ME
 HOME-CARE-SERVICES*:ME
 (PATIENT near CARE)
 (HOME near INTERVENTION)
 (HOME near CARE)
 REHABILITAT*
 (SECONDARY near PREVENT*)
 NURS*
 MULTIDISCIPLIN*
 EXERCISE
 PHYSICAL-FITNESS*:ME
 EXERCISE-THERAPY*:ME
 (PHYSICAL near ACTIVITY)
 (PHYSICAL near TRAIN*)
 (PHYSICAL near FIT*)
 (STRENGTH near TRAIN*)
 (AEROBIC near TRAIN*)
 (RESISTANCE near TRAIN*)
 (((((((#5 or #6) or #7) or #8) or #9) or #10) or #11) or #12) or #13) or #14)
 (((((((#15 or #16) or #17) or #18) or #19) or #20) or #21) or #22)
 (#23 or #24)
 (#4 and #25)
 MEDLINE 1. exp heart failure/
 2. (heart adj6 failure).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
 3. (cardiac adj6 failure).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
 4. 1 or 2 or 3
 5. exp patient care management/
 6. exp home care services/
 7. (patient adj6 care).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
 8. (delivery adj6 care).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
 9. (manag\$ adj6 care).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
 10. (home adj6 intervention).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
 11. (home adj6 care).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
 12. homecare.tw.
 13. rehabilitat\$.tw.
 14. exp rehabilitation/
 15. (secondary adj6 prevent\$).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
 16. nur\$.tw.
 17. multidisciplin\$.tw.
 18. (home adj6 visit).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
 19. (home adj6 assess\$).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
 20. exp primary care/
 21. (patient\$ adj6 management).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
 22. (discharge adj6 plan\$).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
 23. exp patient care planning/
 24. exp patient care team/
 25. exp house calls/
 26. exercise.tw.
 27. exp physical fitness/
 28. exp exercise therapy/
 29. (physical adj6 activity).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
 30. (physical adj6 train\$).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
 31. (physical adj6 fit\$).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]

32. (strength adj6 train\$).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
33. (aerobic adj6 train\$).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
34. (resistance adj6 train\$).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
35. 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34
36. 4 and 35
37. limit 36 to yr=2001-2003
38. Heart failure, congestive/ or "heart failure".mp.
39. (heart adj failure).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
40. (cardiac adj failure).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
41. 38 or 39 or 40
42. exp patient care/ or "patient care".mp.
43. Case management/ or Patient care management/
44. (patient adj6 care).mp.
45. (delivery adj6 care).mp.
46. (manag\$ adj6 care).mp.
47. (home adj intervention).mp.
48. (home adj care).mp.
49. Home care services/ or "homecare".mp.
50. "##'Rehabil\$'.mp.##"/ or Rehabilitation/ or "rehabil\$".mp.
51. (seconary adj prevent\$).mp.
52. "##'Nurs\$'.mp.##"/ or Nursing/ or "nurs\$".mp.
53. Patient care team/ or "multidisciplinary".mp.
54. (home adj visit\$).mp.
55. (home adj assess\$).mp.
56. (primary adj care).mp.
57. (patient adj management).mp.
58. (discharge adj plan\$).mp.
59. Patient care planning/ or "patient-care-planning".mp.
60. Patient care team/ or "patient-care-team".mp.
61. House calls/ or "house-calls".mp.
62. Exercise/ or "exercise".mp.
63. Physical fitness/ or "physical-fitness".mp.
64. Exercise therapy/ or "exercise-therapy".mp.
65. (physical adj activity).mp.
66. (physical adj train\$).mp.
67. (physical adj fit\$).mp.
68. (strength adj train\$).mp.
69. (aerobic adj train\$).mp.
70. (resistance adj train\$).mp.
71. 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70
72. 41 and 71
73. limit 72 to yr=2001-2003
74. 37 or 73

EMBASE

- EMBASE "Congestive heart failure/ or "congestive heart failure".mp.
 "Heart failure/ or "heart failure".mp.
 "Heart failure/ or "cardiac failure".mp.
 "1 and 2 and 3
 "PATIENT CARE MANAGEMENT".mp.
 "HOME CARE SERVICES".mp.

"Patient care/ or "patient care".mp.
 "DELIVERY CARE".mp.
 "HOME INTERVENTION".mp.
 "Home care/ or "home care".mp.
 "HOMECARE".mp.
 "Rehabilitation/ or "rehabilitation".mp.
 "Secondary prevention/ or "secondary prevention".mp.
 "##Nurs#.mp.##"/
 "Nursing/ or "nursing".mp.
 "MULTI DISCIPLINARY".mp.
 "HOME VISIT".mp.
 "HOME ASSESSMENT".mp.
 "Primary medical care/ or "primary care".mp.
 "PATIENT MANAGEMENT".mp.
 "DISCHARGE PLANNING".mp.
 "PATIENT CARE PLANNING".mp.
 "PATIENT CARE TEAM".mp.
 "HOUSE CALLS".mp.
 "Exercise/ or "exercise".mp.
 "PHYSICAL FITNESS".mp.
 "EXERCISE THERAPY".mp.
 "Physical activity/ or "physical activity".mp.
 "PHYSICAL TRAINING".mp.
 "STRENGTH TRAINING".mp.
 "AEROBIC TRAINING".mp.
 "RESISTANCE TRAINING".mp.
 "5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31
 or 32
 "1 or 2 or 3
 "33 and 34
 "from 35 keep 1-8
 "from 35 keep 1-501

CINAHL

- 1) (congestive adj heart adj failure).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 2) (heart adj failure).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 3) (heart adj failure).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 4) (cardiac adj failure).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 5) 1 or 2 or 4
- 6) (patient adj care adj management).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 7) (home adj care adj services).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 8) (patient adj care).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 9) (delivery adj care).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 10) (manag? adj care).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 11) (home adj intervention).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 12) (home adj care).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 13) homecare.mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 14) rehabilitat#.mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 15) (secondary adj prevent#).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 16) (secondary adj prevent?).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 17) nurs?.mp. [mp=title, cinahl subject heading, abstract, instrumentation]
- 18) multidisciplin?.mp. [mp=title, cinahl subject heading, abstract, instrumentation]

19) (home adj visit?).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 20) (home adj assess?).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 21) (primary adj care).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 22) (patient? adj management).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 23) discharge near plan?.mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 24) (patient adj care adj planning?).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 25) (patien adj care adj planning).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 26) (patient adj care adj team?).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 27) (house adj calls?).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 28) exercise.mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 29) (physical adj fitness?).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 30) (exercise adj therapy?).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 31) (physical adj activity).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 32) (physical adj train?).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 33) (physical adj fit?).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 34) (strength adj train?).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 35) (aerobic adj train?).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 36) (resistance adj train?).mp. [mp=title, cinahl subject heading, abstract, instrumentation]
 37) 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 17 or 18 or 19 or 20 or 21 or 22 or 24 or 26 or 27 or 28 or 29 or 30 or 31 or 36
 38) 5 and 37

AMED

1 heart-failure-congestive.mp. [mp=abstract, heading words, title]
 2 heart near failure.mp. [mp=abstract, heading words, title]
 3 (cardiac or cardio\$).tw.
 4 1 or 3
 5 patient-care-management.mp. [mp=abstract, heading words, title]
 6 home-care-services.mp. [mp=abstract, heading words, title]
 7 intervention.mp. [mp=abstract, heading words, title]
 8 prevention.mp. [mp=abstract, heading words, title]
 9 4 and 5 and 6 and 7 and 8
 10 4 and 5
 11 4 and 6
 12 4 and 7
 13 4 and 8
 14 10 and 11 and 12 and 13
 15 10 or 11 or 12 or 13
 16 from 15 keep 1-200

CVD Trials Register at McMaster

(Title = "heart failure" or "cardiac failure" OR Keywords
 = "heart failure" or "cardiac failure" OR #43 = "heart
 failure" or "cardiac failure") AND (Title = home* OR
 care* OR plan* or manag* OR Keywords = home* OR care* OR
 plan* OR manag* OR #43 = home* OR care* OR plan* or
 manag*)

Science Citation Index

Expanded Forward search for papers citing the following references:
 Weinberger 1996; Stewart 1998a; Rich 1995.

SIGLE

Search History

* #4 #1 or #2 or #3 (87 records)

#3 cardiac near failure (13 records)

#2 heart near failure (80 records)

#1 heart failure (79 records)

Appendix 2. Search strategies as run for the update

Appendix 2: Updated review Search Strategies

Project Manager: Stephanie Taylor

Project Assistant: Faisal (F2 trainee)

IS: Tiffany Moxham

PenTAG contact: Rod Taylor

2009 update search strategies

Note these strategies are based on an update search done in 2005 by Margaret Burke the Trials Search Co-ordinator at the Cochrane Heart Group. The main differences from the original review are the addition of an RCT filter and the removal of terms associated to exercise therapy and fitness. The RCT filter 2009 has also been slightly changed in Medline to reflect the reclassification of some trial types. Please note that unlike the 2005 searches the 2009 ones also do not include a comparative or evaluation trials filter.

Where possible all searches are limited to 2003-current and a human filter added, no additional limits were imposed.

Ovid MEDLINE(R) 1950 to January Week 1 2009

Search Date: 21 January 2009

# ?	Searches	Results
1	exp Heart Failure/	61784
2	(heart adj failure).mp.	92192
3	(cardiac adj failure).mp.	8068
4	1 or 3 or 2	97321
5	disease management/	6198
6	(disease adj management).mp.	8995
7	Patient Care Management/	1462
8	Medication Therapy Management/	70
9	exp patient care team/ or patient-centered care/	46781
10	(patient adj3 management).mp.	16012

(Continued)

11	(patient adj care).mp.	103033
12	(delivery adj care).mp.	213
13	(manag\$ adj5 care).mp.	45208
14	(management adj5 program\$).mp.	9398
15	(case adj5 manag\$).mp.	15674
16	home care services/ or home care services, hospital-based/	24131
17	(home adj5 intervention\$).mp.	1419
18	(home adj5 care).mp.	36888
19	(home adj visit\$).mp.	3504
20	homecare.mp.	383
21	Ambulatory Care/	29659
22	(ambulatory adj care).mp.	40927
23	Patient Discharge/	13343
24	(discharg\$ adj5 program\$).mp.	902
25	(practice adj guideline).mp.	13678
26	(comprehensive adj5 care).mp.	10400
27	multidisciplinary.mp.	23515
28	(treatment adj5 plan\$).mp.	28812
29	(nurse adj5 led).mp.	1040
30	(discharg\$ adj5 plan\$5).mp.	2528
31	or/5-30	325455
32	4 and 31	3375
33	randomized controlled trial/	260690
34	controlled clinical trial/	77793

(Continued)

35	Random Allocation/	62374
36	(random\$ or placebo\$).mp.	598728
37	((singl\$ or doubl\$ or trebl\$ or tripl\$) and (blind\$ or mask\$)). tw,sh	107748
38	35 or 33 or 34 or 36 or 37	660736
39	(animals not humans).sh.	3219613
40	38 and 32	510
41	40 not 39	510
42	limit 41 to yr="2003 - 2009"	351

EMBASE 1980 to 2009 Week 03

Search Date: 23 January 2009

1	exp Congestive Heart Failure/	28135
2	congestive heart failure.mp.	34259
3	exp Heart Failure/	118569
4	(heart failure or cardiac failure).mp.	100164
5	4 or 1 or 3 or 2	133446
6	patient care/ or case management/	82587
7	PATIENT CARE MANAGEMENT.mp.	57
8	HOME CARE SERVICES.mp.	336
9	DELIVERY CARE.mp.	137
10	HOME INTERVENTION.mp.	75
11	Home Care/	13619
12	HEMECARE.mp.	214
13	secondary prevention/	7214

(Continued)

14	secondary prevention.mp.	11646
15	MULTI DISCIPLINARY.mp.	1636
16	HOME VISIT.mp.	616
17	HOME ASSESSMENT.mp.	106
18	PATIENT MANAGEMENT.mp.	6745
19	hospital discharge/	26806
20	PATIENT CARE PLANNING.mp.	464
21	PATIENT CARE TEAM.mp.	47
22	disease* manag*.mp.	4478
23	clinical servic* organis*.mp.	0
24	clinical servic* organiz*.mp.	2
25	or/6-24	141755
26	25 and 5	6080
27	Randomized Controlled Trial/	164648
28	Single Blind Procedure/	7906
29	Double Blind Procedure/	71037
30	Crossover Procedure/	20872
31	27 or 28 or 29 or 30	189689
32	(random\$ or factorial\$ or crossover\$ or placebo\$ or (cross adj over) or assign\$).ti,ab	515249
33	((singl\$ or double\$ or triple\$ or treble\$) and (blind\$ or mask\$)).ti,ab	99308
34	controlled clinical trial*.ti,ab.	10267
35	34 or 32 or 33 or 31	568422
36	(animal* not human*).sh,hw.	1987947

(Continued)

37	35 and 26	848
38	37 not 36	848
39	limit 38 to yr="2003 - 2009"	606

Cochrane 2009 Issue 1

Search Date: 23 January 2009

#1	MeSH descriptor Heart Failure explode all trees	3853
#2	(HEART near FAILURE)	8030
#3	(CARDIAC near FAILURE)	1250
#4	(#1 OR #2 OR #3)	8412
#5	MeSH descriptor Patient Care Management, this term only	93
#6	MeSH descriptor Disease Management, this term only	383
#7	MeSH descriptor Home Care Services, this term only	1205
#8	MeSH descriptor Disease Management, this term only	383
#9	(disease adj management)	490
#10	MeSH descriptor Medication Therapy Management, this term only	2
#11	MeSH descriptor Patient Care Team explode all trees	1074
#12	MeSH descriptor Patient-Centered Care, this term only	143
#13	patient NEAR/3 management	4044
#14	delivery adj care	169
#15	patient ADJ care	601
#16	manag* NEAR/5 care	3878
#17	management NEAR/5 program*	1555

(Continued)

#18	case NEAR/5 manag*	1605
#19	MeSH descriptor Home Care Services, this term only	1205
#20	home NEAR/5 intervention	1154
#21	home NEAR/5 care	3406
#22	home NEAR/5 visit*	1401
#23	homecare	58
#24	MeSH descriptor Ambulatory Care, this term only	2866
#25	ambulatory adj care	49
#26	MeSH descriptor Patient Discharge, this term only	811
#27	discharg* NEAR/5 program*	218
#28	practice adj guideline	361
#29	comprehensive NEAR/5 care	406
#30	multidisciplinary	1511
#31	treatment NEAR/5 plan*	2050
#32	nurse* NEAR/3 led	325
#33	discharg* NEAR/5 plan*	373
#34	(#5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33)	21155
#35	(#4 AND 34)	908
#36	(accession number) NEAR Pubmed	325139
#37	(accession number) NEAR/2 Embase	53650
#38	(#36 OR #37)	378789
#39	(#35 AND NOT #38)	368

(Continued)

#40	(#39), from 2003 to 2009	277
#41	(#39), from 2003 to 2009	277

CENTRAL: 3

DARE: 18

ONLY CENTRAL and DARE downloaded

Methods: 4

HTA:2

Cochrane Groups:3

NHSEED: 41

Cochrane Reviews: 206

CINAHL/AMED via NLH Search 2.0 version 2008 release 4.4 build 4601

Search Date: 230109

No.	Database	Search term	Hits
1	CINAHL	(congestive ADJ heart ADJ failure).af	9362
2	CINAHL	HEART FAILURE, CONGESTIVE/	10197
3	CINAHL	(cardiac ADJ failure).af	2087
4	CINAHL	(heart ADJ failure).af	24676
5	CINAHL	1 OR 2 OR 3 OR 4	25436
6	CINAHL	(patient ADJ care ADJ management).af	577
7	CINAHL	(home ADJ care ADJ services).af	1574
8	CINAHL	(patient ADJ care).af	65214
9	CINAHL	(delivery ADJ care).af	228
10	CINAHL	(manag* ADJ care).af	27362
11	CINAHL	(home ADJ intervention).af	209
12	CINAHL	(home ADJ care).af	22532
13	CINAHL	homecare.af	2617

(Continued)

14	CINAHL	multidisciplin*.af	33772
15	CINAHL	(home ADJ visit*).af	7821
16	CINAHL	(home ADJ assess*).af	502
17	CINAHL	(patient* ADJ management).af	4170
18	CINAHL	(discharge ADJ plan*).af	6499
19	CINAHL	(patient ADJ care ADJ plan*).af	2287
20	CINAHL	(patient ADJ care ADJ team*).af	677
21	CINAHL	(house ADJ calls*).af	527
22	CINAHL	DISEASE MANAGEMENT/	3153
23	CINAHL	(disease ADJ management).af	9127
24	CINAHL	(clinical ADJ service ADJ organisation*).af	3
26	CINAHL	PATIENT CARE PLANS/	1745
27	CINAHL	(care AND plan*).af	165458
28	CINAHL	(patient ADJ care ADJ management).af	577
29	CINAHL	6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14	132118
30	CINAHL	15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22	16591
31	CINAHL	23 OR 24 OR 26 OR 27 OR 28	170842
32	CINAHL	29 OR 30 OR 31	187147
33	CINAHL	5 AND 32	6591
34	CINAHL	exp CLINICAL TRIALS/ OR exp CLINICAL TRIAL REGISTRY/	69762
37	CINAHL	(randomized ADJ trial*).ti,ab	4885
38	CINAHL	((controlled clinical trial*).ti,ab	7372
39	CINAHL	((singl* OR double* OR triple* OR treble*) AND (blind* OR mask*).ti,ab	10293

(Continued)

40	CINAHL	((random* OR placebo*).ti,ab	66540
41	CINAHL	37 OR 38 OR 39 OR 40	68404
42	CINAHL	34 OR 41	105367
43	CINAHL	33 AND 42	379
44	CINAHL	43 [Limit to: Publication Year 2003-2009]	290
45	AMED	(congestive ADJ heart ADJ failure).af	169
46	AMED	HEART FAILURE, CONGESTIVE/	197
47	AMED	(cardiac ADJ failure).af	21
48	AMED	(heart ADJ failure).af	499
49	AMED	45 OR 46 OR 47 OR 48	510
50	AMED	(patient ADJ care ADJ management).af	436
51	AMED	(home ADJ care ADJ services).af	1051
52	AMED	(patient ADJ care).af	4204
53	AMED	(delivery ADJ care).af	35
54	AMED	(manag* ADJ care).af	506
55	AMED	(home ADJ intervention).af	10
56	AMED	(home ADJ care).af	1632
57	AMED	homecare.af	32
58	AMED	multidisciplin*.af	1275
59	AMED	(home ADJ visit*).af	181
60	AMED	(home ADJ assess*).af	43
61	AMED	(patient* ADJ management).af	142
62	AMED	(discharge ADJ plan*).af	99
63	AMED	(patient ADJ care ADJ plan*).af	300

(Continued)

64	AMED	(patient ADJ care ADJ team*).af	1427
65	AMED	(house ADJ calls*).af	9
66	AMED	DISEASE MANAGEMENT/	344
67	AMED	(disease ADJ management).af	408
68	AMED	(clinical ADJ service ADJ organisation*).af	0
70	AMED	(care AND plan*).af	2374
71	AMED	(patient ADJ care ADJ management).af	436
72	AMED	50 OR 51 OR 52 OR 53 OR 54 OR 55 OR 56 OR 57 OR 58 OR 59 OR 60	7204
73	AMED	61 OR 62 OR 63 OR 64 OR 65 OR 66 OR 67 OR 68 OR 70 OR 71	4590
74	AMED	72 OR 73	9319
75	AMED	49 AND 74	60
77	AMED	75 [Limit to: Publication Year 2003-2008]	36

WHAT'S NEW

Last assessed as up-to-date: 1 January 2009.

Date	Event	Description
23 December 2011	New citation required and conclusions have changed	Updated with results of new searches. 16 new studies included, and 10 from the original review removed as not meeting revised inclusion criteria Change in authorship reflects changes in team over time
8 September 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 4, 2000

Review first published: Issue 2, 2005

Date	Event	Description
1 February 2005	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Andrea Takeda¹, Stephanie JC Taylor², Martin Underwood³, Rod S Taylor⁴, Sonja G Hood⁵, Henry Krum⁶, Faisal Khan⁷

Andrea Takeda:

Screening retrieved papers against inclusion criteria

Appraising quality of papers

Abstracting data from papers

Writing to authors of papers for additional information

Data management for the review

Entering data into RevMan

Analysis of data

Interpretation of data

Providing methodological perspective

Writing the review

Stephanie Taylor:

Conceiving the review

Designing the review

Coordinating the review

Data collection for the review

Developing search strategy

Screening search results

Organising retrieval of papers

Screening retrieved papers against inclusion criteria

Appraising quality of papers

Abstracting data from papers

Writing to authors of papers for additional information

Entering data into RevMan

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Screening search results

Organising retrieval of papers

Screening retrieved papers against inclusion criteria

Obtaining and screening data on unpublished studies

Analysis of data

Interpretation of data

Providing general advice on the review

Rod Taylor:

Conceiving the update

Designing the review

Data collection for the review

Developing search strategy

Undertaking searches

Screening search results

Screening retrieved papers against inclusion criteria

Appraising quality of papers

Abstracting data from papers

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Undertaking searches
Screening search results
Screening retrieved papers against inclusion criteria
Appraising quality of papers
Abstracting data from papers
Interpretation of data
Providing methodological perspective

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- Benji Haran, PenTAG, Peninsula Medical School, University of Exeter, UK.
- Assistance with data extraction
- New Source of support, Not specified.

External sources

- ELENOR (East London and Essex Network of Researchers), UK.
- DoH (Department of Health) Public Health Career Scientist Award, UK.
- NIHR Cochrane Heart Programme grant, UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Changes in authorship have taken place since the protocol was registered, since a new researcher (AT) joined the team and others have moved on to other fields.

INDEX TERMS

Medical Subject Headings (MeSH)

Aftercare [*organization & administration]; Case Management [*organization & administration]; Cause of Death; Chronic Disease; Health Status; Heart Failure [mortality; *therapy]; Length of Stay; Nurse's Practice Patterns [organization & administration]; Patient Readmission [*statistics & numerical data]; Quality of Life; Randomized Controlled Trials as Topic

MeSH check words

Adult; Humans