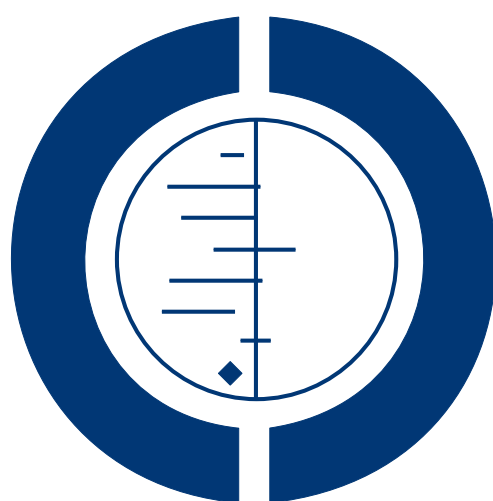


# Structured telephone support or telemonitoring programmes for patients with chronic heart failure (Review)

Inglis SC, Clark RA, McAlister FA, Ball J, Lewinter C, Cullington D, Stewart S, Cleland JGF



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Structured telephone support or telemonitoring programmes for patients with chronic heart failure (Review)  
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[Intervention Review]

# Structured telephone support or telemonitoring programmes for patients with chronic heart failure

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## ABSTRACT

### Background

Specialised disease management programmes for chronic heart failure (CHF) improve survival, quality of life and reduce healthcare utilisation. The overall efficacy of structured telephone support or telemonitoring as an individual component of a CHF disease management strategy remains inconclusive.

### Objectives

To review randomised controlled trials (RCTs) of structured telephone support or telemonitoring compared to standard practice for patients with CHF in order to quantify the effects of these interventions over and above usual care for these patients.

### Search strategy

Databases (the Cochrane Central Register of Controlled Trials (CENTRAL), Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment Database (HTA) on *The Cochrane Library*, MEDLINE, EMBASE, CINAHL, AMED and Science Citation Index Expanded and Conference Citation Index on ISI Web of Knowledge) and various search engines were searched from 2006 to November 2008 to update a previously published non-Cochrane review. Bibliographies of relevant studies and systematic reviews and abstract conference proceedings were handsearched. No language limits were applied.

### Selection criteria

Only peer reviewed, published RCTs comparing structured telephone support or telemonitoring to usual care of CHF patients were included. Unpublished abstract data was included in sensitivity analyses. The intervention or usual care could not include a home visit or more than the usual (four to six weeks) clinic follow-up.

### Data collection and analysis

Data were presented as risk ratio (RR) with 95% confidence intervals (CI). Primary outcomes included all-cause mortality, all-cause and CHF-related hospitalisations which were meta-analysed using fixed effects models. Other outcomes included length of stay, quality of life, acceptability and cost and these were described and tabulated.

## Main results

Twenty-five studies and five published abstracts were included. Of the 25 full peer-reviewed studies meta-analysed, 16 evaluated structured telephone support (5613 participants), 11 evaluated telemonitoring (2710 participants), and two tested both interventions (included in counts). Telemonitoring reduced all-cause mortality (RR 0.66, 95% CI 0.54 to 0.81,  $P < 0.0001$ ) with structured telephone support demonstrating a non-significant positive effect (RR 0.88, 95% CI 0.76 to 1.01,  $P = 0.08$ ). Both structured telephone support (RR 0.77, 95% CI 0.68 to 0.87,  $P < 0.0001$ ) and telemonitoring (RR 0.79, 95% CI 0.67 to 0.94,  $P = 0.008$ ) reduced CHF-related hospitalisations. For both interventions, several studies improved quality of life, reduced healthcare costs and were acceptable to patients. Improvements in prescribing, patient knowledge and self-care, and New York Heart Association (NYHA) functional class were observed.

## Authors' conclusions

Structured telephone support and telemonitoring are effective in reducing the risk of all-cause mortality and CHF-related hospitalisations in patients with CHF; they improve quality of life, reduce costs, and evidence-based prescribing.

## PLAIN LANGUAGE SUMMARY

### Structured telephone support and telemonitoring in the management of patients with chronic heart failure

In the context of limited health funding, and a rapidly expanding population of older patients with chronic heart failure (CHF) it is increasingly difficult for healthcare systems to provide high-quality care to patients with CHF. Multi-disciplinary specialist heart failure clinics are available only to a minority of patients and do not have the capacity for frequent patient review. Patients may be unwilling or unable to make frequent clinic attendance due to financial, transport or disability constraints. Structured telephone support and telemonitoring can provide specialised heart failure care to a large number of patients with limited access to healthcare services. This review demonstrates that CHF interventions utilising information technology can reduce the rates of death and hospitalisation and improve the quality of life. The majority of elderly patients learned to use the technology easily and were satisfied with receiving healthcare in this way.

## BACKGROUND

The efficacy of structured telephone support or telemonitoring as a successful individual component of a heart failure programme remains inconclusive. Whether there are independent and measurable benefits of structured telephone support or telemonitoring for patients with chronic heart failure is the focus of this review.

### Description of the condition

Chronic heart failure (CHF) is a complex, debilitating syndrome due to cardiac dysfunction that impairs the ability of the ventricle to fill with, or eject, blood. As a result, typical symptoms such as dyspnoea and fatigue occur at rest or with reduced physical effort. CHF often results from damage to the myocardium for which the aetiology differs according to the population studied. In high income nations CHF is often the end-product of underlying coronary heart disease (Cowie 1997). In low to medium income nations the syndrome is often the result of longstanding hypertension, cardiomyopathy or rheumatic heart disease (Sliwa

2005). This trend is changing, with the incidence and prevalence of atherosclerotic disease increasing in low to medium income nations (Yusuf 2001). CHF exerts a substantial burden on healthcare systems, due to the high consumption of human resources caused predominantly by repeated and lengthy admissions to hospital (Stewart 2002).

As the prevalence of CHF increases with the ageing of populations internationally, it will become increasingly difficult to maintain the quality of care. Switching resources from crisis management (by hospitalising patients) to health maintenance (through structured telephone support or home telemonitoring) may be an affordable method to maintain and improve the quality of care for CHF.

Trials of pharmacological treatments, including ACE inhibitors, beta-blockers, aldosterone antagonists and, to some extent, angiotensin receptor blockers, and of devices such as implantable defibrillators and cardiac re-synchronisation therapy have demonstrated that these therapies can improve the prognosis of patients with stable heart failure who have a reduced left ventricular ejection fraction (LVEF) (Krum 2009). Recent trials have indicated

an annual mortality of 3% or less for younger patients with mild symptoms with an implanted defibrillator (Moss 2009), about 7% amongst older patients with few implanted devices (GISSI-HF 2008) and about 12% for those with moderate or severe symptoms (Kjekshus 2007). Rates of hospitalisation for worsening heart failure are generally similar, although perhaps proportionately higher in those who have a defibrillator. Fewer trials have been conducted in patients with heart failure who do not have a marked reduction in LVEF and none have been conclusively positive (Cleland 2006). These trials suggest an annual mortality of 4% to 5% and, again, a similar rate of hospitalisation for worsening heart failure (Cleland 2006; Massie 2008). The lack of success of recent pharmacological interventions in altering the outcome of acute heart failure is well reported (Konstam 2007; McMurray 2007; Mebazaa 2007). These trials suggest a six month mortality of 15% to 30% and high rates of readmission. Most trials of telemonitoring have focused on patients being discharged after an exacerbation of heart failure in patients with a low LVEF (Clark 2007a; Cleland 2005 (Telemon)) and have shown a high mortality in patients assigned to usual care which is consistent with the above.

Surveys and epidemiological data provide, at first sight, a gloomier picture (Jhund 2009; Levy 2002). This may reflect the exclusion from research trials of sicker patients by some investigators on compassionate grounds, a lower likelihood that older and sicker patients will agree to research or exclusion by protocols of patients with co-morbidities that carry an adverse prognosis (Cleland 2007; Jhund 2009; Lenzen 2005). Also, patients in trials are likely to be much more closely monitored and this may have had a favourable influence on prognosis, consistent with the evidence from trials of telemonitoring. However, perhaps the most important reason why patients in surveys have an outcome similar to those with acute heart failure is because that is the point at which most patients in surveys of heart failure are enrolled (Cleland 2001). About 20% of patients will die in the first year of new-onset heart failure (Harjola

2010; Jhund 2009; Levy 2002). The mortality one year after an acute exacerbation of chronic heart failure is about 30% (Harjola 2010) but much worse in older patients. In contrast to clinical trials, left ventricular ejection fraction does not appear to be a major determinant of prognosis, possibly because the inclusion of older patients with multiple co-morbidities has an over-riding effect (Bhatia 2006; Cleland 2007).

## Description of the intervention

The effectiveness of multidisciplinary approaches to manage patients with CHF has been demonstrated by meta-analyses, such as those conducted by McAlister (McAlister 2004) and specialist CHF disease management programmes are now recommended in best practice guidelines (ESC Heart Failure Guidelines 2008; Hunt 2005; Krum 2006). To date, trials of specialist, multidisciplinary CHF management programmes have tested multifaceted approaches (multidisciplinary input, home/clinic visits, telephone support). As a consequence, it has been difficult to identify the incremental benefits of the components of each intervention (McAlister 2004; Yu 2006). Nevertheless, it is clear that within most populations access to these programmes is limited as a result of barriers related to funding or accessibility (Clark 2005; Jaarsma 2006).

To meet the needs of CHF populations who have difficulty accessing multidisciplinary CHF disease management programmes, alternative models of care have been proposed and tested (these alternative models typically involve information communication technology and may include self-monitoring and education delivered via standard telephone or more advanced telemonitoring technology (e.g. electronic transfer of physiological data - electrocardiograph (ECG), blood pressure (BP), weight, pulse oximetry, respiratory rate and medicine administration) (Clark 2007a) (Figure 1 and Figure 2).

**Figure 1. Structured telephone support**



**Figure 2. Example of telemonitoring**



In this report, we *a priori* classified programmes as being “structured telephone support” if the monitoring and/or self-care management was delivered using simple telephone technology (data may have been collected and stored by a computer) and “telemonitoring” if there was digital/broadband/satellite/wireless or bluetooth transmission of physiologic and other non-invasive data (Figure 1 and Figure 2).

We consider that structured telephone support and telemonitoring are two similar but distinctly different interventions, as such we have reported outcomes for each intervention separately rather than as either telemonitoring or structured telephone support. It should be noted that in the context of this review the term “remote monitoring” refers to the use of these technologies (structured telephone support or telemonitoring) outside of a CHF specialist centre of care and not necessarily remote in the geographical sense. Most studies have been conducted in urban or semi-rural populations in regions with high population densities. In all studies of structured telephone support, having access to a touch-tone telephone was an essential inclusion criteria. Participants from socio-economically disadvantaged groups may have been excluded if they did not have access to a touch-tone telephone. In the case of tele-

monitoring the information communication technology equipment and monitoring devices were provided by the project regardless of socioeconomic status.

### Why it is important to do this review

In this era of rapidly advancing and wider community access and adaptation to information technology, new trials of remote monitoring interventions have been continually commissioned and published. Earlier systematic reviews and meta-analyses (Clark 2007a; Louis 2003; McAlister 2004) examined the benefits of telemonitoring and/or structured telephone support within CHF disease management programmes on mortality and hospitalisation, however several important large multi-national trials of remote monitoring interventions have since been published.

Although the most recent review of remote monitoring by Clark and colleagues reported beneficial effects on all-cause mortality in 14 trials (Clark 2007a), results for all-cause hospitalisations and HF-specific hospitalisations were inconclusive due to small numbers of events. A number of systematic reviews on this topic have since been published (Chaudry 2007; Dang 2009; DelliFraine



2008; Gaikward 2009; Klersy 2009) and have examined the impact of remote patient monitoring versus usual care. As opposed to this analysis, the systematic review and meta-analysis undertaken by Klersy included interventions employing home visits, frequent visits to CHF specialist clinics, and invasive monitoring under their definition of “remote monitoring” (Klersy 2009).

Given the burgeoning evidence base on this topic and the interests of European Society of Cardiology and the American Heart Association heart failure guideline committees, we felt an updated systematic review incorporating recent evidence was appropriate at this time. Our main aim was to review the efficacy of structured telephone support and telemonitoring as stand-alone components of multidisciplinary CHF management.

## OBJECTIVES

The objective of this study is to update the systematic review and meta-analysis previously completed by Clark 2007a and systematically assess the effects of telemonitoring and/or structured telephone support programmes on:

1. All-cause mortality, CHF-related admission to hospital, all-cause readmissions to hospital and;
2. Length of stay, quality of life, healthcare cost savings in patients with CHF and acceptability of the intervention to patients with CHF.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

We included randomised controlled trials (RCTs) comparing CHF management delivered via structured telephone support or telemonitoring with usual post-discharge care in patients with CHF living within the community. We included RCTs which have been published in the peer-reviewed literature; we also identified abstracts that met our inclusion criteria and these were used to perform sensitivity analyses. We excluded any studies that did not report data for our outcomes of interest in an extractable format (we contacted authors of each primary study in an attempt to get all the data that is possible before excluding any study on this basis).

#### Types of participants

Adults (aged  $\geq 18$  years) of either sex, any age or ethnic group with definitive a diagnosis of CHF. Patients may have been recently discharged from an acute care setting (including emergency departments and one-day-stay procedures) to home (including a relative's home but excluding nursing homes or convalescence homes) or they may have been recruited to a study while managed in the community setting. Studies dealing with general cardiac disorders rather than specifically with CHF were excluded.

#### Types of interventions

Structured telephone support or telemonitoring interventions needed to be structured as opposed to offering telephone follow-up on an “as needed” basis. They must have been initiated by a healthcare professional (medical, nursing, social work, pharmacist) and delivered to patients with CHF living in the community as the only aftercare intervention, without home visits or intensified clinic follow-up. They had to be targeted towards the patient, and intended to address the patient's concerns and problems, not those of caregivers. The patient must not have been visited at home by a specialised CHF healthcare professional or study personnel for the purpose of education or clinical assessment other than an initiation visit to set-up equipment. Usual care consisted of standard post-discharge care without intensified attendance at cardiology clinics or clinic-based CHF disease management programme or home visiting as described above.

#### Types of outcome measures

##### Primary outcomes

- All-cause mortality (total number of deaths at the end of study follow-up in each arm of the study).

##### Secondary outcomes

- All-cause hospitalisations (calculated as the proportion of patients readmitted to hospital at least once during the period of follow-up).
- CHF-related hospitalisations (calculated as the proportion of patients readmitted to hospital at least once during the period of follow-up due to CHF).
- Length of stay.
- Health-related quality of life (difference between mean total score on validated measures such as Minnesota Living with Heart Failure Questionnaire between baseline and at study conclusion for the intervention and control groups).
- Cost of the intervention and cost effectiveness (reported cost of the intervention; reported difference in the cost of medical care during the course of the study between the intervention and control groups).

- Acceptability of the intervention to patients.

## Search methods for identification of studies

This review updates a previously published review which examined the period January 1966 to 6 May 2006 (Clark 2007a) and as such, all databases were searched from 2006 onwards. Language restrictions did not apply to any of the searches.

## Electronic searches

We searched the following databases:

1. Cochrane Central Register of Controlled Trials (CENTRAL), Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment Database (HTA) on *The Cochrane Library* (Issue 4, 2008).
  2. MEDLINE (2006 to 21 November 2008).
  3. EMBASE (2006 to 21 November 2008).
  4. CINAHL (2006 to 27 November 2008).
  5. AMED (2006 to 21 November 2008).
  6. Science Citation Index Expanded and Conference Citation Index on ISI Web of Knowledge (2006 to 21 November 2008).
- The search strategies are listed in [Appendix 1](#).

## Searching other resources

We also searched the following resources ("heart failure" and tele\* / "cardiac failure" and tele\*):

1. National Research Register (NRR) Archive <https://portal.nihr.ac.uk/Pages/NRRArchive.aspx> (28 November 2008 and 19 December 2008).
2. Google Scholar (limited to the first 500 identified hits due to the large volume of information this resource contains) (27 November 2008 and 5 December 2008).
3. IEEE Xplore (26 November 2008 and 5 December 2008).
4. OAIster (27 November 2008 and 5 December 2008).
5. Informit <http://www.informit.com.au/> (28 November 2008 and 19 December 2008).
6. Vivisimo/Clusty <http://clusty.com/> (28 November 2008 and 19 December 2008).
7. Australian Digital Theses Program (28 November 2008 and 19 December 2008).
8. Proquest Digital Dissertations (28 November 2008 and 19 December 2008).

Bibliographies of identified studies and published systematic reviews relevant to this topic area were hand searched. Abstracts and conference proceedings from the following international conferences were handsearched for relevant studies:

1. European Society of Cardiology Congress (2006, 2007, 2008).
2. American College of Cardiology Congress (2006, 2007, 2008).

3. American Heart Association (2006, 2007, 2008).
4. Heart Failure Society of America (2006, 2007, 2007).
5. European Society of Cardiology Heart Failure Congress (2006, 2007, 2008).
6. World Congress of Cardiology (2006, 2008).
7. Asia Pacific Heart Failure Congress (2008).
8. European Society of Cardiology Annual Spring Meeting of Cardiovascular Nursing (2006, 2007, 2008).

## Data collection and analysis

All identified abstracts and results from database searches were reviewed by SCI and RAC for relevance to the review topic. If the reference appeared to be relevant, a full copy of the reference was obtained for detailed review to determine the inclusion/exclusion of the study in the review.

## Selection of studies

Two investigators (SCI and RAC) independently reviewed the results of each search according to exclusion and inclusion criteria. Studies were excluded if home visits were performed as part of the intervention or by the clinical staff involved in the intervention or if there were clinic visits (more than usual care) offered to patients in the intervention or control groups. A third reviewer (JGFC) adjudicated in the instance of disagreement between the first two reviewers.

## Data extraction and management

Two reviewers (SCI and RAC) abstracted the data from the included studies in a blinded manner and all extracted data was checked by a third reviewer (FAM).

## Assessment of risk of bias in included studies

In consideration of Cochrane methodology (Higgins 2008a), study quality and risk of bias was assessed independently by two reviewers (SCI and RAC). The study quality characteristics and bias assessment were rated as 'unclear' (not stated), yes (low risk of bias) and no (high risk of bias) with examples from the text to support this classification.

## Inclusion criteria of the included participants

The definition and confirmation of diagnosis of CHF.

- 'Yes' i.e. low risk of bias - a diagnosis of CHF (systolic or preserved) recorded and confirmed using clinical criteria, echocardiography, or BNP
- 'No' i.e. high risk of bias - diagnosis of CHF not defined

### Generation of the randomisation sequence

- 'Yes' i.e. low risk of bias - random permuted blocks, random computer generated, sealed assignment, sequentially numbered sealed opaque envelopes
- 'No' i.e. high risk of bias - case record numbers, date of birth or days of the week

### Allocation concealment

- 'Yes' i.e. low risk of bias - allocation to each group performed adequately and group assignment revealed after provision of consent
- 'No' i.e. high risk of bias - group assignment revealed prior to subject consent, non-opaque sealed envelopes, case record numbers, date of birth or day of the week

### Baseline comparability of the groups

- 'Yes' i.e. low risk of bias - the baseline characteristics of each study group (in particular age, NYHA Class and/or LVEF) is clearly outlined and any differences identified are accounted for.
- 'No' i.e. high risk of bias - baseline characteristics (in particular age, NYHA Class and/or LVEF) of each study group are not outlined.

### Blinding

Focused on outcomes assessors and data analysts, it is not considered plausible that patients could be blinded to these types of interventions.

- 'Yes' i.e. low risk of bias - independent outcome assessors and data analysts who are blinded to which group the patient belongs to.
- 'No' i.e. high risk of bias - outcomes assessed and data analysed by those involved in the intervention, or those who are aware of group membership.

### Completeness of follow-up

- 'Yes' i.e. low risk of bias - proportion and characteristics of those participants lost to follow-up clearly reported for each group and outcome. A clear outline is provided as to how losses of participants were handled.
- 'No' i.e. high risk of bias - proportion and characteristics of those completing and not completing the study according to group and outcome not reported. No statement regarding how losses to follow up were accounted for in the study analysis.

### Statistical power

- 'Yes' i.e. low risk of bias - a power calculation was performed and reported. The study was adequately powered to detect differences in outcomes.

- 'No' i.e. high risk of bias - a power calculation was not performed. A power calculation was performed and reported but the study was not adequately powered to detect differences in outcomes. A power calculation was performed but not reported, the study states it was adequately powered to detect differences in outcomes.

### Risk of bias (selection, performance, detection and attrition)

Risk of bias was identified for each included study and tabulated according to the following headings.

- Type of bias
- Definition of the type of bias relevant to these types of studies and interventions
- Example from text suggesting a possible source of bias
- Comment on how this potential source of bias may have influenced the study outcomes
- Overall judgement on the importance of this identified potential source of bias on study quality and validity

### Measures of treatment effect

Data were dichotomous and the statistical method used for analysis was Mantel-Haenzel with an analysis model for fixed effects (Higgins 2008b). Risk ratios and 95% confidence intervals were calculated for all-cause mortality, and proportions of patients with at least one all-cause and HF-related hospitalisation. All analyses were performed according using intention-to-treat analysis, that is, all patients and their outcomes were analysed in the groups to which they were allocated, regardless of whether they received the treatment or whether or not they were measured for the outcome. Studies which measured outcomes such as quality of life using tools such as the Minnesota Living with Heart Failure Questionnaire were tabulated and described. Due to inconsistency in reporting of length of stay, this outcome was tabulated also rather than pooled in a meta-analysis.

### Assessment of heterogeneity

Statistical heterogeneity in each outcome of interest was examined using chi-squared test and  $I^2$  statistic as stated in the Cochrane Handbook (Higgins 2008b).

### Data synthesis

Owing to differences in patient populations, programme characteristics, and length of follow-up, all meta-analyses were performed using fixed effects model.

## Sensitivity analysis

Two sensitivity analyses were performed. Our search identified five studies that were only published in abstract form ([Angermann 2007](#); [Blum 2007 \(MCCD\)](#); [Krum 2009 \(CHAT\)](#); [Parati 2009 \(ICAROS\)](#); [Zugck 2008 \(HiTel\)](#)). According to advice from the Cochrane Heart Group we did not include data from these studies in the principal meta-analyses due to the likelihood of these results being interim results or without having undergone extensive peer review to confirm the results and assess the rigor of the study methodology ([McAlister 2006](#)). Data from these studies was added to data from studies which were published in the form of a full peer-reviewed journal publication to assess whether publication status made any difference to the result of the meta-analyses, including the level of heterogeneity.

The second sensitivity analysis was performed to assess the impact of length of follow-up on outcomes. We excluded studies with a follow-up period of six months or less from these sensitivity analyses. This was performed for full peer-reviewed publications only.

## RESULTS

### Description of studies

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

Searching the databases and search engines has retrieved a total of 8033 results:

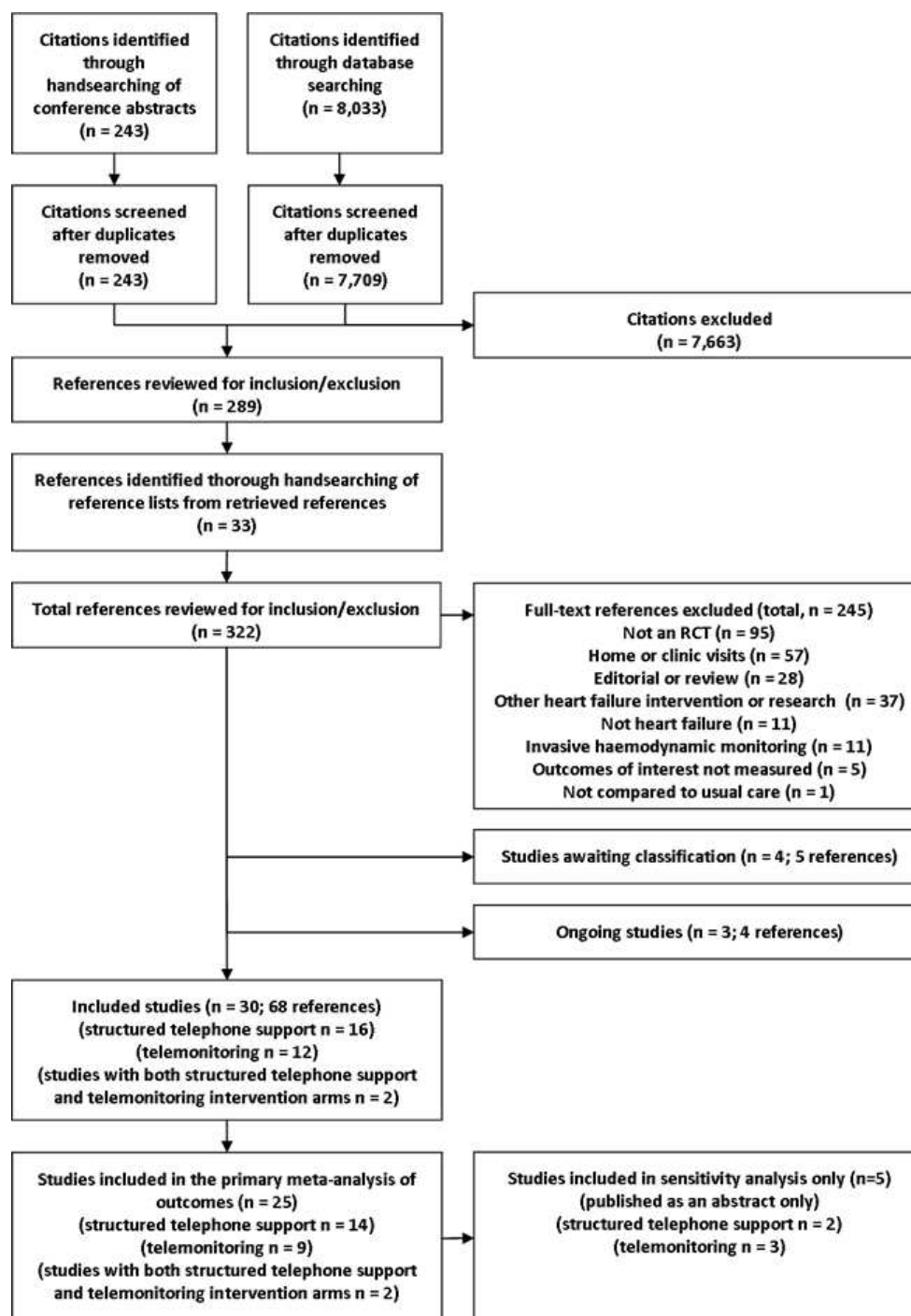
- CENTRAL, DARE, HTA 324

- MEDLINE 254
- EMBASE 205
- CINAHL 52
- AMED 15
- ISI 318
- NRR 2854 and 2331
- Google Scholar 500 and 500
- IEEE Xplore 312 and 11
- OAlster 76 and 2
- Informit 3 and 3
- Vivisimo/Clusty 135 and 110
- Australian Digital Theses Program 2 and 2
- Proquest 6 and 18

324 references were excluded as duplicates. Handsearching of conference abstracts retrieved 243 references. 7663 references out of the remaining 7952 references were excluded in the initial screening process. 289 references were identified to be potentially relevant. Handsearching the bibliographies of these studies identified additional 33 references.

Overall, 322 references were identified as potentially relevant studies and full copies of these references were retrieved for assessment according to our inclusion and exclusion criteria. The majority of the studies ( $n = 245$ ) were excluded as they were not RCTs ( $n = 95$ ), other reasons for exclusion included the intervention or usual care involving home or clinic visits ( $n = 57$ ); the reference was a review or editorial ( $n = 28$ ); the participants did not have heart failure ( $n = 11$ ); the intervention was invasive monitoring ( $n = 11$ ) or because the research was other types of heart failure research, for example, education or exercise programmes ( $n = 37$ ) or the outcomes of interest were not measured in the study ( $n = 5$ ) or the intervention was not compared to usual care ( $n = 1$ ). A study flowchart details these exclusions ([Figure 3](#)).

Figure 3. Study flowchart



In total we have included 16 studies of structured telephone support (two were published abstracts: [Angermann 2007](#), [Krum 2009 \(CHAT\)](#)), 12 studies of telemonitoring (three of which were published abstracts: [Blum 2007 \(MCCD\)](#), [Parati 2009 \(ICAROS\)](#), [Zugck 2008 \(HiTel\)](#)) and two studies with both structured telephone support and telemonitoring intervention arms (compared to usual care). Only studies which were published in full peer-reviewed journals were included in the primary meta-analysis. Studies published only in abstract form were included in a sensitivity meta-analysis for the primary outcomes of interest in this review. Therefore, the primary meta-analysis included 25 studies, 16 comparisons of structured telephone support to usual care (n = 5613 participants) and 11 comparisons of telemonitoring versus usual care (n = 2710 participants). This includes data from the two studies with three arms, which are [Cleland 2005 \(Struct Tele\)](#), [Cleland 2005 \(Telemon\)](#), [Mortara 2009 \(Struct Tele\)](#) and [Mortara 2009 \(Telemon\)](#) (245 participants in total in the control arms of these two studies with both intervention arms) the data from these studies has been separated into our two interventions of interest (structured telephone support and telemonitoring). [Wakefield 2008](#) included two intervention arms, one using standard telephone equipment and the other a videophone, for the purposes of our analyses, these two intervention arms were combined and classed as structured telephone support.

We identified three studies which are currently ongoing ([Chaudry 2007 \(Tele-HF\)](#); [Kohler 2006](#); [Kulshreshtha 2008a](#)).

We have identified four studies which are awaiting classification pending future publications to clarify details on the interventions or outcomes measured ([Dunlap 2006 \(Heart-I\)](#); [Levine 2006 \(Mind My Heart\)](#); [Scherr 2005 \(MobiTEL\)](#); [Yakushin 2006](#)).

For the studies included in the primary meta-analysis of the primary outcomes of interest:

- Trials ranged in size from very large (1518 patients in the [GESICA 2005 \(DIAL\)](#) Trial) in structured telephone support to small (34 patients in [Barth 2001](#)) and in telemonitoring 502 patients ([Kielblock 2007](#)) to 10 ([de Lusignan 2001](#)).
- The total numbers of patients rejected from trials for not being eligible (lack of access to telephone, being of different ethnic origin unable to understand language etc) was not reported.
- Mean age of the participants ranged from 44.5 to 78 years.
- Mean percent male participants was 64%, which ranged from (35% to 99% of participants in included studies being male). Only four out of the 30 included studies recruited more women than men ([DeWalt 2006](#); [Riegel 2002](#); [Riegel 2006](#); [Soran 2008](#)).
- Fourteen (47%) of the studies reviewed originated from the USA; four (13%) Italy; three (10%) Germany; two (7%)

Canada; two (7%) European Union (Germany, Netherlands, UK, Poland, Italy), one UK; one Netherlands; one India; one Argentina and one from Australia.

- Fourteen (47%) of the studies reported lost to follow-up. The mean percent of loss to follow-up was 7.6% (range 0% to 26%).

- Ethnic groups: [Riegel 2006](#) examined the effect of structured telephone support on a Hispanic population; [Soran 2008](#) included older minorities (elderly women and non-white males).

- Length of follow-up of these trials ranged from three to 18 months, with many studies reporting outcomes after 12 months.

- Most of the included studies included participants with symptomatic heart failure, although the definition and inclusion criteria differed amongst the studies, with some studies reporting few details of the diagnostic criteria for heart failure.

Studies included in the primary meta-analysis of the primary outcomes of interest funded by Industry (reported in publications):

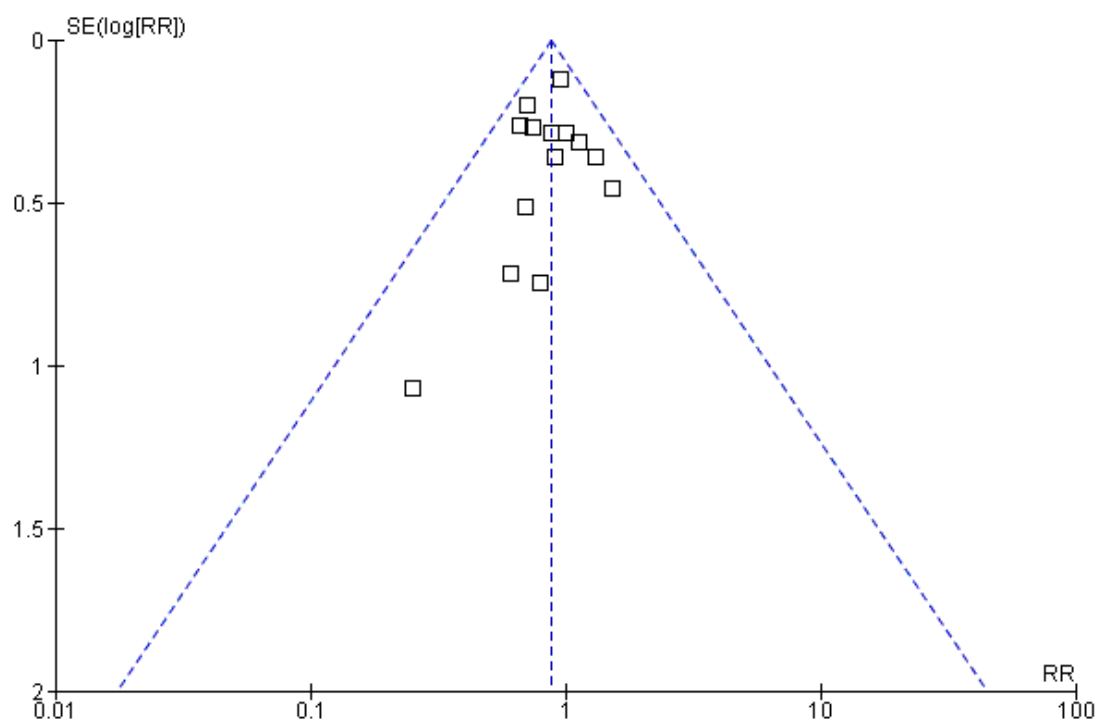
1. [Balk 2008](#) Motiva-Phillips
2. [Cleland 2005 \(Struct Tele\)](#) - Phillips
3. [de Lusignan 2001](#) - Nexan Telemed Ltd, Cambridge
4. [DeWalt 2006](#) - Pfizer Inc
5. [GESICA 2005 \(DIAL\)](#) - Roche, Boehringer Ingelheim, Bago. Pharmacia, Novartis, Merck Sharp & Dohme
6. [Riegel 2002](#) - Pfizer Inc
7. [Tsuyuki 2004](#) - Park Davis Canada (Pfizer Canada)

Twenty-eight of the 30 included studies reported outcomes such as quality of life, cost of the intervention or cost-effectiveness, length of stay, adherence or participant acceptability of the intervention.

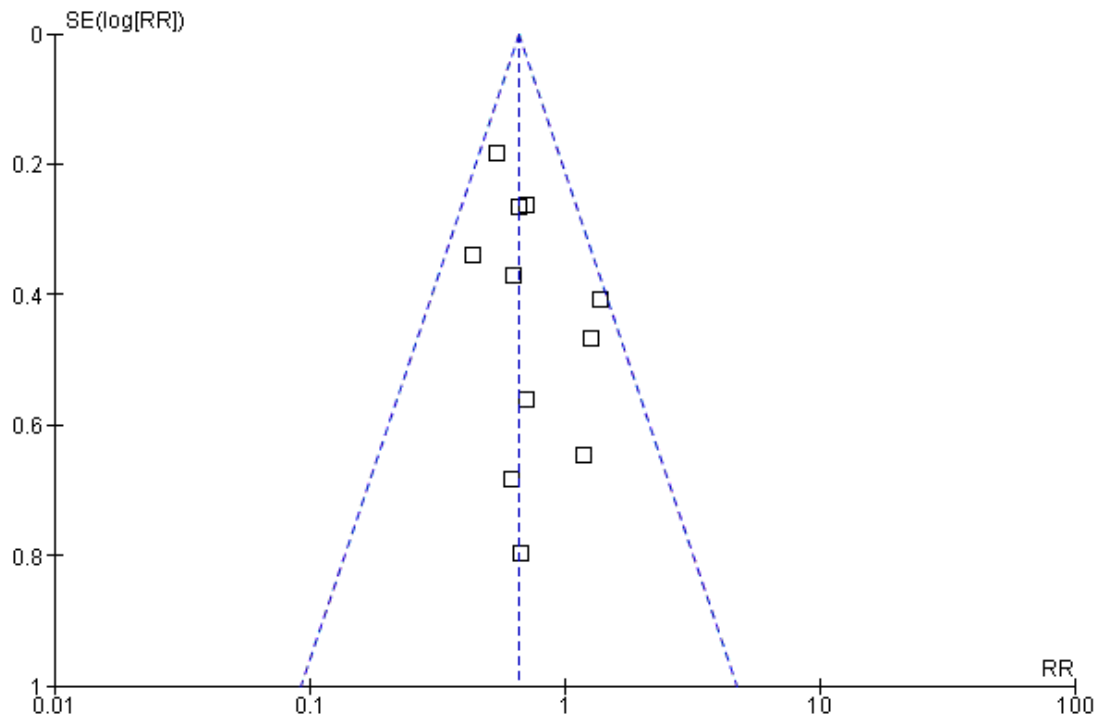
## Risk of bias in included studies

Analysis of the distribution in the funnel plots shown in [Figure 4](#), [Figure 5](#), [Figure 6](#), [Figure 7](#), [Figure 8](#) and [Figure 9](#) demonstrate a strong publication bias towards positive outcomes in the studies selected for this review. The risk of bias analysis due to methodological issues (the definition and confirmation of diagnosis of CHF; generation of the randomisation sequence; allocation concealment; baseline comparability of the groups; blinding; completeness of follow up; statistical power; risk of bias (selection, performance, detection and attrition)) is presented in [Figure 10](#) and [Figure 11](#). This analysis demonstrated low risk of bias for all criteria in 30% to 60% of studies. Areas with the highest risk of bias were; adequate power (20%); comparability of groups at baseline (30%) and reporting of results according to CONSORT guidelines (30%) ([CONSORT 2001](#)) particularly reporting of numbers and reasons for lost to follow-up. The RCT evidence included in this review is also summarised and graded in [Figure 12](#), [Figure 13](#) and [Figure 14](#).

**Figure 4. Funnel plot of comparison 1 - impact of structured telephone support and telemonitoring in CHF on all-cause mortality, analysis 1.1: all-cause mortality (full peer-reviewed publications only): structured telephone support versus usual care**

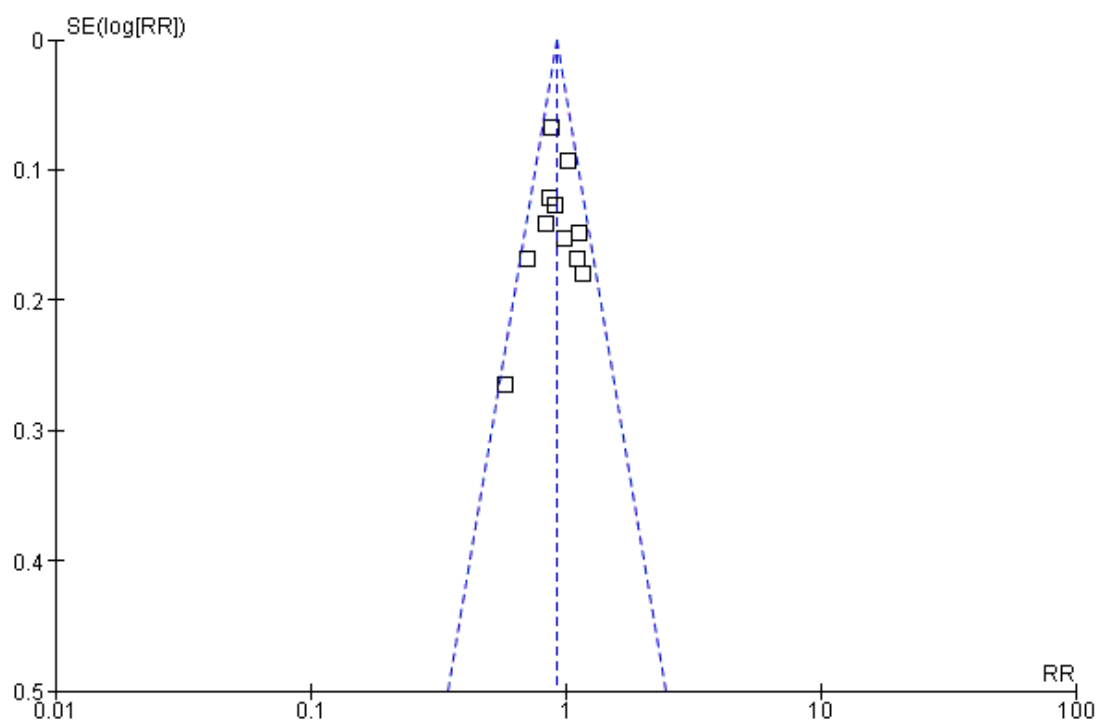


**Figure 5. Funnel plot of comparison 1 - impact of structured telephone support and telemonitoring in CHF on all-cause mortality, analysis 1.2: all-cause mortality (full peer-reviewed publications only): telemonitoring versus usual care**

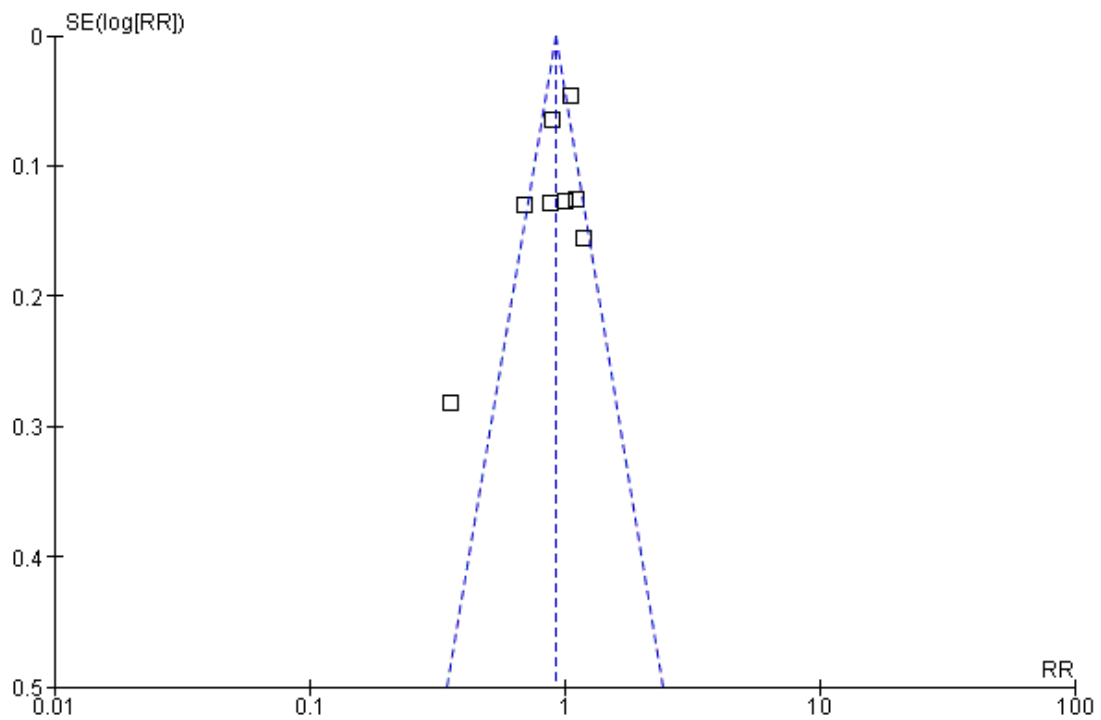




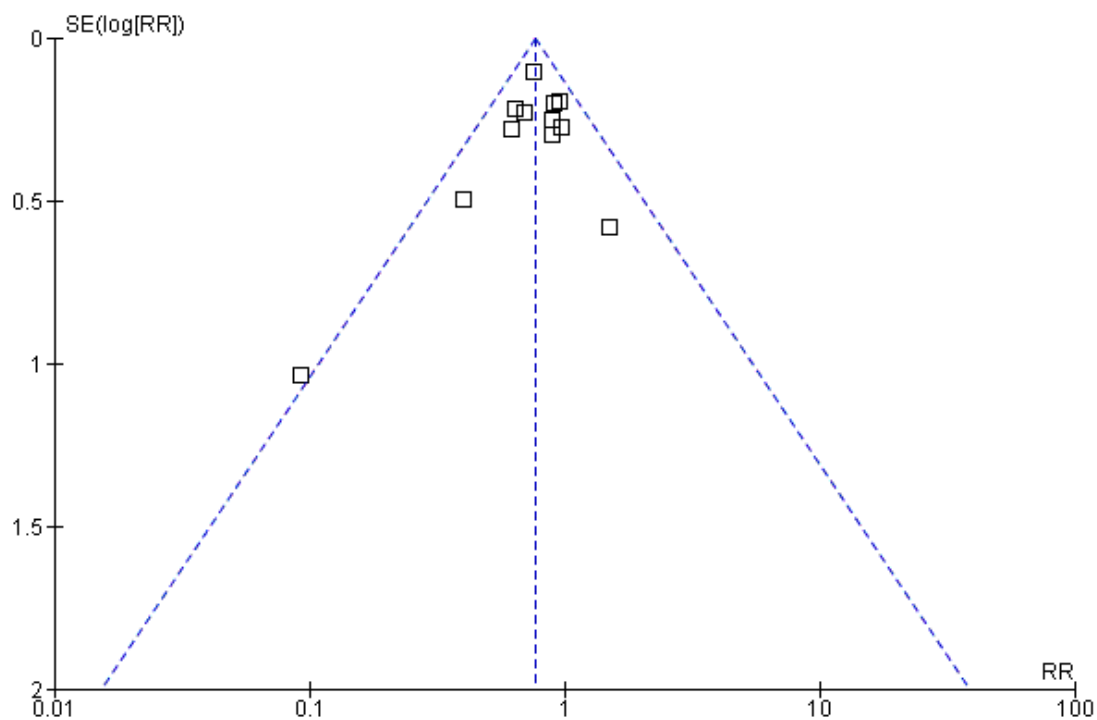
**Figure 6. Funnel plot of comparison 2 - impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation, analysis 2.1: all-cause hospitalisation (full peer-reviewed publications only): structured telephone support versus usual care**



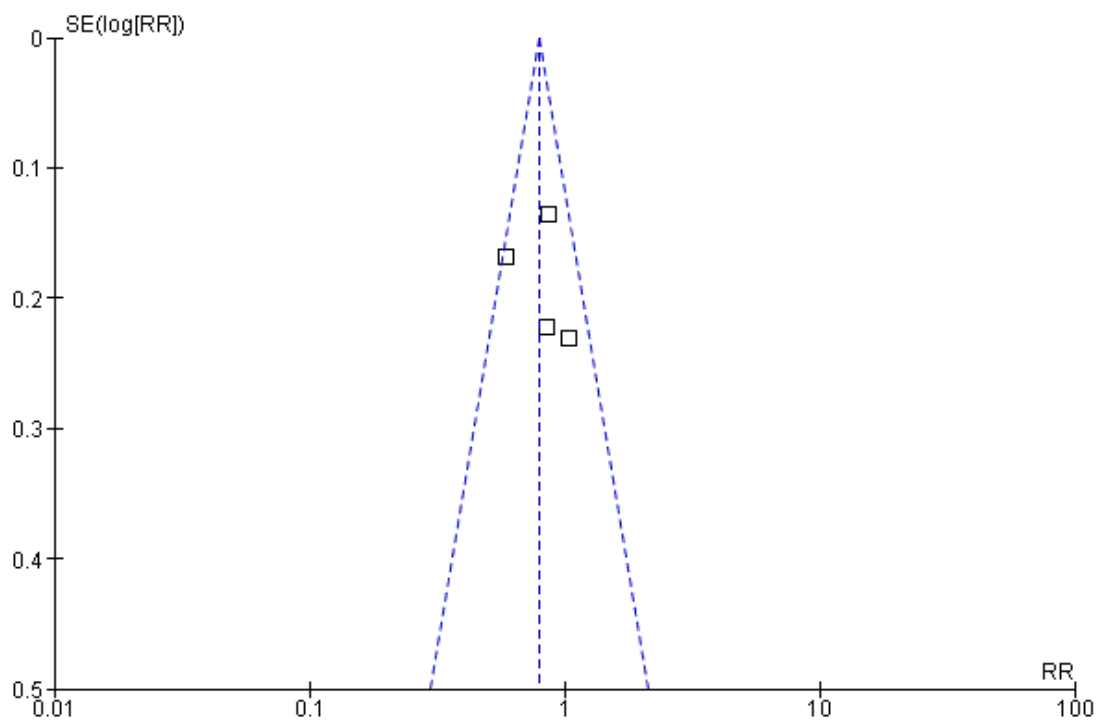
**Figure 7. Funnel plot of comparison 2 - impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation, analysis 2.2: all-cause hospitalisation (full peer-reviewed publications only): telemonitoring versus usual care**



**Figure 8. Funnel plot of comparison 3 - impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation rate, analysis 3.1: CHF-related hospitalisation (full peer-reviewed publications only): structured telephone support versus usual care**



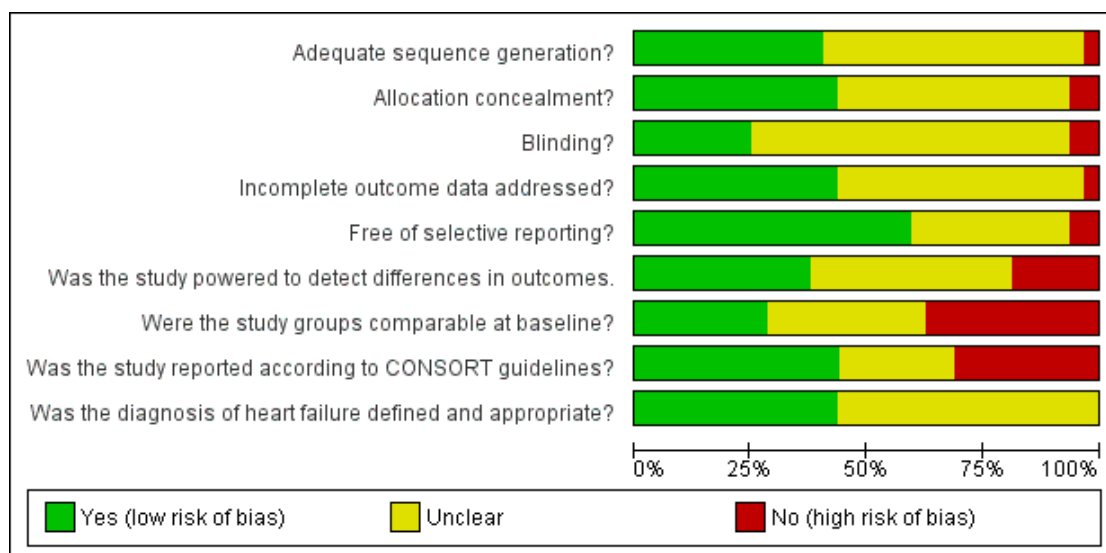
**Figure 9. Funnel plot of comparison 3 - impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation rate, analysis 3.2: CHF-related hospitalisation (full peer-reviewed publications only): telemonitoring versus usual care**



**Figure 10. Risk of bias summary: review authors' judgements about each methodological quality item for each included study.**

	Adequate sequence generation?	Allocation concealment?	Blinding?	Incomplete outcome data addressed?	Free of selective reporting?	Was the study powered to detect differences in outcomes.	Were the study groups comparable at baseline?	Was the study reported according to CONSORT guidelines?	Was the diagnosis of heart failure defined and appropriate?
Angermann 2007	?	?	?	?	?	?	?	?	?
Antonicelli 2008	?	?	?	+	+	+	+	+	+
Balk 2008	+	?	?	+	+	?	+	?	?
Barth 2001	?	?	?	?	?	?	+	+	?
Blum 2007 (MCCD)	+	+	?	+	?	?	?	?	?
Capomolla 2004	?	?	?	?	+	?	+	+	?
Cleland 2005 (Telemon)	+	+	?	+	+	+	?	+	?
Cleland 2005(Struct Tele)	+	+	?	+	+	+	?	+	?
de Lusignan 2001	+	?	?	?	+	?	?	+	?
DeBusk 2004	+	+	+	+	+	+	+	+	+
DeWalt 2006	+	?	+	+	+	?	+	+	+
Galbreath 2004	?	+	+	+	+	?	+	+	+
Gattis 1999 (PHARM)	+	+	+	?	+	?	+	+	?
GESICA 2005 (DIAL)	+	+	+	+	+	?	+	+	?
Giordano 2009	?	?	?	+	+	+	+	+	+
Goldberg 2003 (WHARF)	?	+	+	+	?	+	+	+	+
Kielblock 2007	+	?	?	?	?	?	+	+	?
Krum 2009 (CHAT)	?	?	?	?	?	?	?	?	+
Laramie 2003	?	?	?	?	+	+	+	+	+
Mortara 2009 (Struct Tele)	?	+	+	?	?	+	+	+	+
Mortara 2009 (Telemon)	?	+	+	?	?	+	+	+	+
Parati 2009 (ICAROS)	+	?	?	?	?	?	?	?	+
Rainville 1999	?	+	?	+	+	+	+	+	?
Ramachandran 2007	+	?	?	?	?	+	?	+	+
Riegel 2002	?	+	?	+	+	+	+	?	?
Riegel 2006	?	+	+	+	+	+	?	+	?
Sisk 2006	+	+	?	+	+	+	?	?	+
Soran 2008	?	?	+	?	+	+	+	+	?
Tsuyuki 2004	?	?	?	?	+	+	+	+	?
Wakefield 2008	+	+	?	+	+	+	+	+	?
Woodend 2008	?	?	?	?	+	?	+	+	+
Zugck 2008 (HiTel)	?	+	?	?	?	?	?	?	?

**Figure 11. Risk of bias graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.**



**Figure 12. Summary of findings for all-cause mortality**

Structured Telephone Support or Telemonitoring for Chronic Heart Failure						
Patient or population: patients with Chronic Heart Failure						
Settings: All-cause mortality						
Intervention: Structured Telephone Support or Telemonitoring						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Structured Telephone Support or Telemonitoring				
All-cause mortality (full peer-reviewed publications only): Structured Telephone Support vs Usual Care	Study population		RR 0.88	5563	====	
	127 per 1000	112 per 1000 (97 to 128)	(0.76 to 1.01)	(15 studies)	moderate <sup>1</sup>	
	Medium risk population					
	109 per 1000	96 per 1000 (83 to 110)				
All-cause mortality (full peer-reviewed publications only): Telemonitoring vs Usual Care	Study population		RR 0.66	2710	====	
	154 per 1000	102 per 1000 (83 to 125)	(0.54 to 0.81)	(11 studies)	moderate <sup>1</sup>	
	Medium risk population					
	135 per 1000	89 per 1000 (73 to 109)				
*The basis for the <b>assumed risk</b> (e.g. the median control group risk across studies) is provided in footnotes. The <b>corresponding risk</b> (and its 95% confidence interval) is based on the assumed risk in the comparison group and the <b>relative effect</b> of the intervention (and its 95% CI).						
CI: Confidence interval; RR: Risk ratio;						
GRADE Working Group grades of evidence						
<b>High quality:</b> Further research is very unlikely to change our confidence in the estimate of effect.						
<b>Moderate quality:</b> Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.						
<b>Low quality:</b> Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.						
<b>Very low quality:</b> We are very uncertain about the estimate.						
<sup>1</sup> Some studies did not provide details of sequence generation, allocation concealment or blinding.						

**Figure 13. Summary of findings for all-cause hospitalisation**

Structured Telephone or Telemonitoring for Chronic Heart Failure						
Patient or population: patients with Chronic Heart Failure						
Settings: All-cause hospitalisation						
Intervention: Structured Telephone or Telemonitoring						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Structured Telephone or Telemonitoring				
All-cause hospitalisation (full peer-reviewed publications only): Structured Telephone Support vs Usual Care	Study population		RR 0.92 (0.85 to 0.99)	4295 (11 studies)	==== moderate <sup>1</sup>	
	412 per 1000	379 per 1000 (350 to 408)				
	Medium risk population					
	391 per 1000	360 per 1000 (332 to 387)				
All-cause hospitalisation (full peer-reviewed publications only): Telemonitoring vs Usual Care	Study population		RR 0.91 (0.84 to 0.99)	2343 (8 studies)	==== low <sup>1,2</sup>	
	521 per 1000	474 per 1000 (438 to 516)				
	Medium risk population					
	507 per 1000	461 per 1000 (426 to 502)				
*The basis for the <b>assumed risk</b> (e.g. the median control group risk across studies) is provided in footnotes. The <b>corresponding risk</b> (and its 95% confidence interval) is based on the assumed risk in the comparison group and the <b>relative effect</b> of the intervention (and its 95% CI).						
CI: Confidence interval; RR: Risk ratio;						
GRADE Working Group grades of evidence						
<b>High quality:</b> Further research is very unlikely to change our confidence in the estimate of effect.						
<b>Moderate quality:</b> Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.						
<b>Low quality:</b> Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.						
<b>Very low quality:</b> We are very uncertain about the estimate.						
<sup>1</sup> Some studies did not report details of sequence generation, allocation concealment or blinding.						
<sup>2</sup> Findings from Antonicelli et al (2008) are not consistent with those from other telemonitoring studies.						



**Figure 14. Summary of findings for CHF-related hospitalisations**

Structured Telephone Support or Telemonitoring for Chronic Heart Failure						
Patient or population: patients with Chronic Heart Failure						
Settings: CHF-related hospitalisation						
Intervention: Structured Telephone Support or Telemonitoring						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Structured Telephone Support or Telemonitoring				
CHF Related Hospitalisation (full peer-reviewed publications only): Structured Telephone Support vs. Usual Care	Study population		RR 0.77	4269	----	
	213 per 1000	164 per 1000 (145 to 185)	(0.68 to 0.87)	(13 studies)	moderate <sup>1</sup>	
	Medium risk population					
CHF Related Hospitalisation (full peer-reviewed publications only): Telemonitoring vs. Usual Care	Study population		RR 0.79	1570	----	
	285 per 1000	225 per 1000 (191 to 268)	(0.67 to 0.94)	(4 studies)	moderate <sup>1</sup>	
	Medium risk population					
	300 per 1000	237 per 1000 (201 to 282)				

\*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio;

GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

<sup>1</sup> Some studies did not report details of sequence generation, allocation concealment, or blinding.

Overall the heterogeneity ranged from low to substantial across the primary meta-analysis of the three outcomes of interest ( $I^2$  statistic Low = 0%-40%; Moderate = 30%-60%; Substantial = 50%-90%, Considerable 75%-100%) (Higgins 2008b).

- All-cause mortality (full peer-reviewed publications only):
  - Structured telephone support vs Usual Care: Heterogeneity:  $\text{Chi}^2 = 8.48$ ,  $\text{df} = 13$  ( $P = 0.81$ );  $I^2 = 0\%$
  - Telemonitoring vs Usual Care: Heterogeneity:  $\text{Chi}^2 = 8.84$ ,  $\text{df} = 10$  ( $P = 0.55$ );  $I^2 = 0\%$
- All-cause hospitalisation (full peer-reviewed publications only):
  - Structured telephone support vs Usual Care: Heterogeneity:  $\text{Chi}^2 = 13.09$ ,  $\text{df} = 10$  ( $P = 0.22$ );  $I^2 = 24\%$
  - Telemonitoring vs Usual Care: Heterogeneity:  $\text{Chi}^2 = 31.30$ ,  $\text{df} = 7$  ( $P < 0.0001$ );  $I^2 = 78\%$
- CHF-related hospitalisation (full peer-reviewed publications only):
  - Structured telephone support vs. Usual Care: Heterogeneity:  $\text{Chi}^2 = 11.84$ ,  $\text{df} = 11$  ( $P = 0.38$ );  $I^2 = 7\%$
  - Telemonitoring vs Usual Care: Heterogeneity:  $\text{Chi}^2 = 4.88$ ,  $\text{df} = 3$  ( $P = 0.18$ );  $I^2 = 39\%$

## Effects of interventions

### All-cause mortality

All-cause mortality data were available for 15 peer-reviewed studies comparing structured telephone support with usual care and 11 studies comparing telemonitoring with usual care (Analysis 1.1; Analysis 1.2). Telemonitoring was effective in reducing the risk of all-cause mortality in patients with CHF (telemonitoring RR 0.66, 95% CI 0.54 to 0.81,  $P < 0.0001$ ,  $I^2 = 0\%$ ), as was structured telephone support, but this effect size was not statistically significant on the risk of all-cause mortality (RR 0.88, 95% CI 0.76 to 1.01,  $P = 0.08$ ,  $I^2 = 0\%$ ).

Adding five studies (two on structured telephone support (Angermann 2007; Krum 2009 (CHAT); three on telemonitoring (Blum 2007 (MCCD); Parati 2009 (ICAROS); Zugck 2008 (HiTel)) which were not full peer-reviewed publications to the meta-analysis decreased the effect of structured telephone support (RR 0.96, 95% CI 0.84 to 1.09,  $P = 0.51$ ,  $I^2 = 16\%$ ) (Analysis 1.3). Only minimal change in the effect of telemonitoring on all-cause mortality was observed with the addition of these three studies (RR 0.68, 95% CI 0.57 to 0.82,  $I^2 = 0\%$ ,  $P < 0.0001$ ; Analysis 1.4).

Statistical heterogeneity increased for structured telephone support ( $I^2$  0% to 16%) with the addition of two studies of structured telephone support (Angermann 2007; Krum 2009 (CHAT)), for telemonitoring no change was observed (Analysis 1.3; Analysis 1.4).

Sensitivity analyses, performed to explore the influence of length of follow-up greater than six months on all-cause mortality only minimally decreased the effect of telemonitoring (RR 0.69, 95% CI 0.55 to 0.86,  $P = 0.0009$ ,  $I^2$  0%) on all-cause mortality but did not effect the outcome of structured telephone support on all-cause mortality (Analysis 1.5; Analysis 1.6).

### All-cause hospitalisation

All-cause hospitalisation data were available for 11 studies comparing structured telephone support with usual care and eight studies comparing telemonitoring with usual care (Analysis 2.1; Analysis 2.2). Structured telephone support was effective in reducing the risk of all-cause hospitalisation in patients with CHF (RR 0.92, 95% CI 0.85 to 0.99,  $P = 0.02$ ,  $I^2$  24%), as was telemonitoring (RR 0.91, 95% CI 0.84 to 0.99,  $P = 0.02$ ,  $I^2$  78%).

With the addition of one study of structured telephone support published as an abstract only (Krum 2009 (CHAT)), the effect of this intervention on all-cause hospitalisation in patients with CHF increased minimally (RR 0.90, 95% CI 0.84 to 0.97,  $P = 0.003$ ,  $I^2 = 32\%$ ; Analysis 2.3). Three telemonitoring studies published only as abstracts were added for a sensitivity analysis to examine the influence of peer-reviewed publication on reported all-cause hospitalisation rates (Blum 2007 (MCCD); Parati 2009 (ICAROS); Zugck 2008 (HiTel)). This altered the results (Analysis 2.4) (RR 0.94, 95% CI 0.87 to 1.01,  $P = 0.09$ ,  $I^2 = 73\%$ ).

Sensitivity analyses performed to explore the influence of length of follow-up greater than six months on all-cause hospitalisation found that the effect of structured telephone support was slightly decreased ( $P = 0.03$ ) however, the effect of telemonitoring increased when the period of follow-up was greater than six months (RR 0.87, 95% CI 0.80 to 0.95,  $P = 0.002$ ,  $I^2 = 85\%$ ) (Analysis 2.5; Analysis 2.6).

### CHF-related hospitalisation

CHF-related hospitalisation outcomes were available for 13 structured telephone support studies and four telemonitoring studies (Analysis 3.1; Analysis 3.2). Both types of interventions were effective in reducing the proportion of patients with a CHF-related hospitalisation (structured telephone support RR 0.77, 95% CI 0.68 to 0.87,  $P < 0.0001$ ,  $I^2 = 7\%$  and telemonitoring RR 0.79, 95% CI 0.67 to 0.94,  $P = 0.008$ ,  $I^2 = 39\%$ ).

One structured telephone support study published as an abstract (Krum 2009 (CHAT)) and two telemonitoring studies (Parati 2009 (ICAROS); Zugck 2008 (HiTel)) published as abstracts were added for sensitivity analyses. Addition of this structured telephone support study did not alter the effect observed on CHF-related hospitalisations with this intervention, except for decreasing statistical heterogeneity (0%). However, addition of these two telemonitoring studies improved the effect observed on the CHF-related hospitalisation outcome favourably, and decreased statistical heterogeneity (RR 0.76, 95% CI 0.64 to 0.89,  $P = 0.0006$ ;  $I^2 = 34\%$ ) (Analysis 3.3; Analysis 3.4).

The effect of both interventions on CHF-related hospitalisations were similar to the primary meta-analyses when sensitivity analyses were performed to explore the influence of length of follow-up greater than six months on CHF-related hospitalisations (Analysis 3.5; Analysis 3.6).

### Length of stay

Of the 16 studies reporting on structured telephone support versus usual care, six studies reported length of stay data (Galbreath 2004; Laramée 2003; Riegel 2002; Riegel 2006; Tsuyuki 2004; Wakefield 2008). Only the study by Tsuyuki 2004 reported a statistically significant reduction in length of stay in hospital (Table 1). One telemonitoring study, Parati 2009 (ICAROS) reported a large difference in the total number of days in hospital per patient, but this was not an analysis of length of stay per hospitalisation. Zugck 2008 (HiTel) reported a positive trend towards shorter length of stay for participants in the telemonitoring group, but this result was not statistically significant. Studies which assessed both telemonitoring and structured telephone support (Cleland 2005 (Struct Tele); Mortara 2009 (Struct Tele)) reported no significant difference in length of stay for hospital admissions between groups.

**Table 1. Duration of follow-up, Length of Stay, QOL, Cost, Adherence, Acceptability and all other outcome measures**

Study (year)	Endpoint	Hospital Length of Stay	Health and Quality of Life*	Effect on Cost /case	Cost of the Intervention	Acceptability of Intervention to Patients and "Other" Measures

**Table 1. Duration of follow-up, Length of Stay, QoL, Cost, Adherence, Acceptability and all other outcome measures**  
(Continued)

Both Structured Tele- phone Support and Telemoni- toring						
Cleland et al. (2005) TEN-HMS Study  <i>QoL Outcomes report</i> <i>Louis A et al (2006)</i>	240 days 400 days	LOS for heart failure hospitali- sations (240 days) (Median IQR) UC=11 ( 6-20) NTS =15 (7-29) HTM= 11(6-19)	-	-	-	Overall patient acceptance was good at 91.2%. 96% of patients were well satis- fied with the sys- tem and 97% found the tele- care devices easy to use. 4.1% of patients refused to accept the technology in their homes while 2.9% of pa- tients asked for the equipment to be removed and 1.8% discontin- ued recording.
Mortara et al. (2009) HHH Study	11.6 months (mean)	Over the 12 month fol- low-up Total days in hospital for HF, UC 584 days (1.0%) vs. HT 1175 Days (1.1%), HT1 477 (1.2%), HT2 374(1.2%) , HT3 324 (1.0%) NS in reducing bed days	-	-	-	Pa- tients completed 81% of all prac- ticable vital signs transmissions from home. Overall, 92% of practi- cable recordings were carried out by the patients, confirming high feasibility.
Structured Tele- phone Support						

**Table 1. Duration of follow-up, Length of Stay, QOL, Cost, Adherence, Acceptability and all other outcome measures (Continued)**

Angermann et al. (2007) INH Study	6 months	-	SF-36 Age and sex adjusted physical functioning (P = 0.036) and phys- ical health (P = 0.03)	-	-	Improved NYHA Classification (P = 0.029)
Barth (2001)	2 months	-	MLCHF\$ (P = 0.0005)	-	US \$23.60/ pa- tient	-
DeBusk et al. (2004)	12 months	-	-	-	-	-
DeWalt et al. (2006)	12 months	-	Modified MLCHF\$ to ac- count for all lit- eracy levels (NS) S-TOFHLA (NS)	-	-	HF Knowledge Improved (P = 0.001) Self Efficacy im- proved 2 points (P = 0.0026) Self-care behaviour improved (P < 0.001)
Galbreath et al. (2004) <i>Cost effectiveness report</i> Smith B. et al (2008)	18 months	No statisti- cal changes for in patient bed days between groups P value for group effect 0.899 P value for time effect 0.117	-	NS difference in total healthcare costs	-	6 minute walk test (NS) LVEF (NS) NYHA function class (P < 0.001) Evidence based pharmacother- apy (P = 0.002)
Gattis et al. (1999) PHARM Study	6 months	Not reported	-	-	-	Intervention group closer to target ACEI dose (P < 0.001)
GESICA Inves- tigators (2005) DIAL Trial	16 months (mean)	-	Improved MLCHF\$ Mean total score, intervention vs. control 30.6 vs. 35.0, mean dif- fer-	-	-	In- creased evidence based phar- macotherapy for CHF Increase in di-

**Table 1. Duration of follow-up, Length of Stay, QOL, Cost, Adherence, Acceptability and all other outcome measures**  
(Continued)

			ence =4.4, 95% confidence interval 1.8 to 6.9, P = 0.001			etary compliance
Krum 2009 CHAT Study  Clark et al. (2007)	12 months	.	-	-	-	Adherence 65.8% Adaptation 97% Participants rated the CHAT project with a total acceptability rate of 76.45%
Laramée et al. (2003)	3 months	LOS Intervention vs Control Mean (SD) 6.9 (6.5) vs. 9.5 (9.8), P = 0.15	-	Reduction US \$2482/ patient (average)	US \$228.52/ patient (average)	Adherence to treatment ( Daily Weighs) (P < 0.01) Adherence to medications (P = 0.04) Satisfaction (P < 0.01) patients taking target doses of ACEI and BB
Rainville (1999)	12 months	-	-	-	-	-
Ramachandran et al. (2007)	6 months	Not reported	KCCQ (P < 0.05)	Cost saving INR 14,592 per patient annually	-	Improvement in NYHA Function class (P = 0.004) Improvement in 6 minute walk test (P < 0.02) Slightly higher ACEi/ARB dose in intervention group at study end (P < 0.05) There was a feeling of self-control that the patients in the intervention group acquired through the pro-

**Table 1. Duration of follow-up, Length of Stay, QOL, Cost, Adherence, Acceptability and all other outcome measures**  
(Continued)

						gramme. Additionally, there was a feeling of accessibility to a strong support system.
Riegel et al. (2002)	6 months	HF Hospital days (6 months) Intervention vs. Control Mean (SD) 1.1(3.1) vs. 2.1 (4.6) P = 0.05 (with covariate) All cause days (6 months) Intervention vs. Control Mean (SD) 3.5 (6.6) 4.8 (8.3) P = 0.23 (with covariate)	-	46% reduction in inpatient costs (P = 0.04)	\$US443 / patient	"Patient satisfaction was significantly higher among persons assigned to the intervention group than among those assigned to the usual-care group." (P = 0.01)
Riegel et al. (2006)	6 months	HF Hospital days (6 months) Intervention vs. Control Mean (SD, 95% CI) 3.40(7.1, CI 1.6-5.2) vs. 3.65 (7.8, 1.9-5.4) NS	MLCHF\$, EQ-5D (NS)	NS difference in HF cost of care or all-cause hospital costs	-	Depression (NS)
Sisk et al. (2006) Qol and Cost Effectiveness reported by Herbert (2008)	12 months	-	Compared with UC, intervention patients reported better functioning on both SF-12 (physical component score) (39.9 vs. 36.3, difference 3.6 [CI 1.2 to 6.1] and MLCHF\$ (38.6 vs. 47.3, differ-	A nurse-led disease management program for patients with heart failure improved quality of life at an expected cost to society of under \$25,000 per QALY gained.	The intervention cost \$2177 per patient were more than offset by reduced hospital costs (\$2378 per patient) but higher costs for outpatient procedures, medications, and home health care prevented the in-	-

**Table 1. Duration of follow-up, Length of Stay, QOL, Cost, Adherence, Acceptability and all other outcome measures (Continued)**

			ence -8.8 [CI -15.3 to -2.2])		tervention from being cost-saving over the 12-month study.	
Tsuyuki et al. (2004)	6 months	Cardiovascular Hospital days (6 months) Intervention vs. UC Mean (SD) 6.4 (6.0) vs. 11.6 (10.3) P = 0.003 Total days 341 vs. 812 P = 0.003 All cause days (6 months) Intervention vs. UC Total days 627 vs.1082 P = 0.001	-	\$CAD2531 per patient reduction	-	-
Wakefield et al. (2008)	12 months	There was no significant differences in the mean number of hospital days between groups.	MLCHF\$ (in all groups P = 0.0002)	Mean HF-related readmission costs 86% and 84% lower in the videophone and telephone groups, respectively, compared to UC	-	Satisfaction between video and telephone (NS) Nurse perceptions on the difference in interactions between video and telephone (NS)
<b>Telemonitoring</b>						
Antonicelli et al. (2008)	12 months	-	SF-36 (NS) Except for reported health perception in intervention group, P < 0.046)	-	-	-
Balk et al. (2007)	288 days (mean)	Total days in hospital Intervention vs.	SF-36, Dutch version of MLCHF\$ (NS)	NS difference but a trend towards a reduction	Increase in costs in the Intervention group. No	Dutch Knowledge Score (P < 0.001)

**Table 1. Duration of follow-up, Length of Stay, QOL, Cost, Adherence, Acceptability and all other outcome measures**  
(Continued)

		Control 759 (0-116) vs. 762(0-132) Mean 7.4 vs. 7.9 P value not reported.		tion in contacts with health professionals in intervention group.	decrease in healthcare costs in the intervention group, but the cost of the telemonitoring system increased the total costs in the intervention group.	“Acceptance of the guidance system was high. The ease of use was rated very good or good by 80% of users. 70% mentioned access to doctors and nurses was better”.
Blum et al 2007	794 days (2 years)	Not reported	Scores with the ML- wHF§ improved (P = 0.001) SF36 Mental composite and Physical composites improved (P = 0.001 & P = 0.003)	-	Not yet available	BNP renal Function and weight showed significant improvements over time (P =.011, 0.001 % 0.003)
Capomolla (2004)	12 months	-	-	-	-	-
de Lusignan et al. (2001)	12 months	-	‡CHFSQ (NS§) +GHQ	-	-	Video link over standard telephone lines was not found to be useful by the patients in the study.
Giordano et al. (2008)	12 months	-	-	35% reduction in mean cost for readmission in intervention group (843 EUR compared to 1298 EUR in UC group, P < 0.01)	Daily cost per patient of intervention was 0.65 EUR and mean annual cost per patient was 185 EUR	-
Goldberg et al. (2003) WHARF Trial	6 months (mean)	-	MLCHF§, SF- 12, HDS. All scores were im-	-	-	Compliance with the monitoring system in



**Table 1. Duration of follow-up, Length of Stay, QOL, Cost, Adherence, Acceptability and all other outcome measures**  
(Continued)

			proved but were not statistically significant			the AlereNet arm was 98.5%
Kielblock et al. (2007) and Blasius (2008)	12 months	-	-	Hospital care expenditures for treatment group were 45% lower (P = 0.01) but medication expenditure was 15% higher (NS). Overall, health care costs were 39.5% lower (6.800 EUR/patient/yr) in treatment group (P = 0.05)	Reduction in hospital costs of 7128 EUR per patient (P = 0.01), but an increase in drug expenditure of 245 EUR per patient (NS). Highest cost in death group	The satisfaction survey revealed that 57% of those surveyed considered the programme to be "very good" and 43% "quite good". None of those surveyed responded with "not so good" or "not at all". Increased compliance in taking medicines Improvement in NYHA Functional Class
Parati (2008)	6 months	Intervention vs. UC 214 (6.29 days per patient) vs. 701 (15.57 days per patient)	-	-	-	-
Soran et al. (2008)	6 months	HF Hospital days (6 months) Intervention vs. Control Mean (SD) 9.3(12.2) vs. 10.0(7.3) P = 0.22	SF-12, KCCQ (NS)	-	-	Compliance 97%
Woodend et al. (2003)	12 months	Intervention patients spent 7.13 vs. 6.71 days (control patients) in hospital in 1 year.	Improved MLCHF\$ (P = 0.025) SF 36 -Improved (P < 0.05) Patients receiving telemonitoring consistently reported	-	-	Overall patients found the equipment easy to use. Obtaining ECG most difficult. Satisfaction was calculated on the sum of scores of 10 questions.

**Table 1. Duration of follow-up, Length of Stay, QOL, Cost, Adherence, Acceptability and all other outcome measures (Continued)**

			higher levels of treatment satisfaction. Increase exertional capacity			The mean scores were 92-97=very highly satisfied
Zugck et al. (2008) HiTel Trial	12 months	Significant reduced in duration in hospitalisation both comparing telemedicine (UCT+HCT) vs. UC Mean (SD) 1.5 (4.2) vs. 5.1(7.7) days P = 0.05	-	-	-	-
<b>1 Euro = approx</b>	<b>\$CAD 1.55</b>	<b>\$US1.46</b>	<b>£UK0.09</b>	<b>\$Aust 1.60</b>	<b>68.3 INR (Indian Rupee)</b>	

\*Health related quality of life, variance between baseline and study endpoint, details provided as included in study; ‡CHFSQ, Chronic Heart Failure Symptomatology Questionnaire;+ General Health Questionnaire GHQ § MLCHF, Minnesota Living with Heart Failure Questionnaire; KCCQ, Kansas City Cardiomyopathy Questionnaire; SF-12, Short Form 12 Item; SF-36, Short Form 36 Item; HDS, Health Distress Score; NS, not statistically significant; Patient acceptability measured at 400 days. Blank cells indicate no data available for variable. 95% CI = 95% Confidence Intervals.

### Quality of life

Quality of Life (QoL) was a secondary outcome for 15 of the 30 included studies. Several different psychometric tools were used for evaluation (Chronic Heart Failure Symptomatology Questionnaire (CHFSQ); Minnesota Living with Heart Failure Questionnaire (MLCHF); Kansas City Cardiomyopathy Questionnaire (KCCQ); Short Form 12 Item (SF-12); Short Form 36 Item (SF-36); Health Distress Score (HDS)). Six of the studies in the structured telephone support versus usual care group reported statistical improvements in QoL in all areas of assessment of physical and mental health. Seven of the telemonitoring studies reported QoL, with three telemonitoring studies reporting statistically significant improvements in QoL outcomes. Using a similar mixture of tools as for the structured telephone group areas of QoL particularly significant were higher levels of treatment satisfaction, higher levels of health perception, improved physical composite scores

and mental composite scores (Table 1). Studies which assessed both telemonitoring and structured telephone support (Cleland 2005(Struct Tele); Cleland 2005 (Telemon); Mortara 2009 (Struct Tele); Mortara 2009 (Telemon)) have not reported QoL outcomes.

### Cost

Twelve studies presented detailed cost analysis for these two types of technologies (structured telephone support (Barth 2001; Galbreath 2004; Laramée 2003; Ramachandran 2007; Riegel 2002; Riegel 2006; Sisk 2006; Tsuyuki 2004; Wakefield 2008; and telemonitoring (Balk 2008; Giordano 2009; Kielblock 2007)). Cost of the intervention varied according to intensity and technologies used in the intervention (Table 1). Studies which reported cost reduction in the cost of care per admission or overall cost reduction due to reduction in hospitalisation reported cost savings ranging between 35% and 86%. Reductions were reported

in all studies which measured economic benefit except [Balk 2008](#), [Galbreath 2004](#) and [Riegel 2006](#) where no reduction or increases in cost were reported.

### Adherence, adaptation, satisfaction and other outcomes

Adherence (compliance) was 65.8% ([Clark 2007b](#); [Krum 2009 \(CHAT\)](#)), 97% [Soran 2008](#) and 98.5% ([Goldberg 2003 \(WHARF\)](#)) for structured telephone support and telemonitoring respectively. Adaptation to the technology ([Clark 2007b](#), [Cleland 2005 \(Struct Tele\)](#); [Cleland 2005 \(Telemon\)](#); [Krum 2009 \(CHAT\)](#); [Mortara 2009 \(Struct Tele\)](#); [Mortara 2009 \(Telemon\)](#)) rated at 96% to 97% with few elderly patients unable to learn to use the technology ([Table 1](#)). Satisfaction of patients receiving health care via technology was rated between 57% to 97%.

Other measures evaluated as outcomes for these trials included ([Table 1](#)):

- i) Improved NYHA Functional Class ([Angermann 2007](#); [Galbreath 2004](#); [Kielblock 2007](#); [Ramachandran 2007](#))
- ii) Improved heart failure knowledge and self-care behaviour ([Balk 2008](#); [DeWalt 2006](#))
- iii) Improved six minute walk test ([Galbreath 2004](#); [Ramachandran 2007](#))
- iv) Improved evidence based pharmacotherapy ([Galbreath 2004](#); [Gattis 1999 \(PHARM\)](#); [GESICA 2005 \(DIAL\)](#), [Laramie 2003](#), [Kielblock 2007](#), [Ramachandran 2007](#))
- v) Improved BNP ([Blum 2007 \(MCCD\)](#))

## DISCUSSION

This review has demonstrated that structured telephone support and telemonitoring programmes for patients with CHF living in the community reduce the risk of all-cause mortality by 12% and more than one third respectively, reduce the risk of CHF hospitalisation by more than one fifth and may reduce all-cause hospitalisations 8% to 9%. It provides further confirmation of the efficacy of structured telephone support or telemonitoring as a component of contemporary multidisciplinary heart failure management since our previous systematic review and meta-analysis ([Clark 2007a](#)) on this topic.

While inclusion of the more recently published trials has served to refine the point estimates for these outcomes we reported in our earlier meta-analyses, in the case of all-cause and CHF hospitalisations inclusion of the new data has refined the confidence intervals sufficiently that the results are now statistically significant with both interventions. We have also expanded on prior evidence in this field by demonstrating that the results for the risk of CHF hospitalisation are robust to the inclusion of unpublished data and for all-cause hospitalisations the benefits are greater in

longer-term studies than those only following patients for shorter time frames. Despite decreasing the proportion of patients hospitalised, less impact was observed on the number of days spent in hospital. Not only were benefits on mortality and hospitalisation observed, a statistically significant impact was seen on quality of life with these interventions.

Since completing our previous review of these interventions, ([Clark 2007a](#)), we identified 16 new studies, comprising of seven studies of structured telephone support ([Angermann 2007](#); [DeWalt 2006](#); [Galbreath 2004](#); [Krum 2009 \(CHAT\)](#); [Ramachandran 2007](#); [Sisk 2006](#); [Wakefield 2008](#)), eight studies of telemonitoring ([Antonicelli 2008](#); [Balk 2008](#); [Blum 2007 \(MCCD\)](#); [Giordano 2009](#); [Kielblock 2007](#); [Parati 2009 \(ICAROS\)](#); [Soran 2008](#); [Zugck 2008 \(HiTel\)](#)) and one study with both a telemonitoring and structured telephone support arm ([Mortara 2009 \(Struct Tele\)](#)). Of these new included studies, two structured telephone support studies ([Angermann 2007](#); [Krum 2009 \(CHAT\)](#)) and three telemonitoring studies ([Blum 2007 \(MCCD\)](#); [Parati 2009 \(ICAROS\)](#); [Zugck 2008 \(HiTel\)](#)) are currently published as abstracts only and were excluded from the principal meta-analysis and data were only included in sensitivity analyses.

Structured telephone support and telemonitoring reduced health-care costs, were acceptable to patients, improved prescribing of evidence-based pharmacotherapies, improved patient heart failure knowledge and self care behaviours, and even improved NYHA functional class in those studies that assessed it.

The first RCTs of structured telephone support or telemonitoring (compared to usual care, without home or clinic visits) were published in 1999 ([Gattis 1999 \(PHARM\)](#); [Rainville 1999](#)). In the past decade, information technology has progressed rapidly alongside the need and demand for chronic disease management for conditions such as CHF. Our previous review, published in 2007 included only 14 RCTs of structured telephone support or telemonitoring ([Clark 2007a](#)). This review documents evidence from 30 RCTs of these technologies. In light of this exponential increase in RCT evidence for such interventions in the past decade, and the ever expanding population of patients with CHF these findings are important for future healthcare service planning.

Recently published studies of structured telephone support and telemonitoring programmes have included much longer follow-up on outcomes, with most of the outcomes from studies included in this review reported at 12 months follow-up or longer. In addition, several systematic reviews and meta-analyses have been published on this topic since 2007 ([Chaudry 2007](#); [Dang 2009](#); [DelliFraine 2008](#); [Gaikward 2009](#); [Klersy 2009](#), [Maric 2009](#)). Although superficially the recently published reviews appear similar, there are important differences in inclusion criteria to this review, and particularly the inclusion of home visits or invasive haemodynamic monitoring in their definitions of 'remote monitoring'. Our review

focused solely on non-invasive monitoring and telephone support and, as such, we believe is more relevant for health care service planning in resource-poor environments where access to invasive monitoring or specially trained staff to conduct home visits is not an option.

Differences in the inclusion criteria of the recently published meta-analyses on this topic impairs the ability to directly compare our findings with the findings of previous meta-analyses. However, a critical review of these other reports with our findings highlights the uniqueness and importance of our findings. Klersy and colleagues (Klersy 2009) included 20 RCTs and 12 cohort studies of 'remote monitoring', many of the interventions of the included studies involved home visits and studies of invasive haemodynamic monitoring were also included. The 20 RCTs demonstrated a significant reduction in the risk of all-cause mortality (RR 0.83, 95% 0.73 to 0.95;  $P = 0.006$ ) similar, but smaller than what we have reported here. The reduction in the risk of all-cause hospitalisations was similar, though less than what we have reported, a larger reduction in heart failure-related hospitalisations was reported by Klersy (RR 0.71, 95% CI 0.64 to 0.80) (Klersy 2009). The review and meta-analysis by Klersy did not consider other outcomes such as quality of life, functional capacity or length of stay (Klersy 2009). Another recently completed systematic review by Dang and colleagues (Dang 2009) synthesised nine RCTs of telemonitoring in CHF some of which included home visits, concluding that "more data are needed to determine the ideal patient population, technology and parameters, frequency and duration of telemonitoring...". Maric and colleagues (Maric 2009) completed a systematic review of telemonitoring technologies in heart failure, including 56 studies (not all RCTs) of interventions such as external devices, telephone support, video consultation, web site based telemonitoring. The systematic reviews by Gaikward (Gaikward 2009) and DelliFraine (DelliFraine 2008) were not specific to heart failure. Our findings are broadly consistent with those of a review (Yu 2006) that explored which components of CHF Disease Management Programs (DMPs) were most effective. The authors of that review reported that an effective DMP should be multi-faceted and consists of an in-hospital phase of care, intensive patient education, self-care supportive strategy, optimisation's of medical regimen, and ongoing surveillance and management of clinical deterioration. The cardiac nurse and cardiologist should be actively involved. A flexible approach should be adopted to deliver the follow-up care and Yu 2006 concluded that the characteristics of the care team and the organisation content and delivery method of the DMP were crucial to enhance the discharge outcomes of older people with heart failure.

Although a reduction in the proportion of participants with an all-cause or CHF-related hospitalisation was observed, we did not identify a consistent impact of structured telephone support or telemonitoring on length of stay for such admissions. Length of stay was inconsistently reported, thus preventing meta-analysis of

this outcome. It is reasonable to suppose that while remote monitoring interventions would prevent episodes of hospitalisation through early detection and management of clinical deterioration, in more serious episodes of decompensation, hospitalisation would still be necessary and it cannot be expected that community-based interventions such as structured telephone support or telemonitoring would impact on the care administered in hospital.

We performed two sensitivity analyses to investigate the effects of publication and length of follow-up on outcomes and heterogeneity. Only five studies were not available as full, peer-reviewed publications and were not included in the primary meta-analyses. Addition of these studies to our meta-analyses did not significantly alter our findings and in most instances statistical heterogeneity increased. Little difference was seen when meta-analyses were limited to studies with a follow-up longer than six months with some increases to heterogeneity observed. The two structured telephone support studies and three telemonitoring studies which were only available as abstracts reported similar effects to those studies which were published as full-peer reviewed publications across the three outcomes of interest which were meta-analysed.

Of the three outcomes included in our meta-analysis, the greatest heterogeneity was observed for all-cause hospitalisations for telemonitoring studies ( $I^2 = 78\%$ ). One study with the least number of participants (Antonicelli 2008) reported a substantially lower proportion of patients in the intervention arm (telemonitoring) hospitalised for all-causes over the follow-up period and this difference may account for some of the heterogeneity observed for this outcome. The methodological reasons for this difference in reported outcomes for this particular study is unclear, but may relate to the intervention and the clinical management of these patients. There are no obvious differences in the study participants or study methodology that can be identified to account for this difference.

Jaarsma (Jaarsma 2008) has indicated that intensified intervention in heart failure management does not necessarily produce greater benefits on a composite endpoint of death or heart failure-related hospitalisation regardless of strategy. This then suggests that the key issue for heart failure management becomes one of cost effectiveness, and that is likely to be determined by the number of staff required to support a heart failure management intervention (as the major cost of healthcare in developed society is human resource expenditure).

This review is novel in that we sought to delineate the benefits of one form of CHF disease management on patient outcomes while controlling for other disease management interventions which may confound the benefits of structured telephone support and telemonitoring. It is important to consider the benefits that these sole interventions can deliver as there are some circumstances where such interventions may be the only option for providing specialised CHF management. However, structured

telephone support and telemonitoring (and many other forms of technology delivered heart failure programmes) are now considered to be standard interventions within the multidisciplinary model of heart failure management (ESC Heart Failure Guidelines 2008).

Krumholz and colleagues (Krumholz 2006) have outlined a taxonomy for disease management which encourages authors to describe their study intervention under eight domains. These eight domains include: 1) Patient population; 2) Intervention recipient; 3) Intervention content; 4) Delivery personnel; 5) Method of communication; 6) Intensity and complexity; 7) Environment and 8) Clinical outcomes (Krumholz 2006). We found that the included studies inconsistently reported these details which in turn did not allow us to explore differences in these domains as potential explanations for any observed heterogeneity between studies. Many of the included studies were published prior to publication of the taxonomy, but future reports of such interventions should be clearly described under these headings. Similarly, Clark and colleagues (Clark 2009) have called for a more specific evidence base to support the development of effective programmes for different populations. They have called for future reviews to pool data by sex or age, however, we were unable to do so in this review as very few of the included studies presented outcomes in a manner that permitted these data to be extracted. We have, however identified that for most of the studies men were predominately recruited rather than women. We were also unable to pool outcomes based on age of the participants. An individual patient data meta-analysis would be the best method to stratify outcomes according to important demographic and clinical variables, such as sex, age, cardiac function and co-morbidities.

A major limitation to the studies conducted so far is that the research study is conducted in parallel to the existing service on patients who are willing to participate in research and by staff that are usually super-numerate to the service that delivers routine clinical care. This division between research study and clinical service is likely to make home monitoring less efficient and less effective. Moreover, without a service how can health professionals get experience and training in how to make home monitoring work? Ideally, studies should integrate home monitoring into the routine service. However, until home monitoring, in particular telemonitoring is adopted as a service this is exceedingly difficult.

The nature of the control group should be considered with care when interpreting clinical trials of home telemonitoring. It is likely that marked intensification of more conventional methods of delivering care, such as more home or clinic visits, can deliver results similar to those of home telemonitoring. This may account for the neutral outcome observed in some studies (Cleland 2009; Dar 2009 (HOME-HF)). However, employing health professionals is the by far the largest part of health care costs. Technology that can make staff more efficient and effective may well be cost neutral or cost-saving.

Only one study in this group of included studies commented on the “user satisfaction in terms of ease among health care professionals” (Wakefield 2008) stating that there was no significant difference in the nurses perceptions in interactions between video and telephone support.

It was reported elderly CHF participants were more than able to cope with technological monitoring. Studies reported that patients usually withdrew because of hearing or health literacy issues and some simply preferred not to add healthcare technology into their busy lives (Clark 2007b; Cleland 2005 (Telemon)).

Technology in this area is not static and rapid developments create opportunities and new problems. New sensors can offer more accurate and robust reading or new clinical variables, such as cardiac output and lung congestion using bio-impedance, cardiac function by acoustic or ballisto cardiography or more accurate blood pressures using plethysmography. However, the biggest revolution in this area is the development of tools that analyse the data automatically and provide analyses and advice to both patients and health professionals in making care decisions. These can give patients more control in managing their problems and much more personalised health-care. Expert systems that arise from telemonitoring are likely to form the basis of electronic patient records, which may be accessed by all those engaged in the care of the patient, as well as the patient themselves. This is currently the subject of a major European Union initiative in telehealth called HeartCycle (HeartCycle).

## Strengths and weaknesses of this review

The major strength and advantage of our review is the quantification of the benefit of structured telephone support and telemonitoring in the absence of home visits or more the standard clinic follow-up which will now identify for clinicians and healthcare service planners the value of each of the ‘building blocks’ in contemporary CHF disease management programmes, allowing programmes to be customised according to needs. Another strength of our systematic review and meta-analysis is that we have considered and synthesised evidence on almost all aspects from which an effect of these interventions is important (mortality, hospitalisations, length of stay, quality of life, acceptability, functional capacity and cost). We have also captured several previously unidentified RCTs of structured telephone support or telemonitoring and have highlighted several studies for which results once published will be included in future updates of this review. In addition, 14 of the primary study authors whom we contacted provided us with additional unpublished details or outcome data from their studies. Like any systematic review and meta-analysis, our findings are only as good as the studies which met our inclusion criteria. Future updates of this review will incorporate new data along with the findings of studies which are currently underway but not yet completed (Chaudry 2007 (Tele-HF); Kohler 2006; Kulshreshtha 2008a). We were unable to stratify results according to age, func-

tional class or sex as outcomes were not reported in a manner that allowed us to extract this sub-group specific data. We were unable to consider 'patient-years' as the denominator for our meta-analysis in order to adjust for the differing lengths of follow-up of the included studies as these data were very rarely reported.

We were challenged in correctly identifying all of the outcomes available to report for each included study by the multiple publications arising from some of the included studies. Many studies published hospitalisation and mortality findings in one paper, cost findings in another, and quality of life, acceptability and adherence in another publication. Often these multiple publications were published with a different order or list of authors and the study was not always clear to identify from the title of the paper or the abstract. Despite this challenge, we are confident that we have captured reported outcomes which are currently available for the studies we have included. Future publications arising from RCTs of structured telephone support and telemonitoring should be published in a manner which permits easy identification of the study if outcomes are to be published in multiple publications.

## AUTHORS' CONCLUSIONS

### Implications for practice

Telemonitoring and structured telephone support interventions for assisting in the day-to-day management of patients with CHF are beneficial and may play a significant role in the care of 'standard' management of CHF in the developed world for specific patients. It may be deduced from these findings that there may be additive or synergistic benefits of structured telephone support or telemonitoring as part of home or clinic based specialised heart failure management programmes.

### Implications for research

- There are clear benefits of such programmes on outcomes for patients with CHF.

- Given the weight of evidence from such trials further randomised controlled trials of structured telephone support or non-invasive telemonitoring in comparison to usual care (cardiologist and general practitioner care) are not recommended.

- Future publication of findings of structured telephone support or telemonitoring interventions, and those already published, should present results which would allow stratification of the benefits of such programmes across the heart failure patient population, in particular, outcomes should be presented for both men and women and for age groups (young, middle-aged, old, and elderly) separately.

- More work is required on the business models underlying the cost-effectiveness of telemonitoring in particular. High capital acquisition costs with low running costs argue for long-term monitoring. However, renting equipment changes this balance and argues for monitoring over shorter periods of high-risk or the need for intensive monitoring and education. The business models will help define how the clinical community use the technology.

- Future research into 'remote monitoring' of patients with CHF should not discount the value of these non-invasive interventions over preference for other 'invasive' forms of remote monitoring.

- Future research should focus on intervention intensity, so that the benefits of structured telephone support and telemonitoring performed at different intensities alongside other proven disease management strategies may be elucidated and the 'best' multi-modal strategy identified for each patient sub-group. The aim for the future use of structured telephone support and telemonitoring should be to use these interventions to tailor CHF disease management programmes to the population needs and resources, to the geography of the population and most importantly, to patient preferences.

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\* Indicates the major publication for the study



## CHARACTERISTICS OF STUDIES

### Characteristics of included studies [ordered by study ID]

#### Angermann 2007

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	708 patients hospitalised for symptomatic systolic CHF with LVEF $\leq$ 40%. Mean age 68 years. 71% of participants were male. Germany.
Interventions	Structured telephone support. Patients randomised to the disease management arm received telephone-based monitoring and modular education delivered by trained nurses that included educational material/self-monitoring schemes and multidisciplinary advice. These patients were required to attend six monthly visits to a CHF clinic. Usual care consisted of care provided by the patients GP plus six monthly visits to a CHF clinic.
Outcomes	All cause mortality, time-to-first-event (all-cause death and hospitalisation), days alive and out of hospital, NYHA class, quality of life. Six month follow-up.
Notes	Abstract. Final data still to be published. Contacted author no further outcome data offered until publication but methodology of trial and type of intervention confirmed with authors. The extracted data is from a published abstract.

#### *Risk of bias*

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Unable to assess. Abstract only.
Allocation concealment?	Unclear	Unable to assess. Abstract only.
Blinding? Intervention	Unclear	Unable to assess. Abstract only.
Incomplete outcome data addressed? All outcomes	Unclear	Unable to assess. Abstract only.
Free of selective reporting?	Unclear	Unable to assess. Abstract only.
Was the study powered to detect differences in outcomes.?	Unclear	Unable to assess. Abstract only.

**Angermann 2007** (Continued)

Were the study groups comparable at baseline?	Unclear	Unable to assess. Abstract only.
Was the study reported according to CONSORT guidelines?	Unclear	Unable to assess. Abstract only.
Was the diagnosis of heart failure defined and appropriate?	Unclear	Unable to assess. Abstract only.

**Antonicelli 2008**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	Telemonitoring. 57 patients hospitalised for worsening symptoms and signs of CHF with NYHA class II-IV, evidence of pulmonary congestions on chest x-ray and EF < 40%. Patients with NYHA class II-III with an EF > 40% and diastolic LV dysfunction were also included. Mean age 78 years. 61% of participants were male. Italy
Interventions	Patients randomised to home telemonitoring-based care were contacted by telephone at least once a week to collect information on symptoms and treatment adherence as well as BP, HR, weight and 24h urine output on the previous day. A weekly ECG transmission was also obtained. Patients were then evaluated and their regimen altered when necessary based on this data. Additionally, clinic visits were performed when required based on the data collected or telephone interviews.  Usual care involved receiving stand care based on routinely scheduled clinic visits (every four months) performed by a team specialized in CHF patient management. These subjects were also contacted monthly by telephone to collect data on new hospital admissions, complications and death. Additional clinic visits were performed whenever required when clinical status altered.
Outcomes	Combined rate of mortality and hospitalisation, these rates considered individually, quality of life. 12 month follow-up.
Notes	

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Method of randomisation not stated.
Allocation concealment?	Unclear	Not detailed.

**Antonicelli 2008** (Continued)

Blinding? Intervention	Unclear	Not detailed.
Incomplete outcome data addressed? All outcomes	Yes	No evidence of incomplete outcome data.
Free of selective reporting?	Yes	No evidence of selective outcome reporting.
Was the study powered to detect differences in outcomes.?	Yes	Power calculation performed for sample size for primary outcome - combined rate of mortality and hospitalisation. Study powered for this outcome.
Were the study groups comparable at baseline?	No	Several variables were different between the control and intervention groups at baseline.
Was the study reported according to CONSORT guidelines?	Yes	Study reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Yes	Diagnosis of heart failure based on presence of CHF signs and symptoms, pulmonary congestion on chest x-ray, and ejection fraction on echocardiogram.

**Balk 2008**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	214 patients with CHF and NYHA class I-IV. Mean age 66 years. 70% of participants were male. The Netherlands.
Interventions	Telemonitoring. Patients in the Intervention group were provided a MOTIVA system (TV-channel providing educational material, reminders of medication, health related surveys and motivational messages to encourage the prescribed lifestyle regimen) in addition to scheduled cardiologist appointments. A subgroup of intervention patients also received automated BP and weight devices that automatically communicated readings via the telephone (those who had been hospitalised in the prior year for HF). Patient guidance followed a personalised plan. Control subjects were followed by their cardiologists and HF-nurses according to standard local practice. All patients recorded all contacts with health care professionals and hospital admissions.

**Balk 2008** (Continued)

Outcomes	All-cause hospital days per year, days alive and out of hospital, quality of life, knowledge of disease, self-care. 288 days - mean follow-up.	
Notes		
<i><b>Risk of bias</b></i>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Yes	“Randomisation was performed in a 1:1 ratio, in randomly permuted blocks of 30 per participating centre. Randomisation was independently performed...via a special Web-based application” p1138.
Allocation concealment?	Unclear	Not detailed.
Blinding? Intervention	Unclear	Not detailed. Appears that an independent organization that performed the randomisation also analysed the data.
Incomplete outcome data addressed? All outcomes	Yes	No evidence of incomplete outcome data.
Free of selective reporting?	Yes	No evidence of selective outcome reporting.
Was the study powered to detect differences in outcomes.?	Unclear	No power analysis for sample size - authors state that “...a meaningful power analysis was not possible because of absence of data in the literature and insufficient data from hospitals on hospital admissions for these patients, who had not necessarily had a recent admission to hospital for heart failure treatment...” p1138.
Were the study groups comparable at baseline?	No	Some slight differences were observed between the two groups at baseline.
Was the study reported according to CONSORT guidelines?	Unclear	Not reported using CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Unclear	Specific clinical criteria to confirm heart failure diagnosis not detailed. Patients with chronic heart failure in NYHA class I-IV and under the care of cardiologists were el-

**Balk 2008** (Continued)

		igible.
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**Barth 2001**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	34 patients discharged from acute care to home with primary diagnosis of CHF. Mean age 75 years. 47% of participants were male. USA
Interventions	Structured telephone support. Structured nurse-managed telephonic post-discharge program involving pre-discharge education plus post discharge telephone follow-up. Structured interaction at 72 hours, 144 hours, and then fortnightly. The control group received routine discharge teaching at the time of discharge as per hospital procedure. Patients were contacted at two months for collection of data.
Outcomes	Mortality, rehospitalisation, physician and emergency department visits, quality of life, cost of the intervention. Three months follow-up.
Notes	Included in previous systematic review and meta-analysis <a href="#">Clark 2007a</a> .

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Method of randomisation not stated.
Allocation concealment?	Unclear	Not detailed.
Blinding? Intervention	Unclear	Not detailed.
Incomplete outcome data addressed? All outcomes	Unclear	Not detailed.
Free of selective reporting?	Unclear	Unable to assess, not detailed.
Was the study powered to detect differences in outcomes.?	Unclear	Not detailed.
Were the study groups comparable at base-line?	Yes	No significant differences observed in base-line characteristics between the two groups.
Was the study reported according to CON-SORT guidelines?	No	Study was not reported according to CON-SORT guidelines.

**Barth 2001** (Continued)

Was the diagnosis of heart failure defined and appropriate?	Unclear	Not detailed.
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**Blum 2007 (MCCD)**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	204 subjects with heart failure. Mean age 72 years. 71% of participants were male. USA
Interventions	<p>Telemonitoring.</p> <p>All subjects were given written material about heart failure and self-management activities such as daily weights, medication administration, signs and symptoms of worsening heart failure and were given an opportunity to ask questions or seek clarification as the handout was discussed.</p> <p>The usual care group was not contacted again until time to schedule the six-month follow-up appointment.</p> <p>Intervention subjects were instructed to use the scale, blood pressure cuff/heart rate monitor and the heart rhythm strip monitor at the same time each day. The transmitted data was then compared to individually assigned parameters based on the subject's admission and subsequent evaluations. Readings outside these parameters were flagged for the nurse practitioner (NP) who did the monitoring. This NP, who had extensive experience in the management of heart failure patients contacted the subject to gather more information and, if appropriate, adjusted medications, usually diuretics. There were no specific protocols as to the management decisions and decisions were based on the NP's experience and/or consultation with the subject's cardiologist. If no flags were noted over the period of one month, the subjects were called just to maintain contact, provide encouragement and answer any questions they might have. Subjects were encouraged to call the NP any time they wished and they were given the phone number of the direct line to the NP's office. Reports of weight and vital sign trends were sent to participating cardiologists' office prior to office visits. Monitoring was performed seven days a week.</p>
Outcomes	All-cause mortality, hospitalisations (as provided by the authors). Quality of life using SF-36 and Minnesota Living with Heart Failure Questionnaire (presented in abstract). BNP (outcomes not included in review as only mortality and hospitalisation data provided) 12 month follow-up.
Notes	<p>Abstract and author communication.</p> <p>Meta-analysis performed using number of patients randomised (n = 204).</p>

***Risk of bias***

Item	Authors' judgement	Description
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**Blum 2007 (MCCD)** (Continued)

Adequate sequence generation?	Yes	"The subject's identification information was entered into the Mathematica Policy Research (MPR) randomisation website and the designation of participant (tele-monitored group) or control (usual care) was returned" author correspondence.
Allocation concealment?	Yes	Randomization performed after informed consent given by participant.
Blinding? Intervention	Unclear	Not detailed.
Incomplete outcome data addressed? All outcomes	Yes	"Two subjects declined to continue after signing consent and only partial or no data were collected on them, one in the usual care group and one in the monitored group. Therefore, complete baseline data was collected on 202 subjects. One subject completed all of the first visit data and then declined to accept the monitoring equipment when it was delivered. These subjects were eliminated from the data analysis leaving 201 subjects; 100 in the usual care group and 101 in the monitored group" author correspondence.
Free of selective reporting?	Unclear	Unable to assess. Abstract only.
Was the study powered to detect differences in outcomes.?	Unclear	Unable to assess. Abstract only.
Were the study groups comparable at baseline?	Unclear	Unable to assess. Abstract only.
Was the study reported according to CONSORT guidelines?	Unclear	Unable to assess. Abstract only.
Was the diagnosis of heart failure defined and appropriate?	Unclear	Unable to assess. Abstract only.

## Capomolla 2004

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.	
Participants	133 patients discharged from specialist CHF unit to home. Mean age 57 years. 88% of participants were male. Italy	
Interventions	Telemonitoring. Daily communication of vital signs (including weight, systolic BP, HR) and symptoms with review by nurses and physicians. Access to medical staff via phone as needed was available. Usual care consisted of a referral to the patients primary care physician or cardiology department at discharge. Post-discharge care was governed by the care provider.	
Outcomes	Mortality, re hospitalisation, emergency department visits, compliance with intervention. 12 month follow-up.	
Notes	Included in previous systematic review and meta-analysis <a href="#">Clark 2007a</a> .	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Method of randomisation not stated.
Allocation concealment?	Unclear	Not detailed.
Blinding? Intervention	Unclear	Not detailed.
Incomplete outcome data addressed? All outcomes	Unclear	Not detailed.
Free of selective reporting?	Yes	No evidence of selective outcome reporting.
Was the study powered to detect differences in outcomes.?	Unclear	Sample size calculation not detailed.
Were the study groups comparable at baseline?	Yes	No significant differences in baseline variables evident.
Was the study reported according to CONSORT guidelines?	No	Study not reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Unclear	Not detailed.



### Cleland 2005 (Telemon)

Methods	Randomised controlled trial; multiple intervention arms and control (usual care) arm.
Participants	426 patients with a recent admission for heart failure and LVEF < 40%. Mean age 67 years. 77% of participants were male. Germany, Netherlands, UK
Interventions	Structured telephone support; telemonitoring. Patients assigned to the nurse telephone support arm received a telephone call each month by a heart failure specialist nurse to assess their symptoms and current medications. Patients assigned to telemonitoring received the nurse telephone support and had their weight, BP and ECG monitored twice daily. Usual care consisted of a management plan forwarded to the patient's primary care physician, who was asked to implement it. If the practice involved nurse titration of drugs this was allowed. Patients were assessed at a research clinic every four months; contact with the clinic was discouraged between clinic visits.
Outcomes	Mortality, rehospitalisation, compliance with intervention. 240 day and 450 day follow-up.
Notes	Three armed study with both telephone and telemonitoring. Included in previous systematic review and meta-analysis <a href="#">Clark 2007a</a> . Results included in meta-analysis are from 240 day follow-up.

### *Risk of bias*

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Random permuted blocks - correspondence from author.
Allocation concealment?	Yes	After consent and collection of baseline data an independent statistical centre was contacted - correspondence from author.
Blinding? Intervention	Unclear	Not stated.
Incomplete outcome data addressed? All outcomes	Yes	"...Four were lost to follow-up and 12 declined to comply with regular telemonitoring" p1659. " "Analyses were conducted by intention-to-treat" p1659.
Free of selective reporting?	Yes	Selective outcome reporting not evident.
Was the study powered to detect differences in outcomes.?	Yes	Power calculation performed. Study powered for the primary outcome days lost because of death or hospitalisation in acute

**Cleland 2005 (Telemon)** (Continued)

		medical/surgical beds for any reason during 450 days, after an interim analysis the duration of follow-up was reduced to 240 days.
Were the study groups comparable at baseline?	Unclear	The study groups appear to be similar at baseline.
Was the study reported according to CONSORT guidelines?	Yes	Study reported according the CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Unclear	Unable to assess.

**Cleland 2005(Struct Tele)**

Methods	Randomised controlled trial; multiple intervention arms and control (usual care) arm.
Participants	426 patients with a recent admission for heart failure and LVEF < 40%. Mean age 67 years. 77% of participants were male. Germany, Netherlands, UK
Interventions	Structured telephone support; telemonitoring. Patients assigned to the nurse telephone support arm received a telephone call each month by a heart failure specialist nurse to assess their symptoms and current medications. Patients assigned to telemonitoring received the nurse telephone support and had their weight, BP and ECG monitored twice daily. Usual care consisted of a management plan forwarded to the patient's primary care physician, who was asked to implement it. If the practice involved nurse titration of drugs this was allowed. Patients were assessed at a research clinic every four months; contact with the clinic was discouraged between clinic visits.
Outcomes	Mortality, rehospitalisation, compliance with intervention. 240 day and 450 day follow-up.
Notes	Three armed study with both telephone and telemonitoring. Included in previous systematic review and meta-analysis <a href="#">Clark 2007a</a> . Results included in meta-analysis are from 240 day follow-up.

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Random permuted blocks - correspondence from author.

**Cleland 2005(Struct Tele)** (Continued)

Allocation concealment?	Yes	After consent and collection of baseline data an independent statistical centre was contacted - correspondence from author.
Blinding? Intervention	Unclear	Not stated.
Incomplete outcome data addressed? All outcomes	Yes	"...Four were lost to follow-up and 12 declined to comply with regular telemonitoring" p1659. " "Analyses were conducted by intention-to-treat" p1659.
Free of selective reporting?	Yes	Selective outcome reporting not evident.
Was the study powered to detect differences in outcomes.?	Yes	Power calculation performed. Study powered for the primary outcome days lost because of death or hospitalisation in acute medical/surgical beds for any reason during 450 days, after an interim analysis the duration of follow-up was reduced to 240 days.
Were the study groups comparable at baseline?	Unclear	The study groups appear to be similar at baseline.
Was the study reported according to CONSORT guidelines?	Yes	Study reported according the CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Unclear	Unable to assess.

**de Lusignan 2001**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	20 patients with heart failure confirmed by cardiologist, identified from the database of an academic general practice. Mean age 75 years. Number or proportion of males and females not specified. UK.
Interventions	Telemonitoring. Telemonitoring of vital signs (pulse, BP, weight) and clinical status daily assessed daily by nurses along with video consults with a nurse weekly for three months, fortnightly for three months, then monthly. Usual care consisted of standard general practice treatment; in addition they had their pulse, BP and weight measured quarterly. They were evaluated in the same manner as

**de Lusignan 2001** (Continued)

	the intervention group.	
Outcomes	Mortality, compliance with intervention and medication, patient satisfaction, quality of life. 12 month follow-up.	
Notes	Included in previous systematic review and meta-analysis <a href="#">Clark 2007a</a> .	
<i><b>Risk of bias</b></i>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Yes	“The first 20 patients identified by random table allocation 10 to the telemedicine and 10 to the control group...” p724.
Allocation concealment?	Unclear	Not detailed.
Blinding? Intervention	Unclear	Not detailed.
Incomplete outcome data addressed? All outcomes	Unclear	Not detailed.
Free of selective reporting?	Yes	No evidence of selective outcome reporting.
Was the study powered to detect differences in outcomes.?	Unclear	Sample size calculation not detailed.
Were the study groups comparable at baseline?	Unclear	Not detailed.
Was the study reported according to CONSORT guidelines?	No	Study not reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Unclear	Not detailed.

**DeBusk 2004**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	462 patients hospitalised with a provisional diagnosis of CHF from Kaiser Permanente. Mean age 72 years. 51% of participants were male. USA.

**DeBusk 2004** (Continued)

Interventions	Structured telephone support. Standardised telephonic physician directed nurse-managed case management, involving CHF lifestyle education and medication management. Patients contacted weekly for 6 weeks, biweekly for 8 weeks and then monthly and bimonthly. Usual care not clearly defined, but was provided by the participating Kaiser Permanente medical centres, appeared to involve a high frequency of all of kinds of follow-up clinic visits (13 in 12 months following hospitalisation).	
Outcomes	Mortality, rehospitalisation, emergency and outpatient department visits, prescription of recommended pharmacotherapy. 12 months follow-up.	
Notes	Included in previous systematic review and meta-analysis <a href="#">Clark 2007a</a> .	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	"Equal numbers of patients were allocated to the 2 groups in each medical center by using the Efron procedure". p607.
Allocation concealment?	Yes	"Research staff who were not associated with delivering the intervention randomly assigned patients to treatment conditions by using sealed assignments." p607
Blinding? Intervention	Yes	"Research staff who were not associated with, and were blinded to, the intervention conditions measured health outcomes at 12 months" p608. "Two cardiologists who were not associated with implementing the intervention reviewed medical records on deaths, rehospitalisation, and emergency department visits to determine whether these events were primarily due to heart failure or due to other causes". p608.
Incomplete outcome data addressed? All outcomes	Yes	"During the first year of follow-up, 23 patients (3%) dropped out of the trial (8 in the treatment group and 15 in the usual care group)" p608. The analysis was by intention-to-treat.
Free of selective reporting?	Yes	No evidence of selective reporting.

**DeBusk 2004** (Continued)

Was the study powered to detect differences in outcomes.?	Yes	Power calculation performed. Study powered for risk for rehospitalization for heart failure.
Were the study groups comparable at baseline?	Yes	No statistically significant differences in the two groups at baseline.
Was the study reported according to CONSORT guidelines?	Yes	Study reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Yes	Based on signs and symptoms of heart failure: shortness of breath (dyspnoea at rest, including orthopnoea or paroxysmal nocturnal dyspnoea) and at least 1 corroborating clinical sign (pulmonary congestion on examination, including rales, crackles, or wheezes) or radiologic abnormality (pulmonary congestion on chest radiograph) consistent with heart failure.

**DeWalt 2006**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	127 patients with confirmed HF, NYHA class II-IV symptoms within the last 3 months and currently taking furosemide from the University of North Carolina (UNC) General Internal Medicine Practice. Mean age 62.5 years. 47% of participants were male. USA.
Interventions	Structured telephone support. Intervention patients received self-care education, picture-based educational materials with verbal explanation, a digital scale and scheduled follow-up phone calls (days 3, 7, 14, 21, 28, 56) and monthly during months 3-6 for reinforcement of education and revision of individualised care plan. Control group patients received a general heart failure education pamphlet and usual care from their primary physician (not specified). Data collection occurred at 6 and 12 months via in-person interview and medical record review.
Outcomes	Mortality, all-cause re-hospitalisation, HF-related quality of life, HF self-efficacy, HF knowledge, reported weight monitoring (self-management behaviour). 12 month follow-up.
Notes	Meta-analysis performed using number of patients randomised (n = 127)
<b><i>Risk of bias</i></b>	

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	"..randomised patients by concealed allocation based on a random number generator" p2.
Allocation concealment?	Unclear	Unclear if randomisation performed before or after consent provided.
Blinding? Intervention	No	"Research assistant was not blinded to patients study group" p3.
Incomplete outcome data addressed? All outcomes	Yes	"Patients who did not return any phone calls and did not return for follow-up assessment did not have outcome data for analysis. Patients who withdrew from the study were censored at the time of withdrawal; any data collected prior to withdrawal were included in the analysis" p5. "Of those randomised to the control group, 1 never returned after the first visit, 1 withdrew during the study and 4 died during the study. Follow-up was completed for all of the remaining participants (98%)" p5.
Free of selective reporting?	Yes	No evidence of selective reporting.
Was the study powered to detect differences in outcomes.?	Unclear	Power calculation for sample size to detect differences in heart failure-related quality of life. Study not powered to detect differences in hospitalizations.
Were the study groups comparable at baseline?	No	At baseline, most characteristics were similar between the two groups.
Was the study reported according to CONSORT guidelines?	Yes	Study reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Yes	"Patients had to have a clinical diagnosis of heart failure confirmed by their primary provider through a direct interview, and one of the following: 1) chest x-ray findings consistent with heart failure, 2) ejection fraction <40% by any method, or 3) a history of peripheral edema. They also had to have New York Heart Association class III-V symptoms within the last 3 months" p2.

**Galbreath 2004**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	1069 patients with symptoms of CHF and documented systolic (mean EF 35%) or diastolic dysfunction (echo confirmed). Mean age 71 years. 71% of participants were male. USA.
Interventions	Structured telephone support. All intervention patients received bathroom scales and were designated a disease manager who administered the disease management program telephonically. Initial call frequency was weekly then transitioned to monthly for the duration of the study. Call frequency could be adjusted for acuity or need. After each call a call summary was faxed to the patients primary care provider. An additional randomisation was performed within the intervention arm, with some participants provided with in-home technology (BP monitor, pulse oximeter) - these measurements were reported by the patient to the disease manager, but the data were not forwarded to the primary care provider. These patients also wore activity monitors at regular intervals and had six-monthly measurement of thoracic bioimpedance cardiac output - these data were not forwarded to the primary care physician. The authors state: "because data derived from the technology were not used in clinical management, we combined results from the two treatment groups for the purposes of this analysis." Traditional care patients were managed as usual by their physicians.
Outcomes	All-cause mortality, six-min walk performance, functional therapeutic class improvement, total healthcare costs. Improvement in ejection fraction improvement and medication adherence were assessed in a subgroup. 18 month follow-up.
Notes	

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	"Participants were randomised in a 2:1 ratio between the treatment and control groups" p3519. Method of randomisation not detailed.
Allocation concealment?	Yes	Randomisation performed after informed consent obtained.
Blinding? Intervention	No	"Reviews were performed by study staff, consisting of physicians, nurses, and ancillary health providers" p3519.



**Galbreath 2004** (Continued)

Incomplete outcome data addressed? All outcomes	No	Some evidence of attrition of study participants but actual numbers not presented.
Free of selective reporting?	Yes	No evidence of selective reporting.
Was the study powered to detect differences in outcomes.?	Yes	Sample size calculation performed; study powered for primary and secondary outcomes.
Were the study groups comparable at baseline?	Unclear	Diastolic blood pressure for patients with systolic heart failure the only baseline variable that was statistically significant between the groups.
Was the study reported according to CONSORT guidelines?	No	Study not reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Yes	Based on echocardiographic findings.

**Gattis 1999 (PHARM)**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.	
Participants	181 patients with heart failure being evaluated in cardiology clinic. Mean age 67 years. 68% of participants were male. USA.	
Interventions	Structured telephone support. Clinical pharmacist-led medication review and patient education. Regularly scheduled telephone contact (at two, 12 and 24 weeks) to detect clinical deterioration early. The control group received usual care which did not include the pharmacist providing recommendations regarding drug therapy to the attending physician or providing education to the patient. Patient assessment and education were provided by the attending physician and/or physician assistant or nurse practitioner. The patient was contacted by the pharmacist via telephone to identify clinical events.	
Outcomes	Mortality, rehospitalisation, medication prescription. Six month follow-up.	
Notes	Included in previous systematic review and meta-analysis <a href="#">Clark 2007a</a> .	
<i>Risk of bias</i>		
Item	Authors' judgement	Description

**Gattis 1999 (PHARM)** (Continued)

Adequate sequence generation?	Yes	“...patients were randomised according to a computer-generated randomisation scheme..” p1940.
Allocation concealment?	No	Not detailed.
Blinding? Intervention	Yes	“Clinical events and current drug therapy were documented on follow-up data collection forms during telephone follow-up or return visits” p1941. “..clinical events were adjudicated by a blinded physician clinical events committee using standard adjudication forms” p1941.
Incomplete outcome data addressed? All outcomes	Unclear	Not detailed.
Free of selective reporting?	Yes	No evidence of selective reporting.
Was the study powered to detect differences in outcomes.?	Unclear	Power calculation not detailed.
Were the study groups comparable at baseline?	No	Baseline characteristics were similar between the groups, with the median age of patients in the intervention group slightly higher.
Was the study reported according to CONSORT guidelines?	No	Study not reported according to CONSORT guidelines (losses to follow-up not detailed).
Was the diagnosis of heart failure defined and appropriate?	Unclear	Not detailed.

**GESICA 2005 (DIAL)**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	1518 outpatients with stable CHF. Mean age 65 years. 71% of participants were male. Argentina.
Interventions	Structured telephone support. Nurses trained in the management of patients with CHF performed structured telephone follow-up involving based on adherence to diet and treatment, monitoring of symptoms, control of fluid retention and daily physical activity. Patients were contacted four times

**GESICA 2005 (DIAL)** (Continued)

	in the first fortnight and then as needed. Patients in the control group were followed by their attending cardiologists and received care similar to the intervention group	
Outcomes	Mortality, rehospitalisation, quality of life. Mean 16 month follow-up.	
Notes	Included in previous systematic review and meta-analysis <a href="#">Clark 2007a</a> .	
<i><b>Risk of bias</b></i>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Yes	"We then used concealed randomisation lists to do permuted block randomisation stratified by attending cardiologist " p2.
Allocation concealment?	Yes	After provision of consent, patient's cardiologist contacted study centre (BMJ comment).
Blinding? Intervention	Yes	"The clinical events committee, which was blinded to the patients' treatment group assignment, adjudicated all outcomes" p2.
Incomplete outcome data addressed? All outcomes	Yes	"Follow-up was completed in 1511 (99.5%) randomised patients" p2. "We based all analyses on the intention to treat principle" p2.
Free of selective reporting?	Yes	No evidence of selective reporting.
Was the study powered to detect differences in outcomes.?	Unclear	Power calculation performed. Study was powered for the primary endpoint - all cause mortality or admission to hospital for worsening heart failure.
Were the study groups comparable at baseline?	Yes	The baseline variables were similar between the two groups.
Was the study reported according to CONSORT guidelines?	Yes	Study reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Unclear	Not detailed.

**Giordano 2009**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.	
Participants	460 confirmed CHF patients with LVEF < 40% and at least one hospitalisation for acute HF in the prior year. Mean age 57 years. 85% of participants were male. Italy.	
Interventions	Telemonitoring. Home-Based Telemanagement (HBT) patients received a one-lead trace portable device that transferred results via telephone where a nurse was available for interactive teleconsultation. Scheduled standardised telemonitoring appointments were performed every week to 15 days depending on HF severity discussing symptomology, medications, self-care and, if required, the transmission of the ECG trace. Usual care consisted of patients being referred to their primary care physician (PCP) and cardiologist for clinical management. These patients attended a two-weeks post-discharge PCP appointment and a structured follow-up outpatient cardiologist appointment at 12 months.	
Outcomes	Unplanned cardiovascular hospital readmissions, hospitalisation for HF, haemodynamic instability episode occurrence, cardiovascular mortality. 12 month follow-up.	
Notes		
<i><b>Risk of bias</b></i>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	"Random permuted blocks for each center were used to allocate patients to treatment groups" p193.
Allocation concealment?	Unclear	Not detailed.
Blinding? Intervention	Unclear	Not detailed.
Incomplete outcome data addressed? All outcomes	Yes	"...one patient in UC group and four in HBT group were lost to follow-up" p196. "Analyses were conducted according to the intention-to treat approach" p195.
Free of selective reporting?	Yes	Selective outcome reporting not evident.
Was the study powered to detect differences in outcomes.?	Yes	Sample size calculation performed for primary outcome - one-year readmission rate. Study was adequately powered.

**Giordano 2009** (Continued)

Were the study groups comparable at baseline?	No	“The randomisation groups differed significantly only with regard to use of digitalis and beta-blockers, which was respectively higher and lower in the UC group” p196.
Was the study reported according to CONSORT guidelines?	Yes	Study reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Yes	“...left ventricular ejection fraction (LVEF) < 40% and at least one hospitalisation for acute HF in the previous year” p193.

**Goldberg 2003 (WHARF)**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	280 patients hospitalised with NYHA Class III-IV, with a LVEF < 35%. Mean age 59 years. 68% of participants were male. USA.
Interventions	Telemonitoring. Daily transmission of weight and symptoms using a customised monitor, data was reviewed daily by nurses and concerns reported to the physician. Patients in the control group were instructed to contact their physician for weight increases of more than a pre-specified amount or if their symptoms of heart failure worsened. They had a weight log to bring to visits. Follow-up visits, other than study visits were at the discretion of the treating physician. Telephone contacts were permitted at the discretion of the treating physician or nurse.
Outcomes	Mortality, rehospitalisation, emergency department visits, quality of life, patient satisfaction, compliance with intervention. Mean six month follow-up.
Notes	Included in previous systematic review and meta-analysis <a href="#">Clark 2007a</a> .

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Method of randomisation not detailed.
Allocation concealment?	Yes	Randomised performed after informed consent obtained.
Blinding? Intervention	Yes	“To insure that all hospitalizations, emergency room visits, and deaths were iden-

**Goldberg 2003 (WHARF)** (Continued)

		tified, all patients were contacted by telephone on a monthly basis by a non medical surveyor (blinded to patient treatment group randomisation), located outside of the enrolment sites and Alere monitoring centre" p707.
Incomplete outcome data addressed? All outcomes	Yes	"During the study, 32 patients either refused follow-up data collection or were lost to follow-up. Seven patients received cardiac transplantation and were censored on the day of transplant. Excluding deaths, there was no difference between groups in the percentage of patients who failed to complete six months of follow-up" p707.
Free of selective reporting?	Unclear	Some nominated outcomes (satisfaction) were not reported.
Was the study powered to detect differences in outcomes.?	No	Sample size calculation not reported.
Were the study groups comparable at baseline?	Yes	Groups were comparable at baseline.
Was the study reported according to CONSORT guidelines?	No	Study not reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Yes	"...a left ventricular ejection fraction, measured within 6 months of enrolment, of $\leq 35\%$ " p706.

**Kielblock 2007**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	502 participants discharged after a hospitalisation with heart failure or with a confirmed diagnosis from ICD codes from hospital insurance data. Mean age 74 years. 51% of participants were male. Germany.
Interventions	Telemonitoring. The intervention group all received a set of electronic scales which were attached to the monitoring centre via modem and regular CHF information and education via phone. Daily weight was monitored and responded to by CHF specialist team members. 72 patients also had BP monitored by this method. Control group participants received CHF education from GP.

	<p>The first 50 patients in the intervention group were visited at home by the health coach at the start of the study in order to set-up the telemetric equipment and to assess their ability to use the devices.</p> <p>Patients were contacted whenever their body weight exceeded a threshold value, were phoned by a designated personal adviser and received regular informative material and advice by specialist medical personnel. Patients’ general practitioners sent them follow-up reports.</p> <p>Control group described as patients who had not received the described telemetric intervention.</p>	
Outcomes	Mortality, hospital stay duration, hospital and drug costs, total costs per patient. 12 month follow-up.	
Notes	Translated from German. Authors provided details in English and additional data.	
<i>Risk of bias</i>		
Item	Authors’ judgement	Description
Adequate sequence generation?	No	”Participants were randomised on the basis of date of birth to either the control group (date of birth 21st-31st of the month; n = 251) or assigned as candidates to the management programme (date of birth 1st-20th of the month; n = 746)“ from details of the study provided by the study authors.
Allocation concealment?	Unclear	Not detailed.
Blinding? Intervention	Unclear	Not detailed.
Incomplete outcome data addressed? All outcomes	Unclear	Not detailed.
Free of selective reporting?	Unclear	Unable to assess. Not detailed.
Was the study powered to detect differences in outcomes.?	Unclear	Not detailed.
Were the study groups comparable at base-line?	No	Slightly older (Intervention 71 years vs Control 76 years) and more females (Intervention 42.6% vs Control 55.3%)
Was the study reported according to CONSORT guidelines?	No	No CONSORT Study Flow chart presented

**Kielblock 2007** (Continued)

Was the diagnosis of heart failure defined and appropriate?	Unclear	Yes "patienten mit den relevant ICD-Diagnosen (150.1, 150.11-19 150.9) zur chronisch Herzinsuffizienz wurden Datenbestand der KKH p 418
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**Krum 2009 (CHAT)**

Methods	Cluster randomised controlled trial. Computer generated random sequence. GP practices were the unit of randomisation. GPs were not blinded to allocation group before recruiting and consenting patients.
Participants	405 patients with a recent hospital discharge due to a primary diagnosis of heart failure with an EF of 40% and in NYHA class II-IV were randomised to either usual care or usual care plus telephone monitoring performed at least once per month. Mean age - not reported. % Men - not reported. Australia.
Interventions	Structured telephone support Nurse-led telephone monitoring using the Telewatch System (Baltimore). Patient responded to computer generated CHF self-monitoring questions by pressing the numbers on the touch phone key pad. Nurse survey in-coming calls daily and responded to pre-set variations to patients parameters. Usual care discharge follow-up with GP and copy of guidelines.
Outcomes	The primary endpoint was the change in Packer clinical composite score. HRQOL, BNP. Patients were assessed by a blinded reviewer at baseline and then after 6 and 12 months. 12 months follow-up.
Notes	Final results not published.

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Unable to assess. Abstract only.
Allocation concealment?	Unclear	Unable to assess. Abstract only.
Blinding? Intervention	Unclear	Unable to assess. Abstract only.
Incomplete outcome data addressed? All outcomes	Unclear	Unable to assess. Abstract only.
Free of selective reporting?	Unclear	Unable to assess. Abstract only.



**Krum 2009 (CHAT)** (Continued)

Was the study powered to detect differences in outcomes.?	Unclear	Unable to assess. Abstract only.
Were the study groups comparable at baseline?	Unclear	Unable to assess. Abstract only.
Was the study reported according to CONSORT guidelines?	Unclear	Unable to assess. Abstract only.
Was the diagnosis of heart failure defined and appropriate?	Yes	Unable to assess. Abstract only.

**Laramée 2003**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	287 patients admitted to hospital with primary or secondary diagnosis of CHF LVSD < 40% or radiological evidence of pulmonary oedema. Mean age 71 years. 54% of participants were male. USA.
Interventions	Structured telephone support. Telephonic case management performed by one CHF nurse case manager, involving four major components: early discharge planning, patient and family CHF education, promotion of optimal CHF medications and 12 weeks of telephone follow-up. Usual care consisted of standard care typical of a tertiary care hospital. It included inpatient social service evaluation (25%), dietary consultation (15%), physiotherapy/occupational therapy (17%) and medication and CHF education by nurses. Post-discharge was conducted by the patient's own local physician, 44% received some home care services.
Outcomes	Mortality, rehospitalisation, inpatient and outpatient costs, medication prescription and adherence. Three month follow-up.
Notes	Included in previous systematic review and meta-analysis <a href="#">Clark 2007a</a> .

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	"After simple randomisation of the first 42 patients resulted in large amounts of patients being assigned to one group or the other, patients were randomised in blocks of 8 to ensure an even group allocation across time" p810.

**Laramée 2003** (Continued)

Allocation concealment?	Unclear	Not detailed.
Blinding? Intervention	Unclear	Not detailed.
Incomplete outcome data addressed? All outcomes	Unclear	“Patients who withdrew, died or were otherwise lost before 90 days of follow-up were censored on the day of early attrition”.
Free of selective reporting?	No	One secondary outcome not reported - number of days until first readmission.
Was the study powered to detect differences in outcomes.?	No	Power calculation not detailed.
Were the study groups comparable at baseline?	No	Some variables differed between the study groups.
Was the study reported according to CONSORT guidelines?	Yes	Study reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Yes	Clinical signs and symptoms and either evidence of moderate-to-severe left ventricular dysfunction or radiographic evidence of pulmonary congestion and symptomatic improvement following diuresis.

**Mortara 2009 (Struct Tele)**

Methods	Randomised controlled trial; multiple intervention arms and control (usual care) arm.
Participants	461 heart failure patients with NYHA class II-IV and LVEF $\leq$ 40%. Mean age 60 years. 85% of participants were male. UK, Poland, Italy
Interventions	Structured telephone support; telemonitoring. Patients allocated to home telemonitoring were further randomised into 3 groups. The first group (strategy 1) received monthly supportive telephone contacts from a study nurse to check on their clinical status. The second group (strategy 2) received the same telephone support, but also transmitted their vital signs and other data including details of changes in weight, BP and symptoms weekly by telephone. These patients also performed monthly 24h cardiorespiratory recordings which were not made available to the clinical team. The third group (strategy 3) carried out the same measurements as strategy 2 patients, but the monthly 24h cardiorespiratory recordings were made available for clinical management. Usual care was only described as usual outpatient care.

**Mortara 2009 (Struct Tele)** (Continued)

Outcomes	Mortality and hospitalisation due to HF, all-cause mortality, all-cause hospitalisation, bed-days occupancy (due to cardiovascular cause). Mean 11.6 month follow-up.	
Notes	Strategies 2 and 3 combined and classed as telemonitoring. Authors provided additional unpublished data.	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	"The randomisation list was generated by the coordinating centre with separate blocks held in each country" p313.
Allocation concealment?	Yes	"The individual patient allocation was to be revealed only after the patient identifiers (name, surname and the date of birth) had been received at the national randomisation centre" p313.
Blinding? Intervention	Yes	"All endpoints were adjudicated by an independent, blinded, Endpoint Committee" p314.
Incomplete outcome data addressed? All outcomes	Unclear	"...18 patients dropped out of the study..." p315. No statement asserting that analyses were performed as intention-to-treat.
Free of selective reporting?	Unclear	All-cause mortality listed as a secondary outcome but not reported in publication according to study group. Author contacted for this information. Bed days occupancy for all cardiovascular causes listed as secondary outcome. Not reported, unless "all-causes" is actually all "cardiovascular causes".
Was the study powered to detect differences in outcomes.?	Yes	Power calculation performed, study powered for both primary endpoints - bed-days occupancy for HF in acute medical/surgical beds and composite endpoint of cardiac death and hospitalisation due to HF.
Were the study groups comparable at baseline?	No	Some variables differed between the study groups.

**Mortara 2009 (Struct Tele)** (Continued)

Was the study reported according to CONSORT guidelines?	Yes	Reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Yes	Based on NYHA class and echocardiographic findings.

**Mortara 2009 (Telemon)**

Methods	Randomised controlled trial; multiple intervention arms and control (usual care) arm.
Participants	461 heart failure patients with NYHA class II-IV and LVEF $\leq$ 40%. Mean age 60 years. 85% of participants were male. UK, Poland, Italy
Interventions	Structured telephone support; telemonitoring. Patients allocated to home telemonitoring were further randomised into 3 groups. The first group (strategy 1) received monthly supportive telephone contacts from a study nurse to check on their clinical status. The second group (strategy 2) received the same telephone support, but also transmitted their vital signs and other data including details of changes in weight, BP and symptoms weekly by telephone. These patients also performed monthly 24h cardiorespiratory recordings which were not made available to the clinical team. The third group (strategy 3) carried out the same measurements as strategy 2 patients, but the monthly 24h cardiorespiratory recordings were made available for clinical management. Usual care was only described as usual outpatient care.
Outcomes	Mortality and hospitalisation due to HF, all-cause mortality, all-cause hospitalisation, bed-days occupancy (due to cardiovascular cause). Mean 11.6 month follow-up.
Notes	Strategies 2 and 3 combined and classed as telemonitoring. Authors provided additional unpublished data.

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	"The randomisation list was generated by the coordinating centre with separate blocks held in each country" p313.
Allocation concealment?	Yes	"The individual patient allocation was to be revealed only after the patient identifiers (name, surname and the date of birth) had been received at the national randomisa-

**Mortara 2009 (Telemon)** (Continued)

		tion centre" p313.
Blinding? Intervention	Yes	"All endpoints were adjudicated by an independent, blinded, Endpoint Committee" p314.
Incomplete outcome data addressed? All outcomes	Unclear	"...18 patients dropped out of the study..." p315. No statement asserting that analyses were performed as intention-to-treat.
Free of selective reporting?	Unclear	All-cause mortality listed as a secondary outcome but not reported in publication according to study group. Author contacted for this information. Bed days occupancy for all cardiovascular causes listed as secondary outcome. Not reported, unless "all-causes" is actually all "cardiovascular causes".
Was the study powered to detect differences in outcomes.?	Yes	Power calculation performed, study powered for both primary endpoints - bed-days occupancy for HF in acute medical/surgical beds and composite endpoint of cardiac death and hospitalization due to HF.
Were the study groups comparable at baseline?	No	Some variables differed between the study groups.
Was the study reported according to CONSORT guidelines?	Yes	Reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Yes	Based on NYHA class and echocardiographic findings.

**Parati 2009 (ICAROS)**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	120 Patients (LVEF $\leq$ 40%) NYHA II-III. Mean age 69 years. 75% of participants were male. Italy
Interventions	Telemonitoring. Continuous monitoring of patient parameters (Daily-weight, urine output, fluid intake, blood pressure, heart rate etc.) Hand held transmission device (Smart Phone / PDA) via

**Parati 2009 (ICAROS)** (Continued)

	broadband and wireless. Alarm sounds at medication times. Regular questionnaires (Anxiety, Depression, Anger) Usual Care; Conventional management, returned to medico practitioner and placed in a system of visits to clinics and receiving materials at the clinic.
Outcomes	Mortality, Hospitalisation and Emergency room visits Cost and improvement in LVEF % 12 months follow-up.
Notes	Data from Abstract / Conference Proceedings and contact with authors.

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	"Open randomised parallel-groups"
Allocation concealment?	Unclear	Not detailed.
Blinding? Intervention	Unclear	Unable to assess.
Incomplete outcome data addressed? All outcomes	Unclear	Unable to assess.
Free of selective reporting?	Unclear	Unable to assess.
Was the study powered to detect differences in outcomes.?	Unclear	Unable to assess.
Were the study groups comparable at base-line?	Yes	According to preliminary data
Was the study reported according to CONSORT guidelines?	Unclear	Unable to assess.
Was the diagnosis of heart failure defined and appropriate?	Yes	Echocardiogram LVEF $\leq$ 40%

**Rainville 1999**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	38 patients aged $\geq$ 50 years discharged from hospital with heart failure. Mean age 70 years. 50% of participants were male. USA.

Interventions	Structured telephone support. Usual care plus a pharmacist-led medication review, patient education, medication management prior to discharge and at Day 3, Day 7, 30 days, 90 days and 12 months via telephone. Usual care consisted of routine care and preparation for discharge including written prescriptions, physician discharge instructions and a nurse review of diet, treatment plans and medications. The nurses provided the patient with computer generated drug information sheets. Patients were contacted by a pharmacist at 30 days, 90 days and 12 months to determine readmissions.	
Outcomes	Mortality, rehospitalisation, functional assessment score. 12 month follow-up.	
Notes	Included in previous systematic review and meta-analysis <a href="#">Clark 2007a</a> . Meta-analysis performed using number of patients randomised (n = 38).	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Method of randomisation not detailed.
Allocation concealment?	Yes	“Qualified patients were randomly assigned to a control group or an intervention group, with the patients, nurses, and physicians blinded to the randomisation results” p1339
Blinding? Intervention	Unclear	Not detailed.
Incomplete outcome data addressed? All outcomes	Yes	38 patients randomised; two patients in intervention group and one in control group were excluded during the initial hospitalisation because test results showed normal left ventricular function; long-term dialysis was initiated or because the patient was moving out of state after DC. One control patient was lost to follow-up within the first 30 days after discharge and was excluded from the analysis. Final sample included 34 patients equally divided between the two groups.
Free of selective reporting?	Yes	Selective outcome reporting not evident.
Was the study powered to detect differences in outcomes.?	No	Power calculation not detailed.

**Rainville 1999** (Continued)

Were the study groups comparable at base-line?	No	Some variables differed between the groups.
Was the study reported according to CONSORT guidelines?	No	Study not reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Unclear	Not detailed.

**Ramachandran 2007**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.	
Participants	50 patients attending heart failure clinic with symptoms of CHF and LVEF < 40%. Mean age 44.5 years. 78% of participants were male. India.	
Interventions	Structured telephone support. Intervention group patients were managed in the heart failure clinic and received disease, medication and self-management education and telephonic disease management which consisted of reinforcement of information and drug dose modification. The control group was managed as per usual care in the heart failure clinic.	
Outcomes	Functional status, quality of life, hospitalisation rates, quality of care, drug usage, cost-effectiveness. Six month follow-up.	
Notes	Mortality not reported. No response from authors for further detail.	

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	"An investigator, unaware of the patients' demographic and clinical profile, using a computer-generated list, initiated randomisation" p68.
Allocation concealment?	Unclear	Not detailed.
Blinding? Intervention	Unclear	Not detailed.
Incomplete outcome data addressed? All outcomes	Unclear	Not detailed.



**Ramachandran 2007** (Continued)

Free of selective reporting?	Unclear	No evidence of selective outcome reporting.
Was the study powered to detect differences in outcomes.?	No	Power calculation not performed.
Were the study groups comparable at baseline?	Unclear	Baseline characteristics were similar between the groups.
Was the study reported according to CONSORT guidelines?	Yes	Reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Yes	CHF symptoms and LVEF > 40%.

**Riegel 2002**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	358 patients discharged from hospital with heart failure. Mean age 74 years. 49% of participants were male. USA.
Interventions	Structured telephone support. Telephonic case management by a registered nurse using decision support software, involving patient education and counselling and liaison with primary care physician. Patients were telephoned within 5 days of discharge and thereafter at a frequency guided by the software and case manager (mean 17 calls). Usual care was not standardised, and no formal telephonic case-management was in existence at these institutions. These patients presumably received some education regarding HF management prior to hospital discharge.
Outcomes	Mortality, rehospitalisation, physician and emergency department visits, inpatient costs, patient satisfaction. Six month follow-up.
Notes	Included in previous systematic review and meta-analysis <a href="#">Clark 2007a</a> .

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Method of randomisation not stated. (Physicians were the unit of randomisation)

**Riegel 2002** (Continued)

Allocation concealment?	Yes	"Physicians were not informed of the group to which they were assigned" p706.
Blinding? Intervention	Unclear	Not detailed.
Incomplete outcome data addressed? All outcomes	Unclear	Not detailed.
Free of selective reporting?	Yes	Selective outcome reporting not evident.
Was the study powered to detect differences in outcomes.?	No	Sample size calculation not performed.
Were the study groups comparable at baseline?	No	Some differences in baseline characteristics.
Was the study reported according to CONSORT guidelines?	Unclear	Study reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Unclear	Not detailed.

**Riegel 2006**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	135 hospitalised Hispanic patients with CHF. Mean age 72 years. 46% of participants were male. USA.
Interventions	Structured telephone support. Education, monitoring and guidance by bilingual-bicultural Mexican-American registered nurses via telephone case management standardised using decision support software. Patients were contacted on average within 5 days of discharge and thereafter at a frequency guided by the software and nurse case manager over a 6 month period (mean 13.5 calls to patients and 8.4 additional calls to families). Printed educational material was provided monthly and upon request in the relevant language. Usual care was not standardised and no formal disease management program existed at these institutions. The standard of usual care was that patients were educated regarding HF management before discharge, assuming that the nurse spoke the patient's language or someone bilingual was available to translate. In reality, only a small portion of staff were bilingual .
Outcomes	Mortality, re hospitalisation, cost of care, self-reported health-related quality of life and depression. Six month follow-up.

**Riegel 2006** (Continued)

Notes	Included in previous systematic review and meta-analysis <a href="#">Clark 2007a</a> . Meta-analysis performed using number of patients randomised (n = 135).	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	“After the baseline data were collected, the nurse case manager opened a sealed envelope with the random assignment. These envelopes had been prepared by the project director and attached to the numbered data collection forms, to be opened in sequence” p214. Method of randomisation not detailed.
Allocation concealment?	Yes	See above.
Blinding? Intervention	Yes	“We were unable to strictly blind staff about which patients were in the intervention group, but a research assistant uninvolved with the clinical care collected all follow-up data” p214.
Incomplete outcome data addressed? All outcomes	Yes	For intervention arm, only 69 participants were included in analysis as one outlier excluded from analysis. “One outlier was removed from the data set before analyses began because he spent three months in the hospital while his family debated taking him off life support” p214.
Free of selective reporting?	Yes	Selective outcome reporting not evident.
Was the study powered to detect differences in outcomes.?	Yes	Sample size calculation performed. The study was powered for the primary outcome - HF readmission.
Were the study groups comparable at baseline?	Unclear	Comparison not made.
Was the study reported according to CONSORT guidelines?	Yes	Study reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Unclear	Not detailed.

**Sisk 2006**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	406 non-Hispanic and Hispanic patients with documented systolic dysfunction. Mean age 59 years. 54% of participants were male. USA.
Interventions	Structured telephone support. An in-person appointment was arranged for each intervention patient, which included symptom and disease education and referral to additional patient services (if required). Follow-up telephone calls consisted of patient assessment, recording of admission information reinforcement of self-monitoring and administration of a food-frequency questionnaire (at 2, 4, 8, 12 and 24 weeks and a report sent to patients). Intervention nurses coordinated flow of information between patient and clinician and arranged medication adjustment and required examinations. Usual care patients received guidelines for managing systolic dysfunction, but no other care information was specified.
Outcomes	Mortality, hospitalisations, functional status (including quality of life). 12 month follow-up.
Notes	

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	"The project's statistician used a computer-generated, random-number sequence without blocking or stratification to centrally determine randomizations assignments and concealed treatment group assignments in sealed, opaque envelopes" p275.
Allocation concealment?	Yes	See above.
Blinding? Intervention	Unclear	To measure hospitalizations, we used billing data from the 4 participating hospitals. At quarterly telephone surveys, interviewers who were blinded to treatment assignment asked patients about hospitalizations at nonparticipating hospitals; however, we present the analysis of billing data because they measure hospitalizations independent of possibly socially acceptable responses or survey non-response of the patients. p276.

**Sisk 2006** (Continued)

Incomplete outcome data addressed? All outcomes	Yes	No losses to follow-up in the first 12 months of follow-up.
Free of selective reporting?	Yes	Selective outcome reporting not evident.
Was the study powered to detect differences in outcomes.?	Yes	Power calculation performed for sample size - adequately powered for the primary outcome of probability of hospitalisation.
Were the study groups comparable at baseline?	Unclear	Groups were similar.
Was the study reported according to CONSORT guidelines?	Unclear	Reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Yes	Systolic dysfunction on echo, etc.

**Soran 2008**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	315 patients with HF diagnosis secondary to systolic dysfunction (LVEF $\leq$ 40%). Mean age 76 years. 35% of participants were male. USA.
Interventions	Telemonitoring. Patients randomised to the Heart Failure Monitoring System (HFMS) cohort received a disease management program using telecommunication equipment including an electronic scale and individualised symptom response system linked to a database staffed by nurses. Patients weighed themselves and answered questions related to their heart failure. Patients were contacted if any changes were observed in symptoms or weight. Patients allocated to standard heart failure care (SC) received enhanced patient education, education to clinicians and follow-up. They were provided with a digital home scale to weigh themselves daily and educational materials related to worsening of HF and were asked to record heart failure symptoms. All patients were telephoned 30 days and 3 months post-randomisation for blinded clinical data collection (vital signs, hospital visits, quality of life questionnaires).
Outcomes	Treatment failure (cardiovascular mortality or rehospitalisation for HF within 6 months), length of hospital stay, 6-month all-cause hospitalisation, 6-month heart failure hospitalisation, number of emergency room visits, Medicare expenditure, total patient costs, quality of life. Six month follow-up.
Notes	Number of patients hospitalised calculated from reported % with any hospital admission.

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	"...patients were randomised in a 1:1 ratio.." p712. Method of randomisation not detailed.
Allocation concealment?	Unclear	Not detailed.
Blinding? Intervention	Yes	"Patients were also contacted by telephone...by non-medical personnel masked to treatment assignment to collect clinical data..." p713. "The trial used an independent adjudication event committee to classify deaths, hospitalizations, and adverse events and was monitored by an independent data safety monitoring board..." p712. "The HFHC Trial was a multi centre, randomised controlled clinical trial with blinded endpoint evaluation..." p712.
Incomplete outcome data addressed? All outcomes	Unclear	"Eight patients refused to be re contacted after randomisation and were considered lost to follow-up" p713. "The intention-to-treat principle was used to compare HFMS to SC" p713.
Free of selective reporting?	Yes	No evidence of selective outcome reporting.
Was the study powered to detect differences in outcomes.?	Yes	Sample size calculation for the primary endpoints was performed. Study was powered for these outcomes - (cardiovascular death or rehospitalization; among patients rehospitalisation for heart failure, length of hospital stay was also considered a primary end point).
Were the study groups comparable at baseline?	Yes	No statistically significant differences in the variables reported.
Was the study reported according to CONSORT guidelines?	No	Not reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Unclear	Evidence of systolic dysfunction via a left ventricular ejection fraction of <40% doc-

**Soran 2008** (Continued)

		umented by echocardiography, radionuclide ventriculography, or a contrast ventricular angiogram; current symptoms of heart failure including dyspnoea on exertion, orthopnoea, paroxysmal nocturnal dyspnoea, fatigue, abdominal or lower extremity edema or swelling.
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**Tsuyuki 2004**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	276 patients discharged from hospital with heart failure. Mean age 72 years. 58% of participants were male. Canada.
Interventions	Structured telephone support. Early discharge planning with provision of adherence aids, patient education, regularly scheduled telephone contact with local research coordinator at two and four weeks then monthly thereafter for six months. Recommendations to see primary care physician if not on target dose ACE inhibitor or deterioration. Patients assigned to usual care received a general heart disease pamphlet before discharge, but no formal counselling beyond what was routine at the hospital. Patients were contacted monthly for six months to ascertain clinical events.
Outcomes	Mortality, rehospitalisation, medication adherence, physician and emergency department visits, cost-analysis. 6 month follow-up.
Notes	Included in previous systematic review and meta-analysis <a href="#">Clark 2007a</a> .

***Risk of bias***

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	"Randomization was conducted by a computer-generated sequence using block randomisation (block size of 4), stratified by study site (hospital)" p475.
Allocation concealment?	Unclear	"...patients were randomised via a telephone call to the project office" p475.
Blinding? Intervention	Unclear	Not detailed.

**Tsuyuki 2004** (Continued)

Incomplete outcome data addressed? All outcomes	Unclear	Intervention: early withdrawal n = 5; lost to follow-up n = 3. Control: early withdrawal n = 2; lost to follow-up n = 4.
Free of selective reporting?	Yes	Selective outcome reporting not evident.
Was the study powered to detect differences in outcomes.?	Yes	Sample size calculation performed. Study was powered for the primary outcome - medication adherence.
Were the study groups comparable at baseline?	No	Some variables differed between the groups.
Was the study reported according to CONSORT guidelines?	Yes	Study reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Unclear	Not detailed.

**Wakefield 2008**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	148 patients hospitalised for HF exacerbation. Mean age 69 years. 99% of participants were male. USA.
Interventions	Structured telephone support. Patients allocated to the intervention group were allocated to 1 of 2 interventions: telephone follow-up or videophone follow-up. Intervention patients were contacted by a nurse 3 times in the first week then weekly for 11 weeks. Symptoms and the patients discharge plan was reviewed and reinforced as well as referrals made if required. Additionally, the intervention nurses employed behaviour skill training strategies to maximise self-management, self-monitoring and self-efficacy. Usual care was not specified except to state that "subjects contacted their primary care nurse case manager by telephone if needed".
Outcomes	Mortality, readmissions, hospital days, time to first readmission, urgent care clinic visits, quality of life, intervention dose and technical issues. 12 month follow-up.
Notes	Telephone and videophone intervention arms were combined and classed as structured telephone support.

***Risk of bias***



**Wakefield 2008** (Continued)

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	"The project coordinator prepared sealed envelopes containing group assignments in blocks of 24" p754.
Allocation concealment?	Yes	"Following informed consent and baseline data collection, study nurses opened the envelope to assign subjects to one of three treatment conditions: usual care, telephone follow-up, or videophone follow-up" p754.
Blinding? Intervention	Unclear	Not detailed.
Incomplete outcome data addressed? All outcomes	Yes	"At 3 months, 85% (n = 126) completed follow-up; at 6 months, 74% (n = 109) completed follow-up" p757. "All data analyses were conducted using an intent-to-treat approach" p755.
Free of selective reporting?	Yes	Selective outcome reporting not evident.
Was the study powered to detect differences in outcomes.?	No	Power calculation performed to determine sample size for readmission at 3 months. Study not powered for this outcome.
Were the study groups comparable at baseline?	Yes	No statistically significant differences between groups at baseline.
Was the study reported according to CONSORT guidelines?	Yes	Study reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Unclear	Not detailed.

**Woodend 2008**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	121 patients with symptomatic heart failure (NYHA Class II or greater). Mean age 68 years. 74% of participants were male. Canada.
Interventions	Telemonitoring. Daily transmission of weight and periodic transmission of ECG and BP. Weekly video conferences by tele-home care nurse. Video conferences more frequent in first few weeks

**Woodend 2008** (Continued)

	and tapered over the 3 months. Usual care was not described.	
Outcomes	Mortality, rehospitalisation, quality of life, emergency department visits, patient satisfaction. 12 month follow-up.	
Notes	Mortality data included in previous systematic review and meta-analysis <a href="#">Clark 2007a</a> .	
<i><b>Risk of bias</b></i>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Adequate sequence generation?	Unclear	Method of randomisation not detailed.
Allocation concealment?	Unclear	Not detailed.
Blinding? Intervention	Unclear	Not detailed.
Incomplete outcome data addressed? All outcomes	Unclear	Not detailed.
Free of selective reporting?	No	Some nominated outcomes not reported (morbidity).
Was the study powered to detect differences in outcomes.?	Unclear	Sample size calculation not reported.
Were the study groups comparable at baseline?	Yes	The groups differed at baseline.
Was the study reported according to CONSORT guidelines?	No	Study not reported according to CONSORT guidelines.
Was the diagnosis of heart failure defined and appropriate?	Yes	Symptomatic HF (New York Heart Association [NYHA] Class II or greater.

**Zugck 2008 (HiTel)**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	88 patients recruited from hospital, mean LVEF was $24 \pm 7\%$ . Inclusion criteria NYHA II-IV on optimum therapy and telephone at home. Mean age 58.1 years. 82% of participants were male. Germany.

**Zugck 2008 (HiTel)** (Continued)

Interventions	Telemonitoring. Intervention group transmitted to monitoring centre via modem vital signs, BP SpO2and received lifestyle and medication education. NYHA III and IV transmitted weekly and NYHA II monthly. Medical advice was available 24/7. Usual care not described.	
Outcomes	All cause hospitalisation. Three month follow-up.	
Notes	Translated from German and English abstracts. Authors provided further details.	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	"After screening all patients were randomised with a standard procedure" - correspondence from author.
Allocation concealment?	No	Unable to assess.
Blinding? Intervention	Unclear	Unable to assess.
Incomplete outcome data addressed? All outcomes	Unclear	Unable to assess.
Free of selective reporting?	Unclear	Unable to assess.
Was the study powered to detect differences in outcomes.?	Unclear	Unable to assess.
Were the study groups comparable at baseline?	Unclear	Unable to assess.
Was the study reported according to CONSORT guidelines?	Unclear	Unable to assess.
Was the diagnosis of heart failure defined and appropriate?	Unclear	Unable to assess.

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

Study	Reason for exclusion
Akosah 2005	Contra to protocol: intervention included frequent clinic visits.
Albanese 2001	Contra to protocol: invasive impedance monitoring (SCOOP II Trial Evaluating CRT/ICD/Impedance Monitoring).
Albert 2007	Contra to protocol: intervention was an education video.
Aliti 2007	Discussion paper.
Anderson 2005	Contra to protocol: intervention was a heart failure clinic.
Artinian 2003	Contra to protocol: web-based intervention, not an RCT.
Artinian 2006	Contra to protocol: intervention specific for hypertension, not heart failure.
Arya 2008	Contra to protocol: invasive haemodynamic monitoring.
Baden 2007a	Contra to protocol: not an RCT.
Baden 2007b	Contra to protocol: not an RCT.
Baer 1999	Assessment of correlation between electronic patient measurements and manual nurse measurements.
Baldauf 2008	Contra to protocol: not an RCT.
Barber 1999	Contra to protocol: not an RCT, quasi experimental design.
Benatar 2003	Contra to protocol: comparison was between telemonitoring and home visits (not usual care).
Bennett 2006	Contra to protocol: intervention was a computer-based intervention.
Blue 2001	Contra to protocol: intervention included home visits.
Bocchi 2007 (REMADHE)	Contra to protocol: intervention involved intensive group education sessions and face-to-face individual/group communication.
Bolz 2005	Review paper.
Bondmass 1999	Contra to protocol: not an RCT.
Bondmass 2002	Contra to protocol: not an RCT.
Bondmass 2007	Contra to protocol: not an RCT.

(Continued)

Bourge 2008 (COMPASS-HF)	Contra to protocol: invasive implantable haemodynamic monitoring.
Bowles 2007	Review paper.
Bowles 2008	Systematic review.
Boyne 2008	Contra to protocol: not an RCT, pre- and post-test study design.
Brennan 2006	Contra to protocol: not an RCT.
Brownsell 2006a	Author contacted: primary and secondary outcomes for this review were not measured.
Brownsell 2006b	Author contacted: primary and secondary outcomes for this review were not measured.
Brownsell 2008	Author contacted: primary and secondary outcomes for this review were not measured.
Caldwell 2005	Contra to protocol: education session with one follow-up telephone call.
Calvin 2008	Contra to protocol: participants received 18 education sessions aimed to develop self-management skills. The intervention did not include telemonitoring or structured telephone support.
Capomolla 2002	Contra to protocol: intervention was a day hospital.
Cherry 2000	Review article.
Chetney 2003	Contra to protocol: not an RCT.
Chetney 2008	Contra to protocol: not an RCT.
Clappers 2006	Review of abstracts.
Clark 2008	Interviews with carers of patients with heart failure regarding their experiences.
Clarke 2005	Conference discussion paper.
Cline 1998	Contra to protocol: Intervention group received education on heart failure and self management, with follow up at an outpatient clinic.
Cole 2006	Contra to protocol: not an RCT.
Cordisco 1999	Contra to protocol: not an RCT.
Courtney 2009	Contra to protocol: intervention was an exercise programme.
Cross 1999	Contra to protocol: not an RCT.

(Continued)

Dalmiani 2001	Contra to protocol: not an RCT.
Dang 2006	Contra to protocol: not an RCT.
Dansky 2008a	Contra to protocol: intervention included home visits.
Dansky 2008b	Contra to protocol: not an RCT.
Dar 2009 (HOME-HF)	Contra to protocol: both study groups recieved a home visit from study nurse.
de Feo 2002	Contra to protocol: not an RCT.
Dedier 2008	Contra to protocol: intervention specific for hypertension, not heart failure.
Deepak 2008	Contra to protocol: not an RCT.
Del Sindaco 2007	Contra to protocol: intervention included clinic and home visits.
Demarzo 2006	Contra to protocol: invasive haemodynamic monitoring.
Dimmick 2003	Contra to protocol: not an RCT.
Dollard 2004	Review paper.
Dougherty 2005	Contra to protocol: invasive monitoring.
Doughty 2002	Contra to protocol: intervention included regular clinic visits.
Downey 2001	Contra to protocol: not an RCT.
Ducharme 2005	Contra to protocol: intervention was an outpatient clinic.
Duffy 2005	Contra to protocol: intervention included home visits.
Duffy 2008	Discussion paper.
Dunagan 2005	Contra to protocol: intervention included home visits.
Dunn 2006	Contra to protocol: not an RCT, intervention included clinic visits.
Dunn 2007	Contra to protocol: not an RCT, intervention included clinic visits.
Ekman 1998	Contra to protocol: intervention was a nurse-led outpatient clinic and telephone follow-up.
Ellery 2006	Contra to protocol: intervention was invasive monitoring.

(Continued)

Evangelista 2004	Contra to protocol: web-based education and counseling for patients with heart failure.
Feldman 2004	Contra to protocol: intervention was email-communication to nurses.
Feldman 2005	Contra to protocol: intervention was email-communication to nurses.
Finkelstein 2004	Contra to protocol: intervention included home visits.
Finkelstein 2006	Contra to protocol: intervention included home visits.
Foley 2008	Contra to protocol: not an RCT.
Fragrasso 2007	Not an intervention for management of heart failure, validation of remote clinical examination.
Friedberg 2008	Review of COACH study.
Furse 2008	Contra to protocol: not an RCT.
Gambetta 2007	Contra to protocol: not an RCT.
Grancelli 2007	Editorial for previous version of this review.
Gregory 2006 (SPAN-CHF)	Contra to protocol: intervention included home visits.
Gund 2008	Contra to protocol: not an RCT.
Hanssen 2007	Contra to protocol: intervention was telephone follow-up of patients following a myocardial infarction.
Harkness 2006	Review of DIAL Trial.
Harrison 2002	Contra to protocol: intervention included home visits.
Hart-Wright 2006	Contra to protocol: not an RCT.
Heidenreich 1999	Contra to protocol: not an RCT.
Heisler 2007	Contra to protocol: not an RCT.
Helms 2007	Discussion / review paper.
Ho 2007	Contra to protocol: intervention included home visits.
Holst 2007	Contra to protocol: not structured telephone support or telemonitoring, telephone follow-up following an education intervention.
Hoover 2007	Contra to protocol: not an RCT.

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Hudson 2005	Contra to protocol: not an RCT.
Huynh 2006	Contra to protocol: intensive education session; not structured telephone support or telemonitoring.
Jaarsma (COACH Study)	Contra to protocol: intervention included clinic and home visits.
Jaarsma 1999	Review paper.
Jenkins 2001	Contra to protocol: intervention included home visits.
Jerant 2001	Contra to protocol: intervention included home visits.
Jerant 2003	Contra to protocol: intervention included home visits.
Johnston 2000	Intervention not specific to heart failure patients.
Jolly 2007	Home-based exercise intervention.
Jones 2002	Review paper.
Karlsson 2005	Contra to protocol: intervention was an outpatient clinic.
Kashem 2007	Contra to protocol: web-based intervention.
Kasper 2002	Contra to protocol: intervention included home visits.
Khoury 2008	Contra to protocol: invasive haemodynamic monitoring.
Kimmelsteil 2004	Contra to protocol: intervention included home visits.
Kirschner 2006	Discussion paper.
Kline 2006	Contra to protocol: not an RCT.
Koehler 2006	Review of TEN-HMS study.
Koelling 2005	Contra to protocol: intervention was a face-to-face education session.
Kottmair 2005	Discussion paper.
Koutkias 2003	Contra to protocol: not an RCT.
Krumholz 2002	Contra to protocol: frequent clinic and home visits.
Kutzleb 2006	Contra to protocol: not an RCT.



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Kwok 2008	Contra to protocol: intervention included home visits.
LaFramboise 2003	Contra to protocol: not an RCT.
Lehmann 2006	Contra to protocol: not an RCT.
Lucas 2007	Contra to protocol: not an RCT.
Machingo 2003	Contra to protocol: not an RCT.
Maddukuri 2006	Contra to protocol: not an RCT.
Madigan 2008	Contra to protocol: not an RCT.
Maglaveras 2002	Contra to protocol: Not RCT
Maglaveras 2003	Contra to protocol: not an RCT
Maglaveras 2006	Contra to protocol: not an RCT
Mair 2007	Review paper.
Makaya 2008	Contra to protocol: intervention included home visits.
Mansfield 2006	Contra to protocol: not an RCT.
Marangelli 2007	Contra to protocol: not an RCT.
Martensson 2005	Contra to protocol: intervention included home visits.
Mau 2006	Contra to protocol: intervention included home visits.
McCauley 2006	Contra to protocol: intervention included home visits.
McCoy 2007	Contra to protocol: intervention included home visits.
McDonald 2002	Contra to protocol: frequent clinic visits with unstructured telephone follow-up.
McManus 2004	Contra to protocol: not an RCT.
Mendoza 2002	Contra to protocol: not an RCT.
Mistiaen 2006	Review paper.
Morales-Ascencio 2008	Contra to protocol: not an RCT.

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Morcillo 2005	Intervention was a single, home-based educational intervention.
Morguet 2006	Contra to protocol: not an RCT.
Morguet 2007a	Contra to protocol: not an RCT.
Morguet 2007b	Contra to protocol: not an RCT.
Morguet 2008	Contra to protocol: not RCT.
Mueller 2002	Contra to protocol: not an RCT.
Murtaugh 2005	Contra to protocol: intervention was email-communication to nurses.
Myers 2006	Contra to protocol: not an RCT.
Nanevich 2000	Contra to protocol: not an RCT.
Naylor 1999	Contra to protocol: intervention included home visits.
Naylor 2004	Contra to protocol: intervention included home visits.
Nguyen 2007	Contra to protocol: not an RCT.
Nobel 2003	Contra to protocol: not an RCT.
Noel 2004	Contra to protocol: intervention not specific to patients with heart failure.
Nohria 2007	Contra to protocol: intervention was invasive haemodynamic monitoring.
Nucifora 2006	Contra to protocol: intervention was not structured telephone support (a telephone number was available for patients to talk to a nurse).
O'Reilly 1999	Contra to protocol: not an RCT.
Oddone 1999	Contra to protocol: not an RCT.
Oeff 2005a	Contra to protocol: not an RCT.
Oeff 2005b	Discussion paper.
Ojeda 2005	Contra to protocol: intervention included clinic visits. A telephone number was made available to patients to contact clinic staff.
Opasich 2005	Review paper.

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Pasqualini 2006	Contra to protocol: not an RCT.
Philbin 2000	Report on a quality improvement intervention.
Phillips 2008	Report of a 24 hour telephone support program for patients and caregivers at the end of life.
Picard 2008	Review paper.
Piepoli 2006	Contra to protocol: not an RCT.
Piorkowski 2006	Contra to protocol: invasive haemodynamic monitoring.
Pugh 2001	Contra to protocol: nurse visits were part of the intervention.
Quinn 2006	Contra to protocol: not an RCT.
Quinn 2008	Contra to protocol: not an RCT.
Rabelo 2007	Contra to protocol: not an RCT.
Rahimpour 2008	Contra to protocol: not an RCT.
Reble 2006	Contra to protocol: not an RCT.
Repoley 2006	Contra to protocol: not an RCT.
Rich 2002	Review paper.
Ross 2004	Comparison of interactive internet electronic record.
Roth 2005	Contra to protocol: not an RCT, not specific to heart failure.
Roth 2006	Contra to protocol: not an RCT, not specific to heart failure.
Rozenman 2007	Contra to protocol: invasive haemodynamic monitoring.
Saxon 2007	Contra to protocol: invasive haemodynamic monitoring.
Scalvini 2004	Contra to protocol: not an RCT.
Scalvini 2005a	Contra to protocol: not an RCT.
Scalvini 2005b	Contra to protocol: not an RCT.
Scalvini 2006	Contra to protocol: GP monitoring vs home based monitoring.

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Scherr 2006	Contra to protocol: intervention not specific for heart failure patients.
Schmidt 2008	Medication box which monitored medication adherence.
Schneider 2004	Contra to protocol: not an RCT.
Schofield 2005	Contra to protocol: not an RCT.
Schofield 2008	Contra to protocol: not an RCT.
Schwarz 2008	Contra to protocol: intervention involved caregivers as well as the patient with heart failure.
Scott 2004	Contra to protocol: not an RCT.
Seibert 2008a	Contra to protocol: not an RCT.
Serxner 1998	Contra to protocol: not an RCT.
Shah 2007	Discussion paper.
Shah 2008	Contra to protocol: intervention based in clinic.
Shearer 2007	Author contacted: primary and secondary outcomes for this review were not measured.
Simpson 2006	Heart transplant technology.
Slater 2006	Contra to protocol: not an RCT.
Slater 2008	Contra to protocol: not an RCT.
Smart 2005	Contra to protocol: not an RCT.
Smeulders 2006	Contra to protocol: intervention based in clinic.
Spaeder 2006	Contra to protocol: very frequent clinic visits.
Sprenger 2007	Contra to protocol: not an RCT.
Steckler 2008	Contra to protocol: not an RCT.
Stromberg 2003	Contra to protocol: intervention based in clinic.
Stromberg 2006	Contra to protocol: intervention based in clinic.
Sullivan 2006	Contra to protocol: not an RCT.
Terschuren 2007	Contra to protocol: not an RCT.

(Continued)

Thompson 2005	Contra to protocol: intervention included home and clinic visits.
Thompson 2008	Review of Woodend 2003.
Tramarin 2005	Collection of abstracts, not relating to structured telephone support or telemonitoring in heart failure.
Trudel 2007	Study included patients with diabetes and hypertension. Intervention not specific to heart failure.
VA Technology Assessment	Report on telemonitoring technologies.
Vaccaro 2001	Contra to protocol: not an RCT. Compared 638 matched controls.
Valle 2004	Contra to protocol: intervention consisted of education for patient and family, prescribed diet and guideline-based pharmacotherapy and did not include structured telephone support or telemonitoring.
van den Bussche 2004	Contra to protocol: not an RCT, observation study.
Villalba 2006a	Contra to protocol: not an RCT.
Villalba 2006b	Contra to protocol: not an RCT.
Vrijhoef 2007	Contra to protocol: not an RCT.
Waldman 2008	Included patients with coronary artery disease, intervention not specific to heart failure.
Walsh 2005	Contra to protocol: not an RCT.
Waywell 2007	Contra to protocol: not an RCT.
Weintraub 2005	Contra to protocol: intervention included home-visits.
West-Fraser 2008	Contra to protocol: home visits by cardiac nurses to both groups (communication from author).
Westlake 2007	Contra to protocol: intervention was web-based.
Wheeler 2006	Contra to protocol: intervention included home visits.
Whitten 2007	Review.
Wierchowicki 2005	Contra to protocol: intervention included home visits.
Wierchowicki 2006	Contra to protocol: intervention included home visits.
Willyard 2006	Contra to protocol: not an RCT.

(Continued)

Wong 2005	Intervention for patients with chronic obstructive pulmonary disease.
Wongpiriyayothar 2008	Contra to protocol: intervention included home visits.
Wright 2003	Contra to protocol: intervention consisted of symptom diary, attended three education session and clinic visits.
Wu 2006	Comparison of internet-based technology.
Zaphiriou 2006	Contra to protocol: intervention included a home visit.
Zentner 2007	Contra to protocol: not an RCT.
Zugck 2006	Contra to protocol: not an RCT.

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

#### Dunlap 2006 (HearT-I)

Methods	Randomised controlled trial; Intervention versus usual care
Participants	455 patients to date (NYHA Class II or greater). Mean age no data. % of participants were male - no data. USA.
Interventions	Structured Telephone Support Three components; 1) computer initiated medication refill and clinic appointment reminders; 2) IVR access to education modules 3) Computer initiated phone calls with a series of question regarding weight and symptom
Outcomes	All cause hospitalisation; Unscheduled outpatient visits. KCCQ; Satisfaction ; Adherence to medications; knowledge of self care and heart failure 12 months follow-up.
Notes	Unable to contact authors to determine or clarify intervention and usual care arms

#### Levine2006(Mind My Heart)

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	234 patients Mean age not reported. % of participants were male- not reported. USA.

**Levine2006(Mind My Heart)** (Continued)

Interventions	Telemonitoring. Intervention group transmitted to monitoring centre via modem vital signs, BP SpO2. Usual care no further contact with project staff.
Outcomes	Technology use and Satisfaction Survey
Notes	No primary outcomes reported. Unable to contact authors

**Scherr 2005 (MobiTEL)**

Methods	Open randomised controlled trial; Intervention versus usual care
Participants	57 = 28 Telemonitoring / 29 Usual Care patients (NYHA Class II or greater). Recruiting on-going at time of report Mean age 63 years. % of participants were male - no data. Austria.
Interventions	Telemonitoring Mobile phone and digital weight scale; data transferred to telemonitoring centre
Outcomes	Combined end-point of CVD mortality and CHF hospitalisation NYHF Class; MLWHFQ; Cost Effectiveness Six months follow-up.
Notes	Published after census data of review. Primary outcomes only reported as combined outcomes

**Yakushin 2006**

Methods	Randomised controlled trial; intervention arm and control (usual care) arm.
Participants	78 patients Mean age 56 years. % of participants were male-not reported. Russian Federation.
Interventions	Unable to determine intervention from abstract Some telephone follow-up Usual care not described.
Outcomes	Hospitalisations and Cardiovascular death
Notes	Unable to contact authors

## Characteristics of ongoing studies *[ordered by study ID]*

### Chaudry 2007 (Tele-HF)

Trial name or title	Telemonitoring to Improve Heart Failure (Tele-HF)
Methods	Randomised control trial Centralised randomisation performed by telephone stratified by study site and force randomised within each study site in blocks of 20 (10 intervention: 10 control) Power calculated for all-cause mortality and hospitalisation. 1640 participants (820 in each group)
Participants	Discharged from a HF hospitalisation within 30 days of enrolment in the study Exclusion < 18 years, No English or Spanish, < 6 months predicted survival
Interventions	Telemonitoring Participants made daily toll-free call to an automated telemonitoring system with pre-recorded surveys about daily weight and symptoms (Pharos Innovations, Chicago) Data downloads were viewed daily for variances and patients contacted by phone for follow-up Usual Care Discharge follow-up with Physician and discussion of guidelines
Outcomes	Follow-up 6 months All cause mortality All cause re-admission
Starting date	Study is now completed. Results due in approximately 12 months.
Contact information	Dr Sarwat I Chaudhry , Yale University School of Medicine, PO Box 208025 New Haven CT 06520-8025
Notes	Final results not published

### Kohler 2006

Trial name or title	Partnership for the Heart -the Heart Coach System
Methods	A randomised prospective multi-centre study
Participants	450 patients with chronic heart failure NYHA Function Class II-III
Interventions	The German Federal Ministry of Economics and Technology launched an invitation to tender for a telemonitoring platform system (www.nextgenerationmedia.de). The total cost of the project is EURO8 million (grant EURO4.9 million) The aim is to demonstrate the superiority of a telemedicine home care monitoring system.
Outcomes	Primary endpoints Mortality, duration of inpatient treatment and costs. Secondary Endpoints quality of life.
Starting date	2005-2008
Contact information	Friedrich Köhler MD, Charite-Universitätsmedizin Berlin, friedrich.koehler@charite.de



**Kohler 2006** (Continued)

Notes	Awaiting contact from authors for further details or publications
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**Kulshreshtha 2008a**

Trial name or title	Remote Monitoring Program
Methods	Randomised control trial
Participants	150 Eligible patients from Massachusetts General Hospital
Interventions	Participants transmitted daily vital signs data and weight to a nurse who coordinated care with a physician. Timely interventions and teaching were offered over the course of the 6 month study.
Outcomes	All cause readmission HF related admission mortality ER Visits and Length of Stay
Starting date	2008
Contact information	Dr Ambar Kulshreshtha, Harvard Medical School, Boston MA
Notes	Only abstract available. No response after several attempts to contact authors.

## DATA AND ANALYSES

### Comparison 1. Impact of structured telephone support and telemonitoring in CHF on all-cause mortality

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All-cause mortality (full peer-reviewed publications only): structured telephone support vs usual care	15	5563	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.76, 1.01]
2 All-cause mortality (full peer-reviewed publications only): telemonitoring vs usual care	11	2710	Risk Ratio (M-H, Fixed, 95% CI)	0.66 [0.54, 0.81]
3 Sensitivity analysis (full peer-reviewed publications and abstracts): all-cause mortality: structured telephone support vs usual care	17	6676	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.84, 1.09]
4 Sensitivity analysis (full peer-reviewed publications and abstracts): all-cause mortality: telemonitoring vs usual care	14	3079	Risk Ratio (M-H, Fixed, 95% CI)	0.68 [0.57, 0.82]
5 Sensitivity analysis (full peer-reviewed publications only), follow-up period (>6 months), all-cause mortality: structured telephone support vs usual care	9	4292	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.74, 1.02]
6 Sensitivity analysis (full peer-reviewed publications only), follow-up period (>6 months), all-cause mortality: telemonitoring vs usual care	8	1994	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.55, 0.86]

### Comparison 2. Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All-cause hospitalisation (full peer-reviewed publications only): structured telephone support vs usual care	11	4295	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.85, 0.99]

2 All-cause hospitalisation (full peer-reviewed publications only): telemonitoring vs usual care	8	2343	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.84, 0.99]
3 Sensitivity analysis (full peer-reviewed publications and abstracts), all-cause hospitalisation: structured telephone support vs usual care	12	4700	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.84, 0.97]
4 Sensitivity analysis (full peer-reviewed publications and abstracts), all-cause hospitalisation: telemonitoring vs usual care	11	2712	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.87, 1.01]
5 Sensitivity analysis (full peer-reviewed publications only), follow-up period (> 6 months), all-cause hospitalisation: structured telephone support vs usual care	6	3058	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.83, 0.99]
6 Sensitivity analysis (full peer-reviewed publications only), follow-up period (> 6 months), all-cause hospitalisation: telemonitoring vs usual care	6	1748	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.80, 0.95]

### Comparison 3. Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation rate

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 CHF-related hospitalisation (full peer-reviewed publications only): structured telephone support vs usual care	13	4269	Risk Ratio (M-H, Fixed, 95% CI)	0.77 [0.68, 0.87]
2 CHF-related hospitalisation (full peer-reviewed publications only): telemonitoring vs usual care	4	1570	Risk Ratio (M-H, Fixed, 95% CI)	0.79 [0.67, 0.94]
3 Sensitivity analysis (full peer-reviewed publications and abstracts), CHF-related hospitalisation rate: structured telephone support vs usual care	14	4674	Risk Ratio (M-H, Fixed, 95% CI)	0.77 [0.68, 0.87]

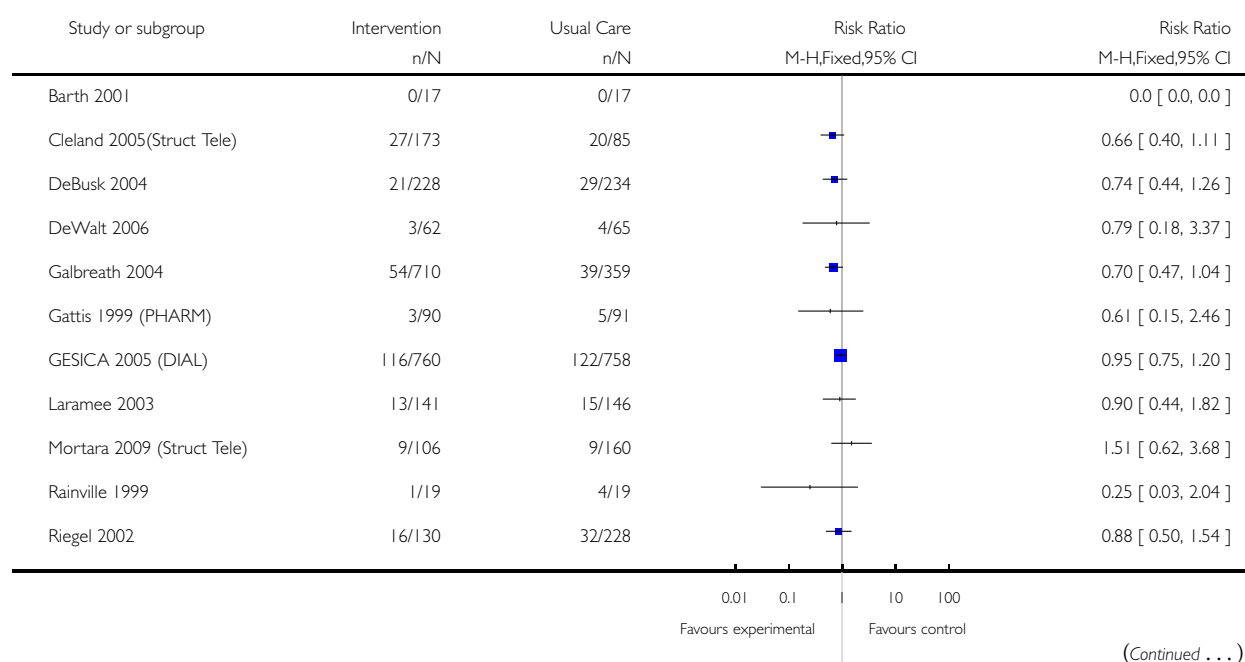
4 Sensitivity analysis (full peer-reviewed publications and abstracts), CHF-related hospitalisation rate: telemonitoring vs usual care	6	1735	Risk Ratio (M-H, Fixed, 95% CI)	0.76 [0.64, 0.89]
5 Sensitivity analysis (full peer-reviewed publications only), follow-up period (> 6 months), CHF-related hospitalisation: structured telephone support vs usual care	6	2948	Risk Ratio (M-H, Fixed, 95% CI)	0.76 [0.65, 0.89]
6 Sensitivity analysis (full peer-reviewed publications only), follow-up period (> 6 months), CHF-related hospitalisation: telemonitoring vs usual care	4	1570	Risk Ratio (M-H, Fixed, 95% CI)	0.79 [0.67, 0.94]

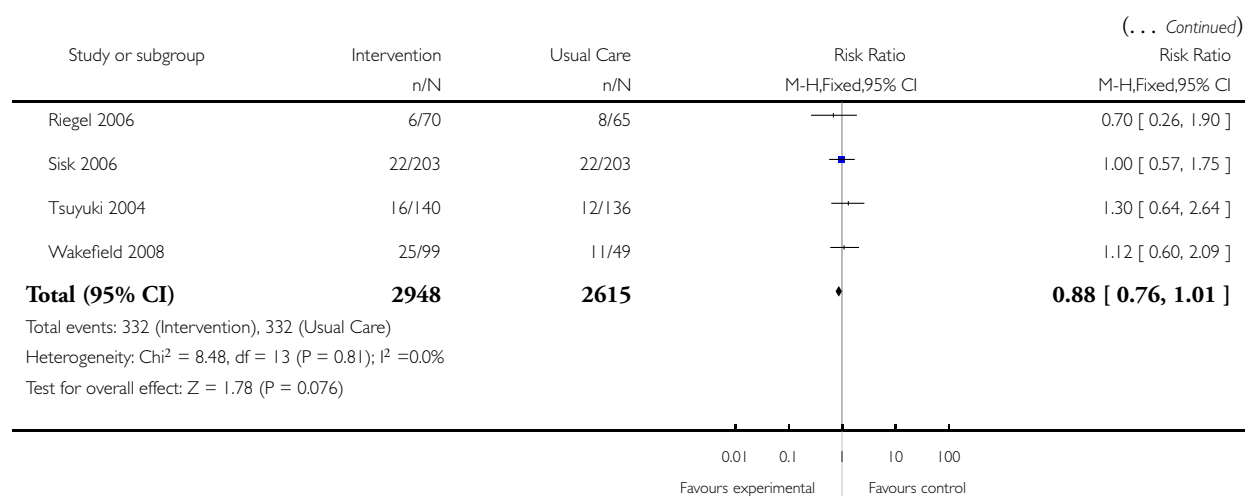
**Analysis 1.1. Comparison 1 Impact of structured telephone support and telemonitoring in CHF on all-cause mortality, Outcome 1 All-cause mortality (full peer-reviewed publications only): structured telephone support vs usual care.**

Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 1 Impact of structured telephone support and telemonitoring in CHF on all-cause mortality

Outcome: 1 All-cause mortality (full peer-reviewed publications only): structured telephone support vs usual care



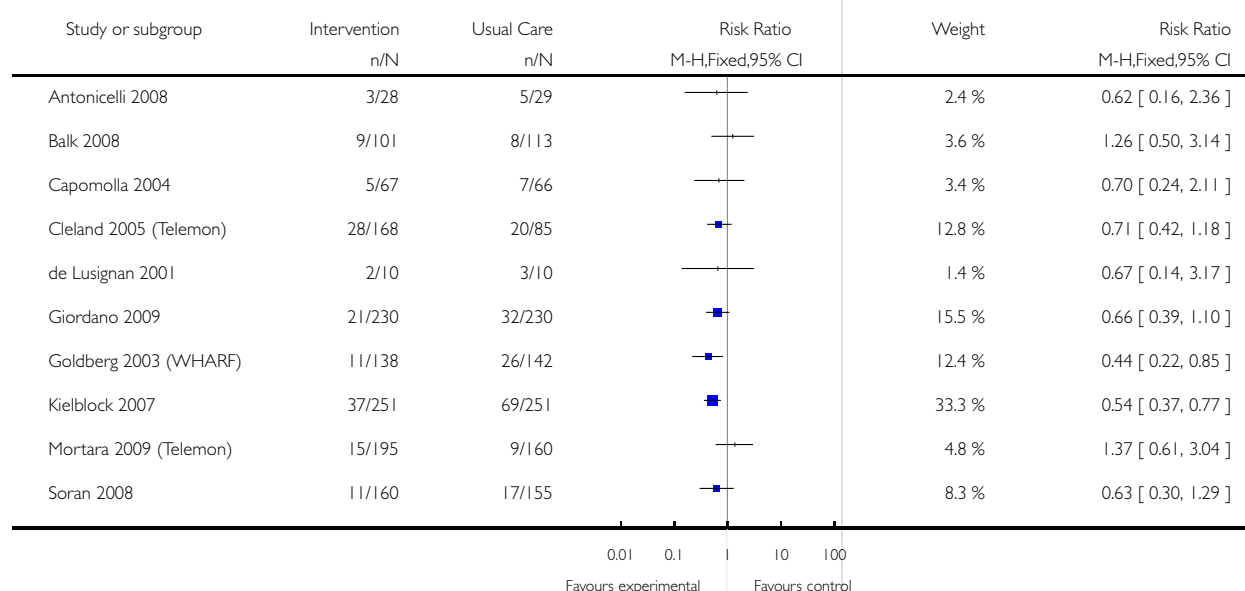


## Analysis 1.2. Comparison 1 Impact of structured telephone support and telemonitoring in CHF on all-cause mortality, Outcome 2 All-cause mortality (full peer-reviewed publications only): telemonitoring vs usual care.

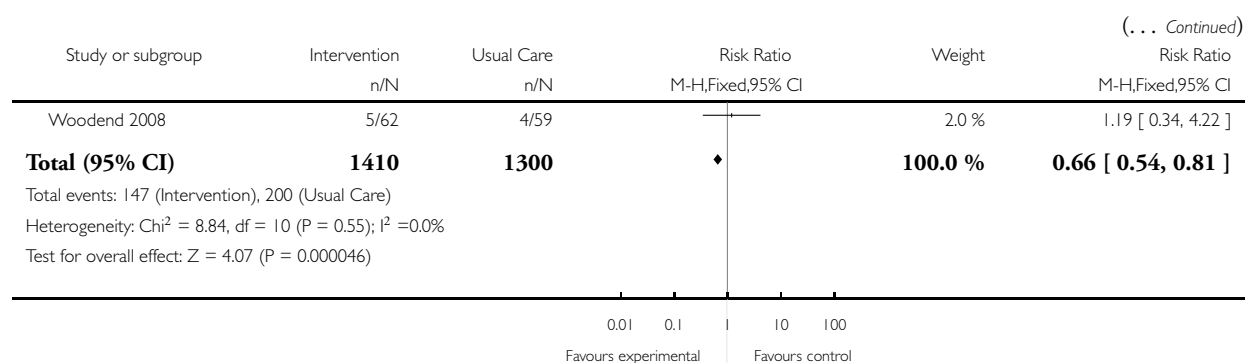
Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 1 Impact of structured telephone support and telemonitoring in CHF on all-cause mortality

Outcome: 2 All-cause mortality (full peer-reviewed publications only): telemonitoring vs usual care



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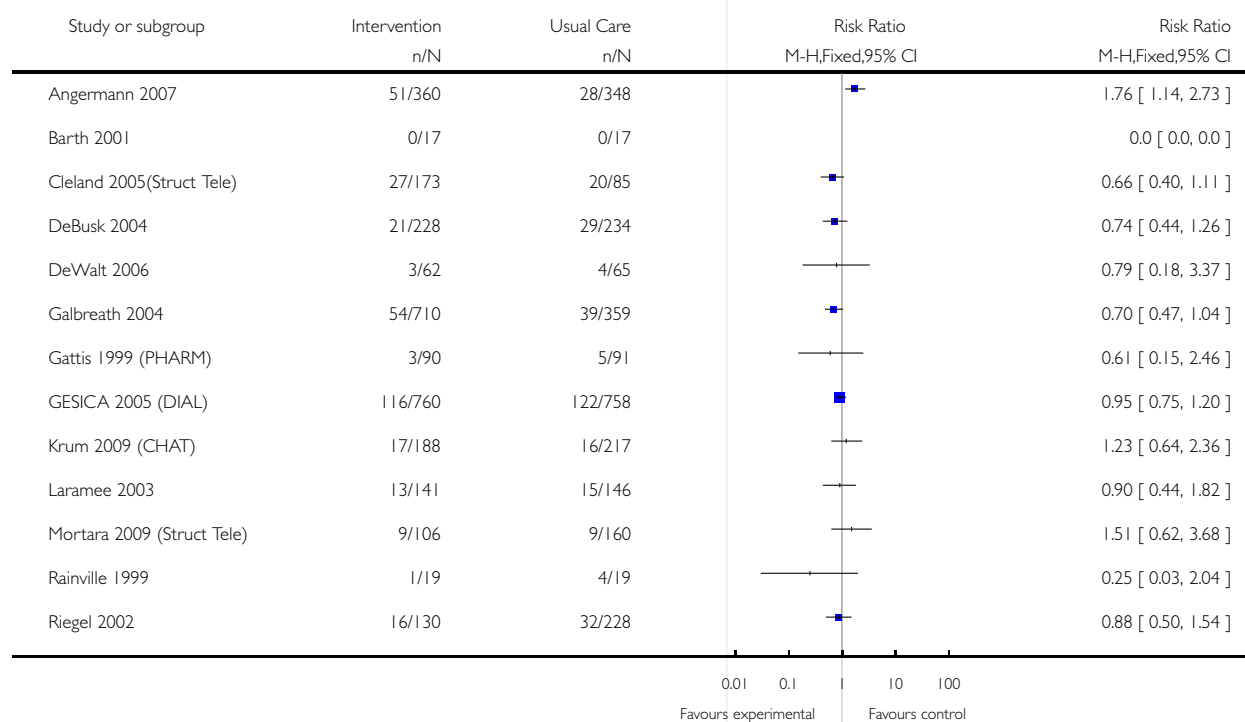


**Analysis 1.3. Comparison 1 Impact of structured telephone support and telemonitoring in CHF on all-cause mortality, Outcome 3 Sensitivity analysis (full peer-reviewed publications and abstracts): all-cause mortality: structured telephone support vs usual care.**

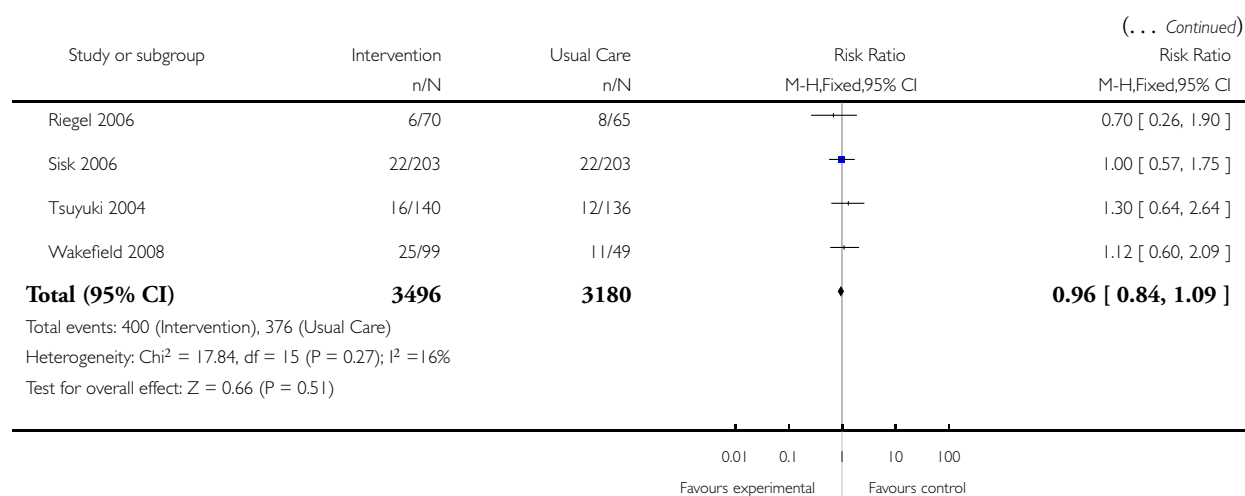
Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 1 Impact of structured telephone support and telemonitoring in CHF on all-cause mortality

Outcome: 3 Sensitivity analysis (full peer-reviewed publications and abstracts): all-cause mortality: structured telephone support vs usual care



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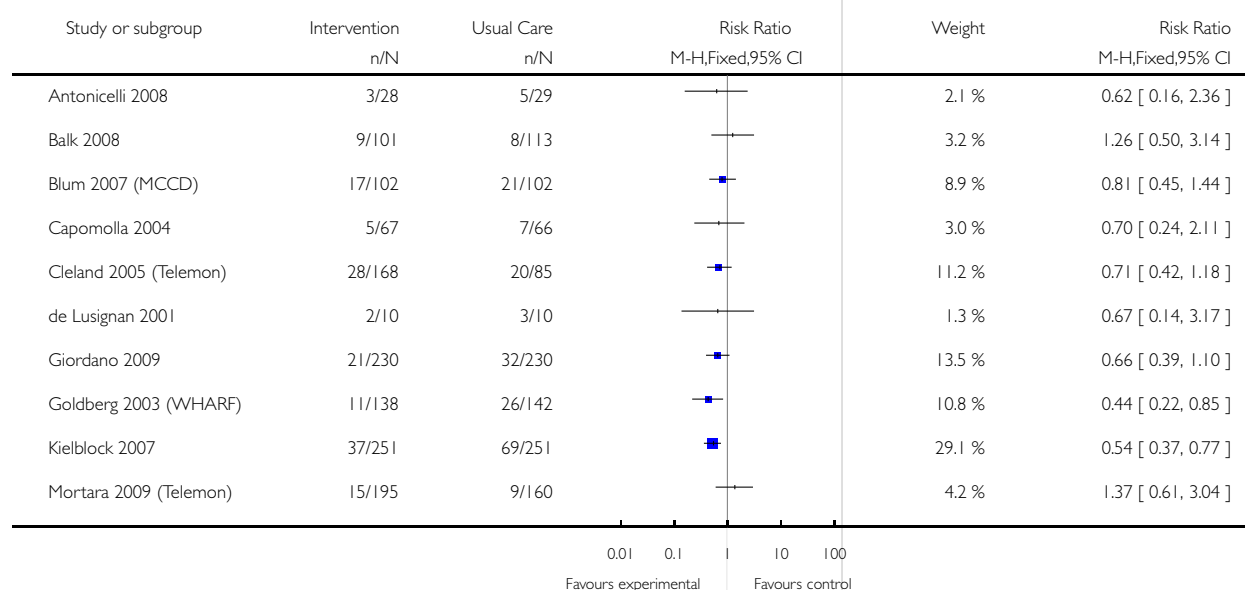


**Analysis 1.4. Comparison 1 Impact of structured telephone support and telemonitoring in CHF on all-cause mortality, Outcome 4 Sensitivity analysis (full peer-reviewed publications and abstracts): all-cause mortality: telemonitoring vs usual care.**

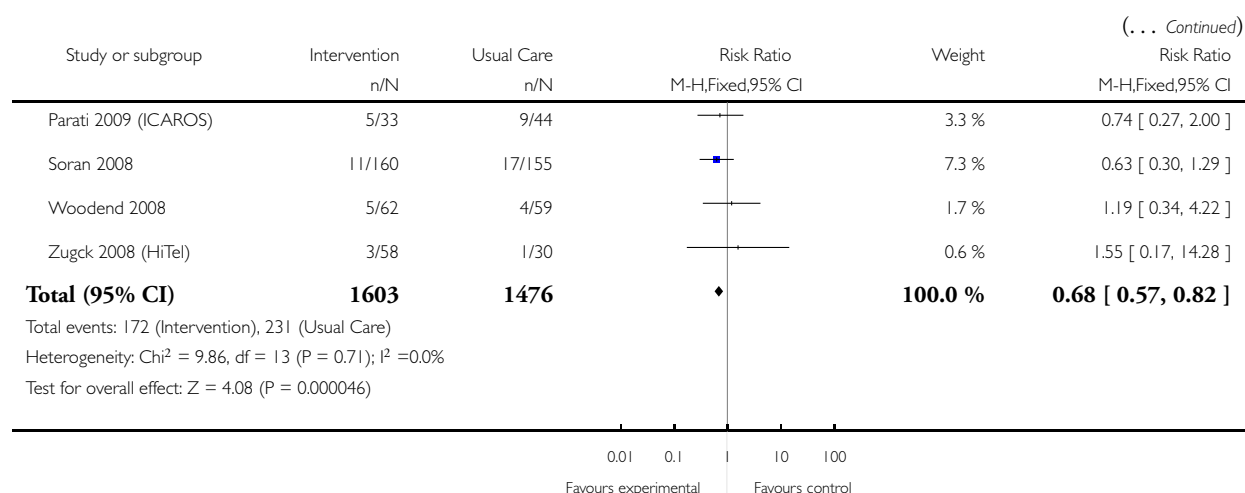
Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 1 Impact of structured telephone support and telemonitoring in CHF on all-cause mortality

Outcome: 4 Sensitivity analysis (full peer-reviewed publications and abstracts): all-cause mortality: telemonitoring vs usual care



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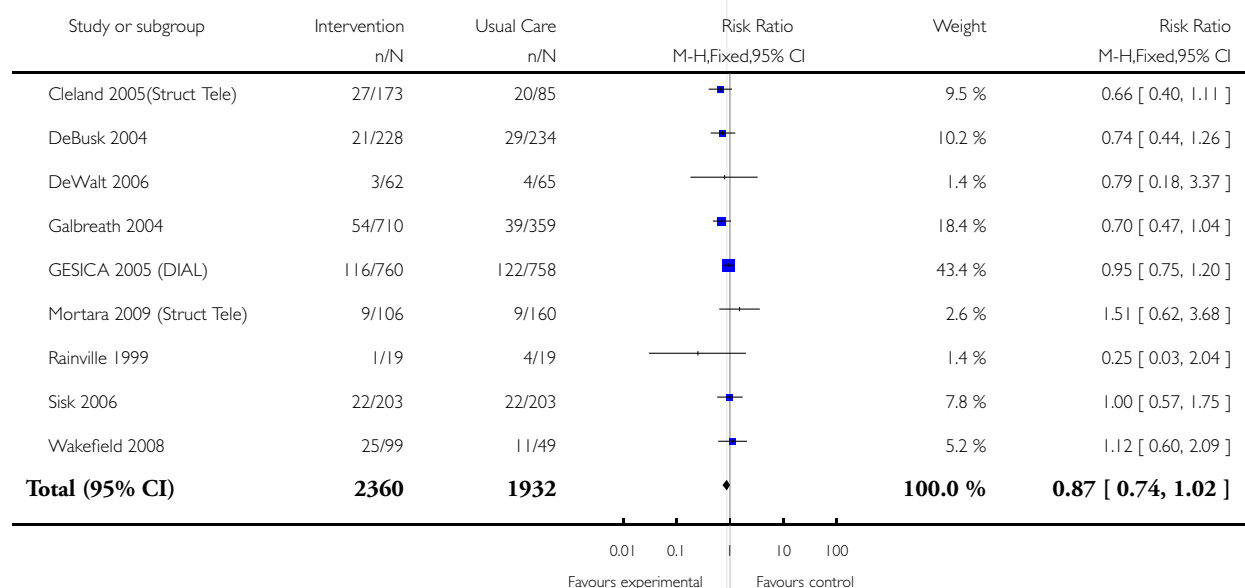


**Analysis 1.5. Comparison 1 Impact of structured telephone support and telemonitoring in CHF on all-cause mortality, Outcome 5 Sensitivity analysis (full peer-reviewed publications only), follow-up period (>6 months), all-cause mortality: structured telephone support vs usual care.**

Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

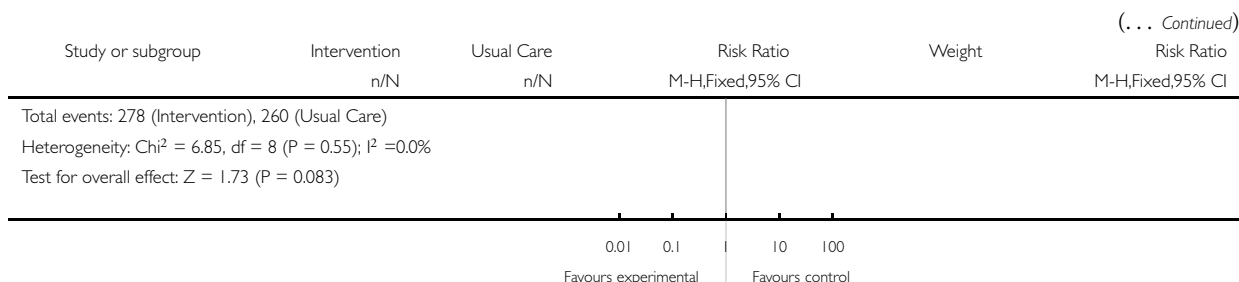
Comparison: 1 Impact of structured telephone support and telemonitoring in CHF on all-cause mortality

Outcome: 5 Sensitivity analysis (full peer-reviewed publications only), follow-up period (>6 months), all-cause mortality: structured telephone support vs usual care



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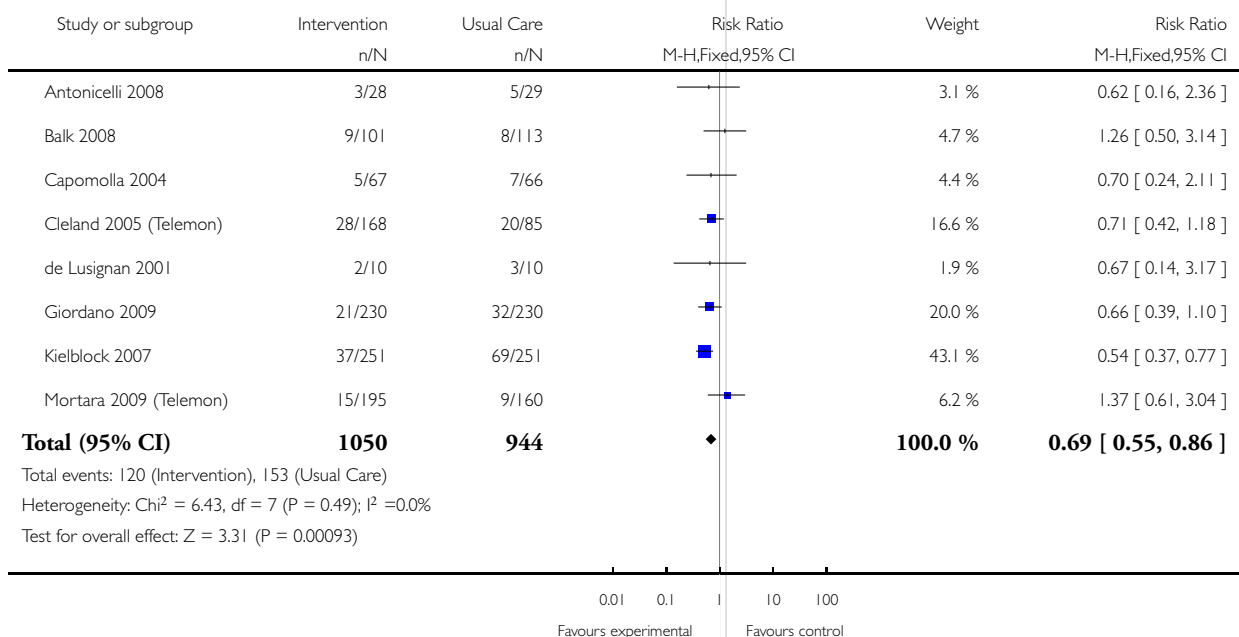


**Analysis 1.6. Comparison 1 Impact of structured telephone support and telemonitoring in CHF on all-cause mortality, Outcome 6 Sensitivity analysis (full peer-reviewed publications only), follow-up period (>6 months), all-cause mortality: telemonitoring vs usual care.**

Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 1 Impact of structured telephone support and telemonitoring in CHF on all-cause mortality

Outcome: 6 Sensitivity analysis (full peer-reviewed publications only), follow-up period (>6 months), all-cause mortality: telemonitoring vs usual care

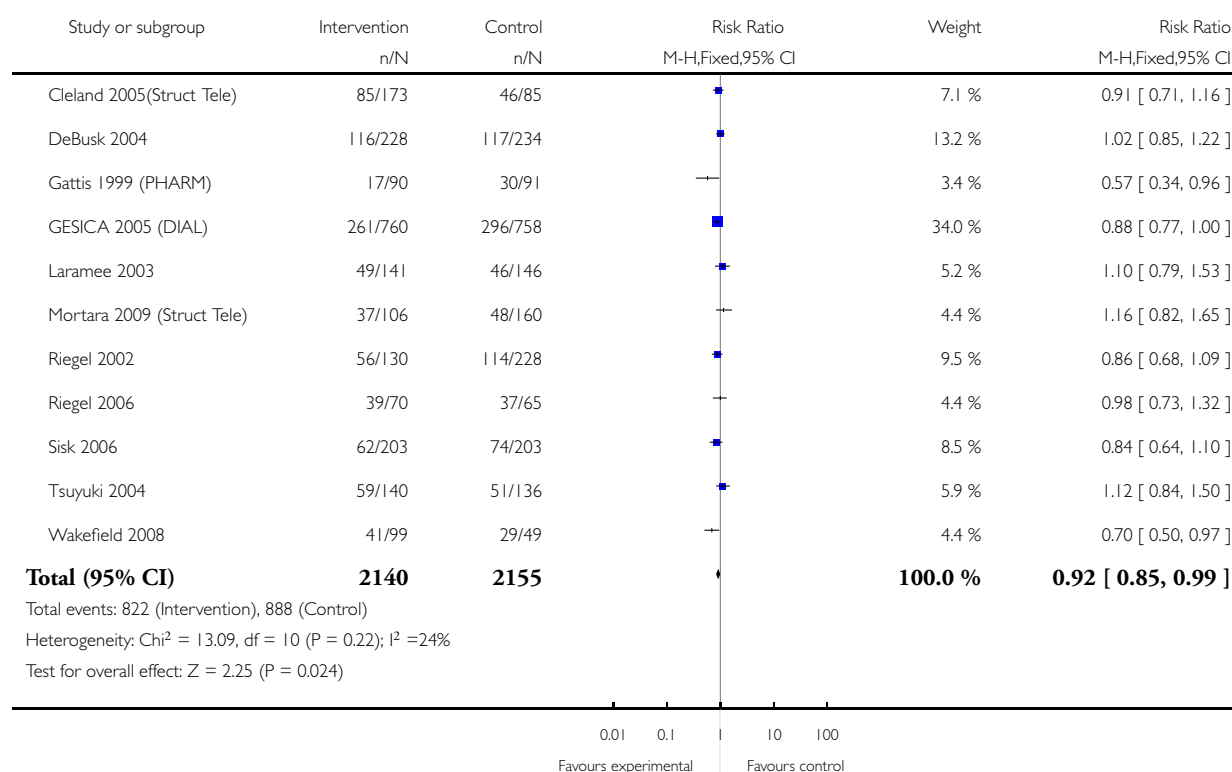


## Analysis 2.1. Comparison 2 Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation, Outcome 1 All-cause hospitalisation (full peer-reviewed publications only): structured telephone support vs usual care.

Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 2 Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation

Outcome: 1 All-cause hospitalisation (full peer-reviewed publications only): structured telephone support vs usual care

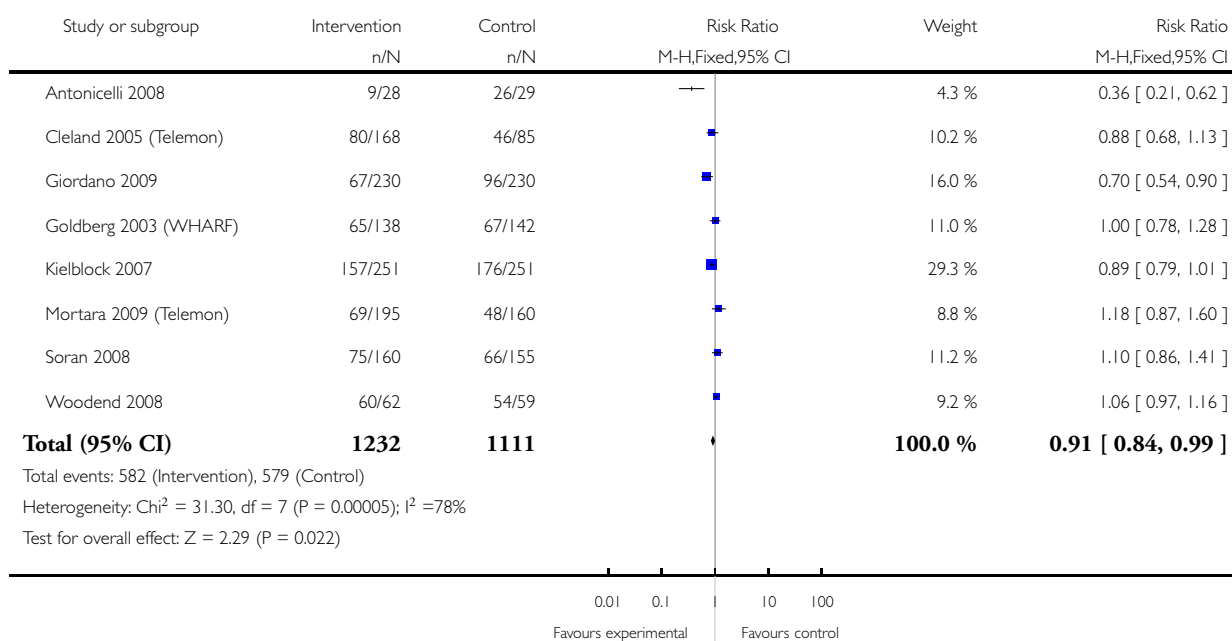


**Analysis 2.2. Comparison 2 Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation, Outcome 2 All-cause hospitalisation (full peer-reviewed publications only): telemonitoring vs usual care.**

Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 2 Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation

Outcome: 2 All-cause hospitalisation (full peer-reviewed publications only): telemonitoring vs usual care

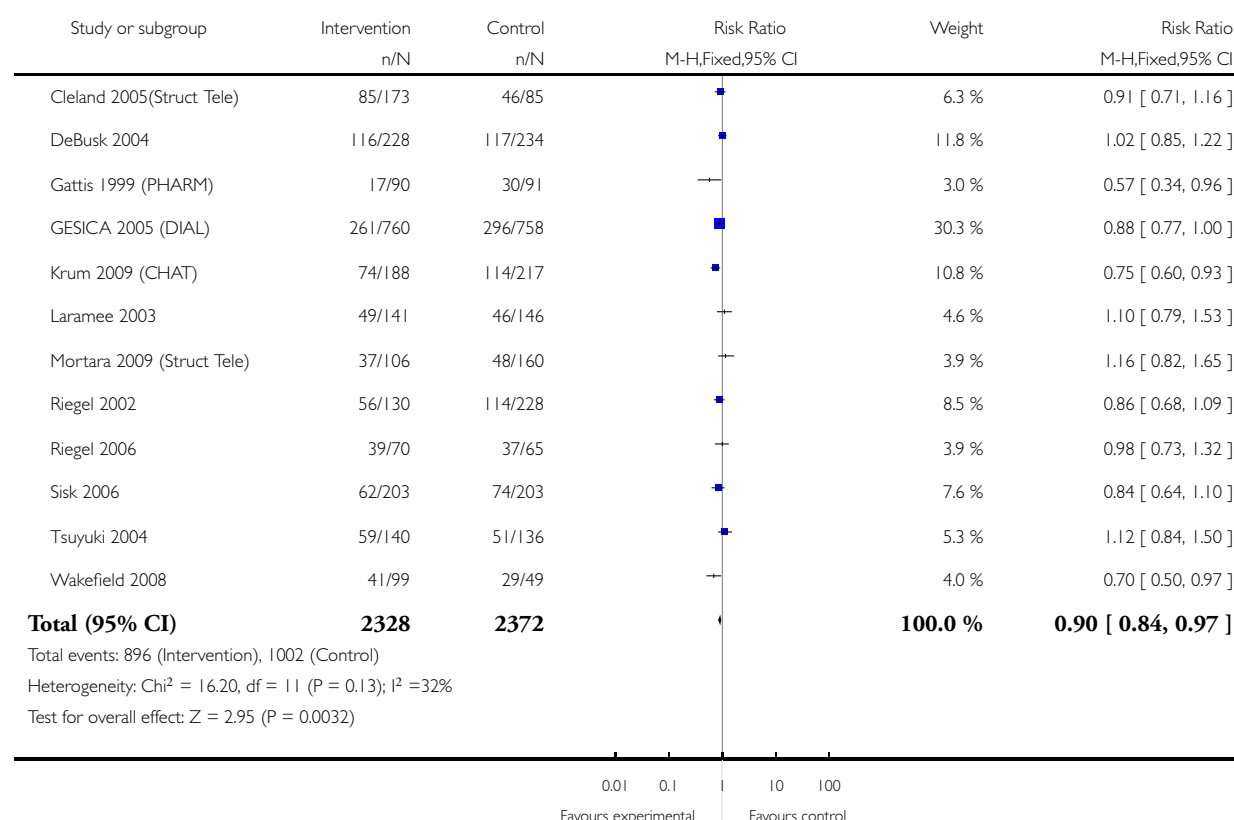


### Analysis 2.3. Comparison 2 Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation, Outcome 3 Sensitivity analysis (full peer-reviewed publications and abstracts), all-cause hospitalisation: structured telephone support vs usual care.

Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 2 Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation

Outcome: 3 Sensitivity analysis (full peer-reviewed publications and abstracts), all-cause hospitalisation: structured telephone support vs usual care

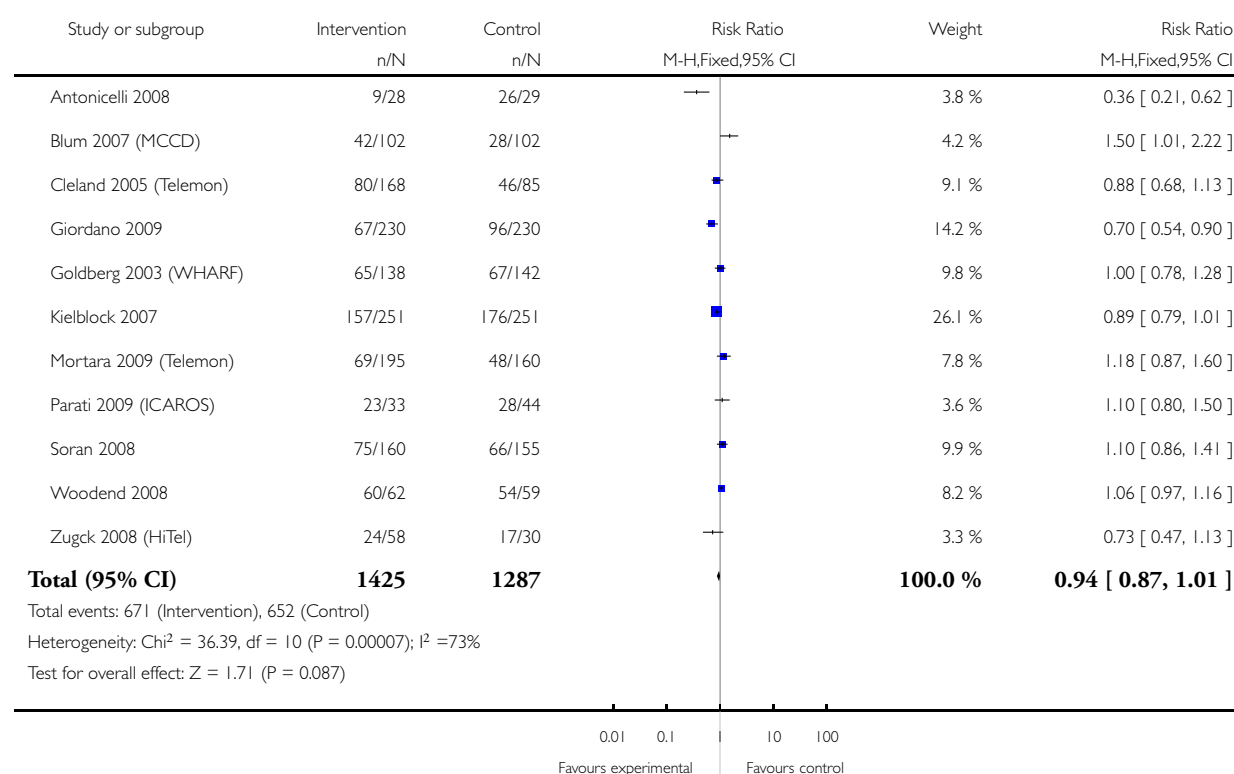


# **Analysis 2.4. Comparison 2 Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation, Outcome 4 Sensitivity analysis (full peer-reviewed publications and abstracts), all-cause hospitalisation: telemonitoring vs usual care.**

Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 2 Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation

Outcome: 4 Sensitivity analysis (full peer-reviewed publications and abstracts), all-cause hospitalisation: telemonitoring vs usual care

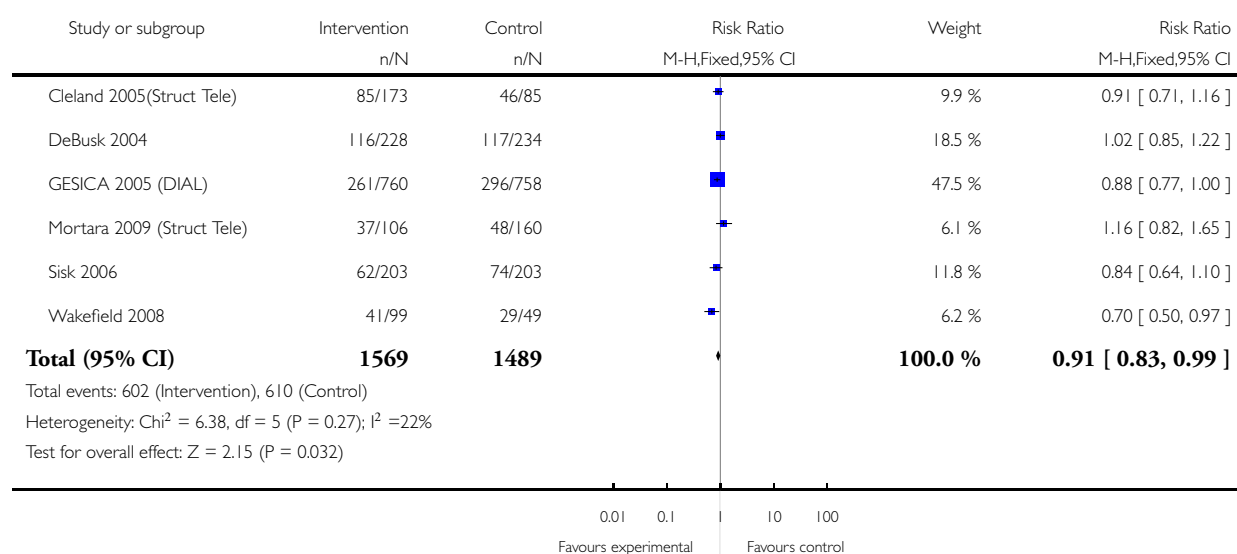


**Analysis 2.5. Comparison 2 Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation, Outcome 5 Sensitivity analysis (full peer-reviewed publications only), follow-up period (> 6 months), all-cause hospitalisation: structured telephone support vs usual care.**

Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 2 Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation

Outcome: 5 Sensitivity analysis (full peer-reviewed publications only), follow-up period (> 6 months), all-cause hospitalisation: structured telephone support vs usual care

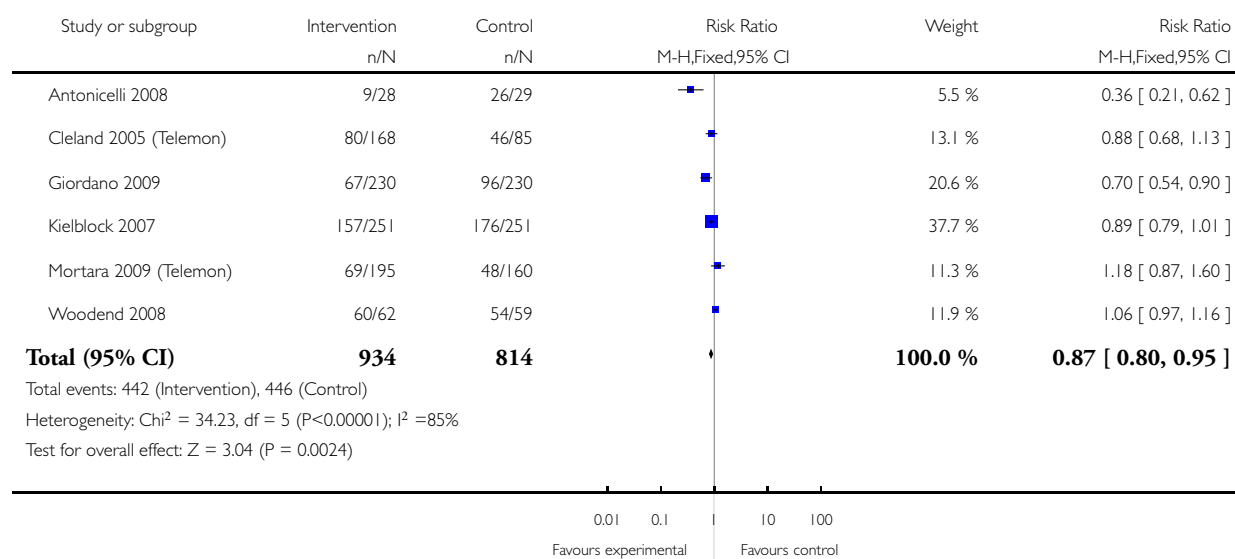


**Analysis 2.6. Comparison 2 Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation, Outcome 6 Sensitivity analysis (full peer-reviewed publications only), follow-up period (> 6 months), all-cause hospitalisation: telemonitoring vs usual care.**

Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 2 Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation

Outcome: 6 Sensitivity analysis (full peer-reviewed publications only), follow-up period (> 6 months), all-cause hospitalisation: telemonitoring vs usual care

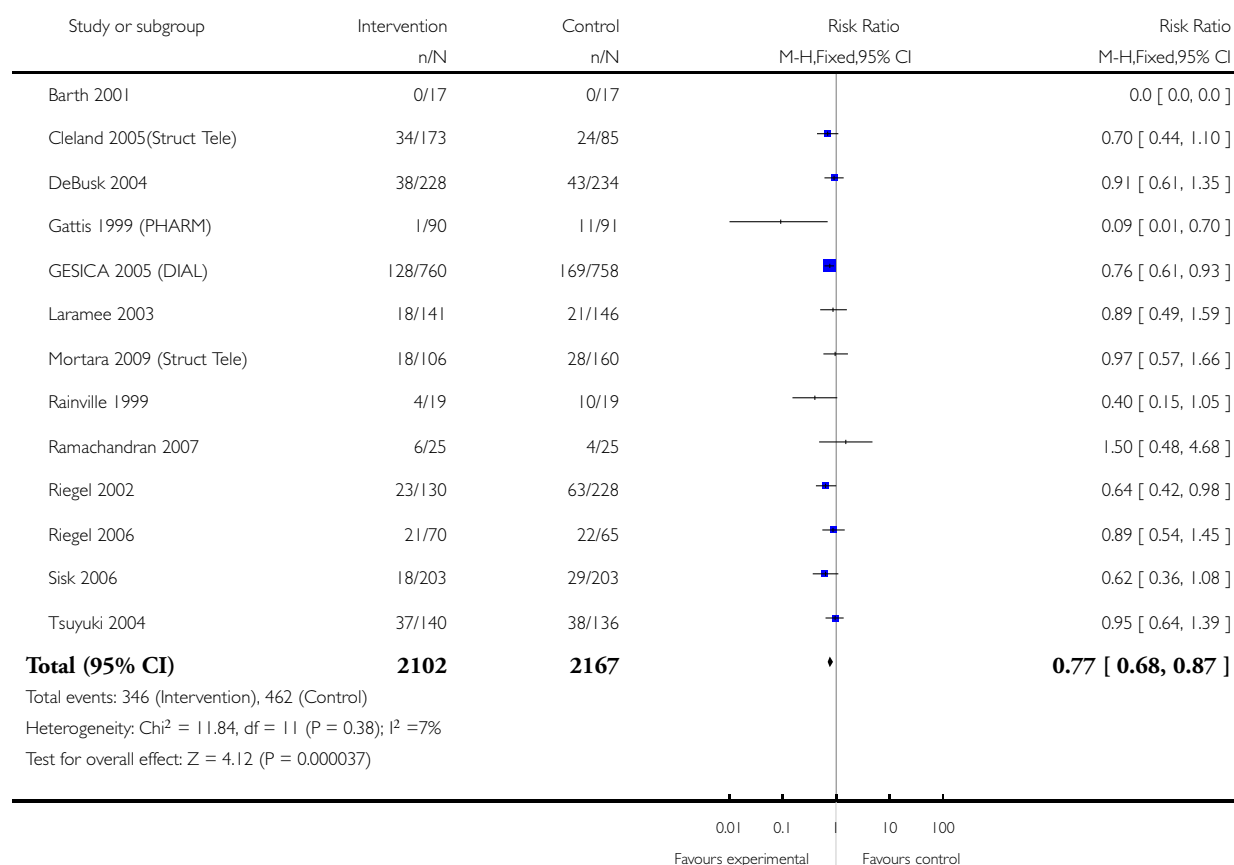


**Analysis 3.1. Comparison 3 Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation rate, Outcome 1 CHF-related hospitalisation (full peer-reviewed publications only): structured telephone support vs usual care.**

Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 3 Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation rate

Outcome: 1 CHF-related hospitalisation (full peer-reviewed publications only): structured telephone support vs usual care



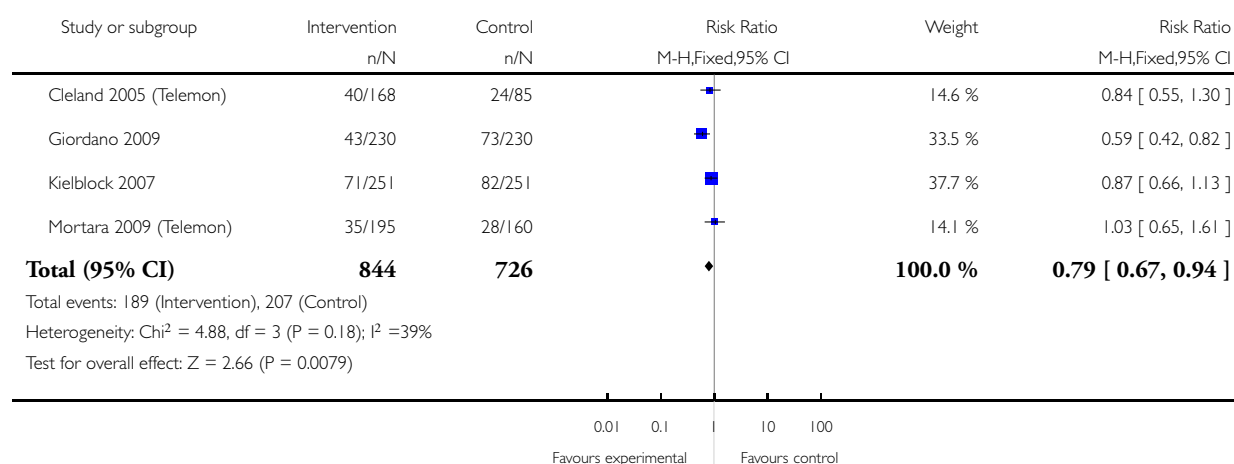


**Analysis 3.2. Comparison 3 Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation rate, Outcome 2 CHF-related hospitalisation (full peer-reviewed publications only): telemonitoring vs usual care.**

Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 3 Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation rate

Outcome: 2 CHF-related hospitalisation (full peer-reviewed publications only): telemonitoring vs usual care

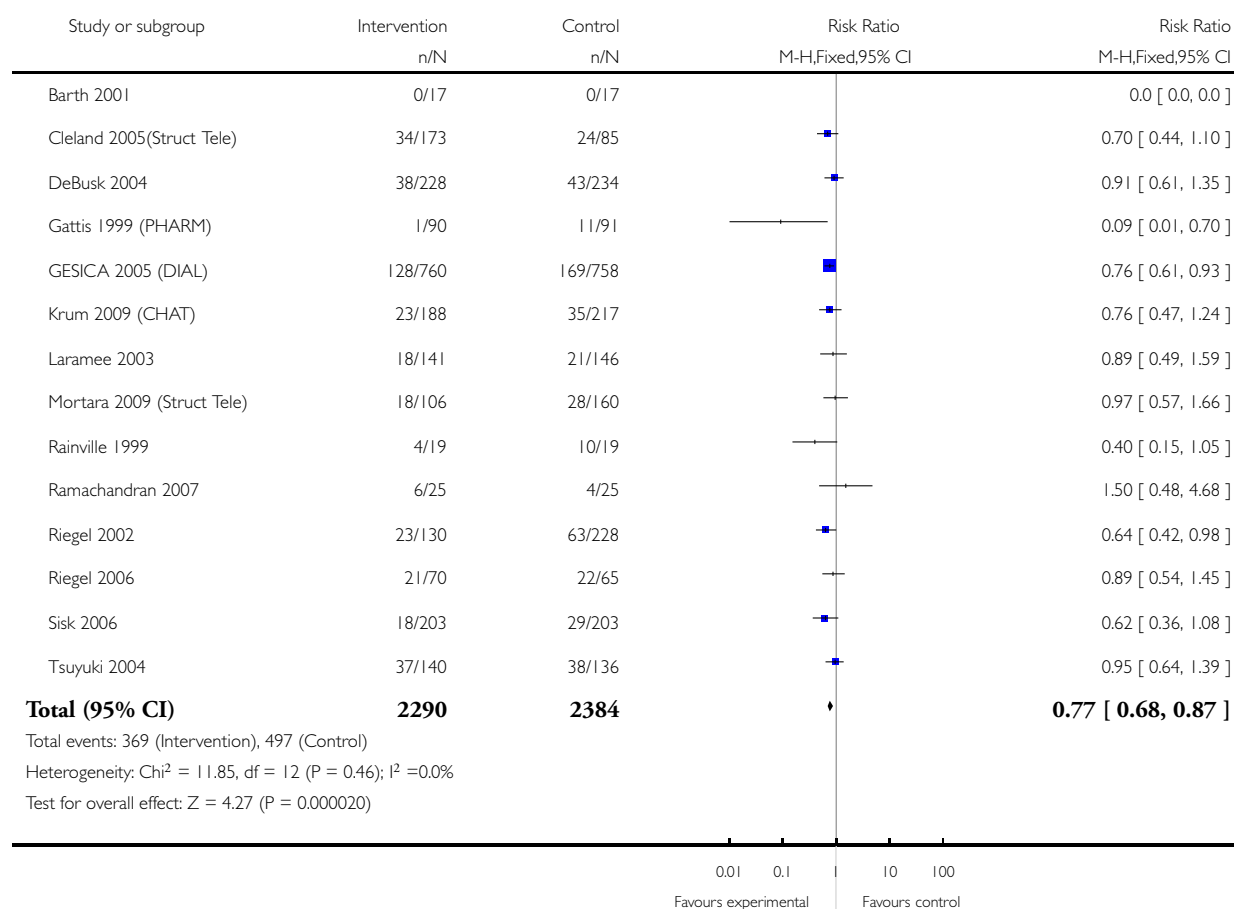


**Analysis 3.3. Comparison 3 Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation rate, Outcome 3 Sensitivity analysis (full peer-reviewed publications and abstracts), CHF-related hospitalisation rate: structured telephone support vs usual care.**

Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 3 Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation rate

Outcome: 3 Sensitivity analysis (full peer-reviewed publications and abstracts), CHF-related hospitalisation rate: structured telephone support vs usual care

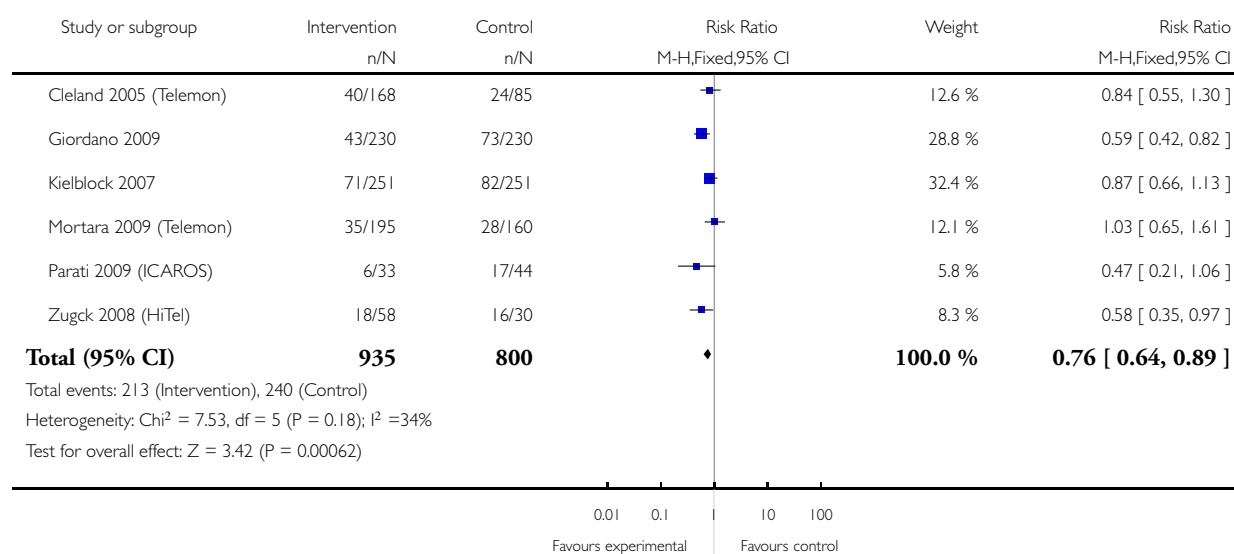


**Analysis 3.4. Comparison 3 Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation rate, Outcome 4 Sensitivity analysis (full peer-reviewed publications and abstracts), CHF-related hospitalisation rate: telemonitoring vs usual care.**

Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 3 Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation rate

Outcome: 4 Sensitivity analysis (full peer-reviewed publications and abstracts), CHF-related hospitalisation rate: telemonitoring vs usual care

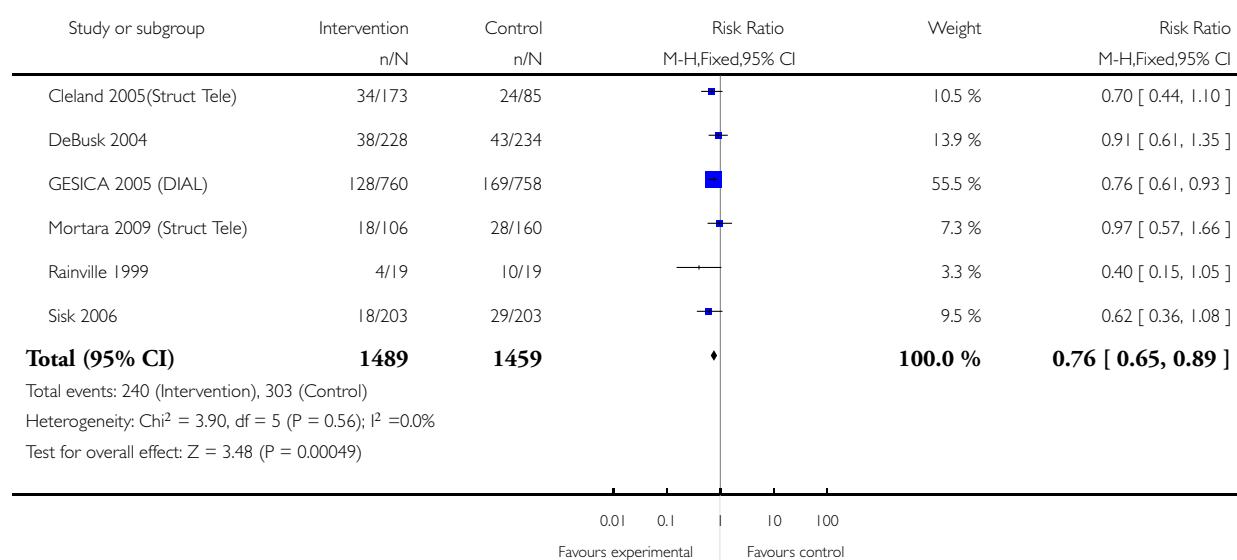


**Analysis 3.5. Comparison 3 Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation rate, Outcome 5 Sensitivity analysis (full peer-reviewed publications only), follow-up period (> 6 months), CHF-related hospitalisation: structured telephone support vs usual care.**

Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 3 Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation rate

Outcome: 5 Sensitivity analysis (full peer-reviewed publications only), follow-up period (> 6 months), CHF-related hospitalisation: structured telephone support vs usual care

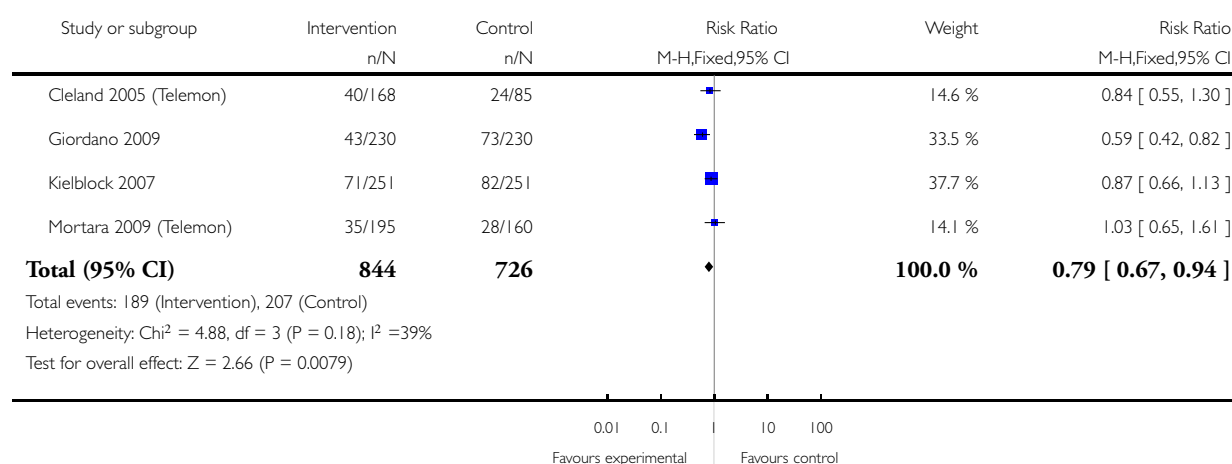


### Analysis 3.6. Comparison 3 Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation rate, Outcome 6 Sensitivity analysis (full peer-reviewed publications only), follow-up period (> 6 months), CHF-related hospitalisation: telemonitoring vs usual care.

Review: Structured telephone support or telemonitoring programmes for patients with chronic heart failure

Comparison: 3 Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation rate

Outcome: 6 Sensitivity analysis (full peer-reviewed publications only), follow-up period (> 6 months), CHF-related hospitalisation: telemonitoring vs usual care



## APPENDICES

### Appendix I. Search strategies

#### Cochrane Central Register of Controlled Trials (CENTRAL), Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment Database (HTA) on *The Cochrane Library*

- #1 MeSH descriptor Heart Failure explode all trees
- #2 heart next failure in All Text
- #3 cardiac next failure in All Text
- #4 (#1 or #2 or #3)
- #5 MeSH descriptor telemedicine explode all trees
- #6 MeSH descriptor telecommunications explode all trees
- #7 MeSH descriptor case management this term only
- #8 MeSH descriptor comprehensive health care explode all trees
- #9 MeSH descriptor disease management this term only
- #10 MeSH descriptor home care services this term only
- #11 MeSH descriptor Home Care Services, Hospital-Based this term only
- #12 MeSH descriptor Nurse Clinicians this term only
- #13 MeSH descriptor nurse practitioners this term only
- #14 MeSH descriptor monitoring, ambulatory this term only

#15 MeSH descriptor clinical protocols this term only  
 #16 MeSH descriptor patient care planning this term only  
 #17 tele\* in All Text  
 #18 (remote in All Text near/3 consult\* in All Text)  
 #19 disease next management in All Text  
 #20 nurse next led in All Text  
 #21 phone\* in All Text  
 #22 (manage\* in All Text near/3 program\* in All Text)  
 #23 (nurse\* in All Text near/3 manage\* in All Text)  
 #24 case next management in All Text  
 #25 (home in All Text near/3 service\* in All Text) 7  
 #26 nurse next practitioner\* in All Text  
 #27 nurse next clinician\* in All Text  
 #28 care next plan\* in All Text  
 #29 (#5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13)  
 #30 (#14 or #15 or #16 or #17 or #18 or #19 or #20 or #21)  
 #31 (#22 or #23 or #24 or #25 or #26 or #27 or #28)  
 #32 (#29 or #30 or #31)  
 #33 (#4 and #32)

#### **Medline and Medline In Process on Ovid**

1 exp Heart Failure/  
 2 heart failure.tw.  
 3 cardiac failure.tw.  
 4 or/1-3  
 5 exp Telemedicine/  
 6 exp Telecommunications/  
 7 Case Management/  
 8 exp Comprehensive Health Care/  
 9 disease management/  
 10 tele med\$.tw.  
 11 telecare\$.tw.  
 12 telecardiol\$.tw.  
 13 telemonitor\$.tw.  
 14 teleconsult\$.tw.  
 15 teleconferenc\$.tw.  
 16 telecommunicat\$.tw.  
 17 telephon\$.tw.  
 18 telehealth\$.tw.  
 19 telemetry.tw.  
 20 (remote\$ adj3 consult\$.tw.  
 21 tele-med\$.tw.  
 22 tele-consult\$.tw.  
 23 tele-conferenc\$.tw.  
 24 tele-health\$.tw.  
 25 Home Care Services/  
 26 Home Care Services, Hospital-Based/  
 27 disease management.tw.  
 28 Nurse Clinicians/  
 29 Nurse Practitioners/  
 30 nurse led.tw.  
 31 Monitoring, Ambulatory/

32 telehome.tw.  
 33 tele-home.tw.  
 34 phone\$.tw.  
 35 Clinical Protocols/  
 36 Patient Care Planning/  
 37 or/5-36  
 38 37 and 4  
 39 randomized controlled trial.pt.  
 40 controlled clinical trial.pt.  
 41 Randomized controlled trials/  
 42 random allocation/  
 43 double blind method/  
 44 single-blind method/  
 45 or/39-44  
 46 exp animal/ not humans/  
 47 45 not 46  
 48 clinical trial.pt.  
 49 exp Clinical Trials as Topic/  
 50 (clin\$ adj25 trial\$).ti,ab.  
 51 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj (blind\$ or mask\$)).ti,ab.  
 52 placebos/  
 53 placebo\$.ti,ab.  
 54 random\$.ti,ab.  
 55 research design/  
 56 or/48-55  
 57 56 not 46  
 58 57 or 47  
 59 38 and 58  
 60 (2006\$ or 2007\$ or 2008\$).ed.  
 61 59 and 60

## EMBASE (Ovid)

1 exp Heart Failure/  
 2 heart failure.tw.  
 3 cardiac failure.tw.  
 4 or/1-3  
 5 exp Telemedicine/  
 6 exp Telecommunications/  
 7 Case Management/  
 8 disease management/  
 9 telemed\$.tw.  
 10 telecare\$.tw.  
 11 telecardiol\$.tw.  
 12 telemonitor\$.tw.  
 13 teleconsult\$.tw.  
 14 teleconferenc\$.tw.  
 15 telecommunicat\$.tw.  
 16 telephon\$.tw.  
 17 telehealth\$.tw.  
 18 telemetry.tw.  
 19 (remote\$ adj3 consult\$).tw.  
 20 tele-med\$.tw.

21 tele-consult\$.tw.  
 22 tele-conferenc\$.tw.  
 23 tele-health\$.tw.  
 24 Home Care/  
 25 Home Monitoring/  
 26 disease management.tw.  
 27 Nurse Practitioners/  
 28 nurse led.tw.  
 29 Ambulatory Monitoring/  
 30 telehome.tw.  
 31 tele-home.tw.  
 32 phone\$.tw.  
 33 Patient Care Planning/  
 34 or/5-33  
 35 4 and 34  
 36 controlled clinical trial/  
 37 random\$.tw.  
 38 randomized controlled trial/  
 39 follow-up.tw.  
 40 double blind procedure/  
 41 placebo\$.tw.  
 42 placebo/  
 43 factorial\$.ti,ab.  
 44 (crossover\$ or cross-over\$).ti,ab.  
 45 (double\$ adj blind\$).ti,ab.  
 46 (singl\$ adj blind\$).ti,ab.  
 47 assign\$.ti,ab.  
 48 allocat\$.ti,ab.  
 49 volunteer\$.ti,ab.  
 50 Crossover Procedure/  
 51 Single Blind Procedure/  
 52 or/36-51  
 53 52 and 35  
 54 (2006\$ or 2007\$ or 2008\$).em.  
 55 53 and 54

## **CINHAL (Ovid)**

1 cardiac output, decreased/ or heart failure, congestive/ or dyspnea, paroxysmal/ or ventricular dysfunction/ or ventricular dysfunction, left/ or ventricular dysfunction, right/  
 2 (heart adj failure).tw.  
 3 (cardiac adj failure).tw.  
 4 1 or 3 or 2  
 5 (home adj care).tw.  
 6 (patient adj care).tw.  
 7 patient care/ or case management/ or "continuity of patient care"/ or discharge planning/ or disease management/ or multidisciplinary care team/ or nursing care/ or nursing care delivery systems/ or differentiated nursing practice/ or functional nursing/ or modular nursing/ or primary nursing/ or progressive patient care/ or team nursing/ or total patient care nursing/ or nursing care studies/ or nursing intensity/ or nursing process/ or nursing assessment/ or nursing care plans/ or nursing diagnosis/ or nursing interventions/ or nursing outcomes/ or nursing protocols/ or nursing care plans, computerized/ or nursing skills/ or patient care conferences/ or clinical conferences/ or patient-family conferences/ or primary health care/ or "quality of health care"/ or accountability/ or guideline adherence/ or "outcomes (health care)"/ or medical futility/ or outcome assessment/ or "outcomes of prematurity"/ or treatment outcomes/ or fatal outcome/ or treatment failure/ or practice guidelines/



8 (manag\* adj care).tw.  
 9 managed care programs/ or health maintenance organizations/ or independent practice associations/ or preferred provider organizations/ or provider-sponsored organizations/  
 10 health maintenance organizations/ or medical practice/ or nursing practice/ or advanced nursing practice/ or nursing practice, evidence-based/ or nursing practice, research-based/ or nursing practice, theory-based/ or "scope of nursing practice"/ or occupational therapy practice/ or prescribing patterns/ or prescriptive authority/ or professional practice, evidence-based/ or medical practice, evidence-based/ or exp nursing practice, evidence-based/ or occupational therapy practice, evidence-based/ or physical therapy practice, evidence-based/ or exp professional practice, research-based/ or exp professional practice, theory-based/  
 11 (home adj care).tw.  
 12 home health care/ or home apnea monitoring/ or home intravenous therapy/ or home nursing, professional/  
 13 home care.mp. [mp=title, subject heading word, abstract, instrumentation]  
 14 patient care/ or after care/ or cardiovascular care/ or home nursing/ or nursing care/ or self care/ or self administration/ or self medication/  
 15 (home adj intervention\*).tw.  
 16 (secondary adj prevent\*).tw.  
 17 (disease adj management).tw.  
 18 homecare.tw.  
 19 rehabilitat\*.tw.  
 20 rehabilitation/ or rehabilitation, cardiac/ or conditioning, cardiopulmonary/ or rehabilitation, community-based/  
 21 community health nursing/ or home nursing, professional/ or rehabilitation nursing/ or rural health nursing/  
 22 nurs\*.tw.  
 23 nurses/ or advanced practice nurses/ or clinical nurse specialists/ or nurse practitioners/ or case managers/  
 24 multidisciplin\*.tw.  
 25 (discharge adj plan\*).tw.  
 26 patient discharge/ or discharge planning/ or early patient discharge/ or patient discharge education/ or transfer, discharge/  
 27 or/5-26  
 28 27 and 4  
 29 telecommunications/ or interactive voice response systems/ or telecommuting/ or teleconferencing/ or telefacsimile/ or telehealth/ or telemedicine/ or remote consultation/ or telepathology/ or teleradiology/ or telenursing/ or telepsychiatry/ or telephone/ or wireless communications/  
 30 telecommunicat\*.tw.  
 31 (tele adj communicat\*).tw.  
 32 telemed\*.tw.  
 33 (tele adj med\*).tw.  
 34 telecar\*.tw.  
 35 (tele adj car\*).tw.  
 36 telemonitor\*.tw.  
 37 (tele adj monitor\*).tw.  
 38 teleconsult\*.tw.  
 39 (tele adj consult\*).tw.  
 40 teleconferenc\*.tw.  
 41 (tele adj conferenc\*).tw.  
 42 telehealth\*.tw.  
 43 (tele adj health\*).tw.  
 44 telephon\*.tw.  
 45 telemetr\*.tw.  
 46 (tele adj metr\*).tw.  
 47 (remote adj consult\*).tw.  
 48 phon\*.tw.  
 49 (electronic\* adj communicat\*).tw.  
 50 (tele adj nurs\*).tw.  
 51 telehealth/ or telemedicine/ or remote consultation/ or telenursing/  
 52 or/29-51

53 52 and 28  
 54 Experimental Studies/  
 55 exp Clinical trials/  
 56 ((control\* or clinic\* or prospectiv\*) adj5 (trial\* or study or studies)).tw.  
 57 ((allocat\* or assign\* or divid\*) adj5 (condition\* or experiment\* or treatment\* or control\* or group\*)).tw.  
 58 ((singl\* or doubl\*) adj (blind\* or mask\*)).tw.  
 59 cross?over\*.tw.  
 60 placebo\*.tw.  
 61 exp Clinical research/  
 62 Comparative studies/  
 63 exp Evaluation research/  
 64 exp "control (research)"/  
 65 Random assignment/  
 66 exp Prospective studies/  
 67 exp Evaluation research/  
 68 random\*.tw.  
 69 RCT.tw.  
 70 (compar\* adj5 (trial\* or study\* or studies)).tw.  
 71 or/54-70  
 72 53 and 71  
 77 limit 72 to yr="2006 - 2008"

#### **AMED (Allied and Complementary Medicine)**

1 exp Heart Failure Congestive/  
 2 heart failure.tw.  
 3 cardiac failure.tw.  
 4 or/1-3  
 5 exp Telecommunications/  
 6 exp Comprehensive Health Care/  
 7 disease management/  
 8 telemed\$.tw.  
 9 telecare\$.tw.  
 10 telecardiol\$.tw.  
 11 telemonitor\$.tw.  
 12 teleconsult\$.tw.  
 13 teleconferenc\$.tw.  
 14 telecommunicat\$.tw.  
 15 telephon\$.tw.  
 16 telehealth\$.tw.  
 17 telemetry.tw.  
 18 (remote\$ adj3 consult\$).tw.  
 19 tele-med\$.tw.  
 20 tele-consult\$.tw.  
 21 tele-conferenc\$.tw.  
 22 tele-health\$.tw.  
 23 Home Care Services/  
 24 disease management.tw.  
 25 nurse led.tw.  
 26 telehome.tw.  
 27 tele-home.tw.  
 28 phone\$.tw.  
 29 Clinical Protocols/

30 exp patient care management/  
31 nurses/  
32 "Rural health services"/  
33 community health nursing/  
34 or/5-33  
35 4 and 34  
36 (2006\$ or 2007\$ or 2008\$).up.  
37 35 and 36

### **Science Citations Index and Conference Citations Index on ISI Web of Knowledge**

# 11 #9 and #10  
Databases=SCI-EXPANDED, CPCI-S Timespan=2006-2008  
# 10 ts=(random\* or (clinical same trial) or rct or groups or (clinical same study)) and ts=("heart failure" or "cardiac failure")  
# 9 #1 and #8  
# 8 #2 or #3 or #4 or #5 or #6 or #7  
# 7 ts=("case management")  
# 6 ts=("home care")  
# 5 ts=("disease management")  
# 4 ts=((nurse same led) or (nurse same practitioner\*) or (nurse same clinician\*))  
# 3 ts=(remote\* same consult\*)  
# 2 ts=(tele\* or phone\* )  
# 1 ts=("heart failure" or "cardiac failure")

## **HISTORY**

Protocol first published: Issue 3, 2008

Review first published: Issue 8, 2010

## **CONTRIBUTIONS OF AUTHORS**

### **Sally C Inglis**

Responsible for conception and design of this study and the previous version of this review (Clark 2007a). Responsible for coordinating and completing the review. Responsible for all data included in the review including designing, undertaking searches, retrieving search results, screening papers for inclusion, appraising quality of papers, extracting data from papers, contacting paper authors for information, entering data into RevMan, analysis and interpretation of data, drafting of the review or revising it critically for important intellectual content and final approval of the version to be published. Performed previous work that was the foundation of this study.

### **Robyn A Clark**

Responsible for conception and design of this study and the previous version of this review (Clark 2007a). Responsible for conceiving the initial idea for the previous review (Clark 2007a). Responsible for all data included in the review including designing, undertaking searches, retrieving search results, screening papers for inclusion, appraising quality of papers, extracting data from papers, contacting paper authors for information, entering data into RevMan, analysis and interpretation of data, drafting of the review or revising it critically for important intellectual content and final approval of the version to be published. Performed previous work that was the foundation of this study.

### **Finlay A McAlister**

Responsible for checking data extraction, assisting with analyses and interpretation of data (providing a methodological and clinical view), revising the review critically for important intellectual content and final approval of the version to be published. Performed previous work that was the foundation of this study.

### **Jocasta Ball**

Responsible to retrieving studies for review, for drafting of the review and final approval of the version to be published.

### **Christian Lewinter**

Responsible for handsearching of conference abstracts, retrieving studies for review and final approval of the version to be published.

### **Damien Cullington**

Responsible for handsearching of conference abstracts, retrieving studies for review and final approval of the version to be published.

### **Simon Stewart**

Responsible for interpretation of data (providing a clinical view) and final approval of the version to be published. Performed previous work that was the foundation of this study.

### **John GF Cleland**

Consulted on design of review. Responsible for adjudicating paper inclusion, interpretation of data (providing a methodological and clinical view), revising the review critically for important intellectual content and final approval of the version to be published. Performed previous work that was the foundation of this study. Guarantor for this review.

## **DECLARATIONS OF INTEREST**

Professor Cleland has received research funds (within the last five years) from the European Union and Phillips Health care for the conduct of TENS-HMS study. He has received honoraria from Phillips for speaking on the subject of telemonitoring (this funding is not connected with this review).

## SOURCES OF SUPPORT

### Internal sources

- No internal source of funding was received for this review, Australia.

### External sources

- National Health and Medical Research Council of Australia, Australia.
- National Heart Foundation of Australia, Australia.
- National Institute of Clinical Studies, Australia.
- Alberta Heritage Foundation for Medical Research, Canada.

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Since our protocol was published we decided to limit the studies included to randomised controlled trials only, we also decided to limit the inclusion of data in our meta-analysis to studies for which a full peer-reviewed publication was available. We also decided that the planned sensitivity analysis was no longer appropriate due to considerable advances in diagnosis and knowledge of chronic heart failure and performed sensitivity analyses examining type of publication and length of intervention.