Structured telephone support or non-invasive telemonitoring for patients with heart failure (Review)

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[Intervention Review]

Structured telephone support or non-invasive telemonitoring for patients with heart failure

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A B S T R A C T

Background

Specialised disease management programmes for heart failure aim to improve care, clinical outcomes and/or reduce healthcare utilisation. Since the last version of this review in 2010, several new trials of structured telephone support and non-invasive home telemonitoring have been published which have raised questions about their effectiveness.

Objectives

To review randomised controlled trials (RCTs) of structured telephone support or non-invasive home telemonitoring compared to standard practice for people with heart failure, in order to quantify the effects of these interventions over and above usual care.

Search methods

We updated the searches of the Cochrane Central Register of Controlled Trials (CENTRAL), Database of Abstracts of Reviews of Effects (DARE), Health Technology AsseFssment Database (HTA) on the Cochrane Library; MEDLINE (OVID), EMBASE (OVID), CINAHL (EBSCO), Science Citation Index Expanded (SCI-EXPANDED), Conference Proceedings Citation Index- Science (CPCI-S) on Web of Science (Thomson Reuters), AMED, Proquest Theses and Dissertations, IEEE Xplore and TROVE in January 2015. We handsearched bibliographies of relevant studies and systematic reviews and abstract conference proceedings. We applied no language limits.

Selection criteria

We included only peer-reviewed, published RCTs comparing structured telephone support or non-invasive home telemonitoring to usual care of people with chronic heart failure. The intervention or usual care could not include protocol-driven home visits or more intensive than usual (typically four to six weeks) clinic follow-up.

Data collection and analysis

We present data as risk ratios (RRs) with 95% confidence intervals (CIs). Primary outcomes included all-cause mortality, all-cause and heart failure-related hospitalisations, which we analysed using a fixed-effect model. Other outcomes included length of stay, health-related quality of life, heart failure knowledge and self care, acceptability and cost; we described and tabulated these. We performed meta-regression to assess homogeneity (the null hypothesis) in each subgroup analysis and to see if the effect of the intervention varied according to some quantitative variable (such as year of publication or median age).

Main results

We include 41 studies of either structured telephone support or non-invasive home telemonitoring for people with heart failure, of which 17 were new and 24 had been included in the previous Cochrane review. In the current review, 25 studies evaluated structured telephone support (eight new studies, plus one study previously included but classified as telemonitoring; total of 9332 participants), 18 evaluated telemonitoring (nine new studies; total of 3860 participants). Two of the included studies trialled both structured telephone support and telemonitoring compared to usual care, therefore 43 comparisons are evident.

Non-invasive telemonitoring reduced all-cause mortality (RR 0.80, 95% CI 0.68 to 0.94; participants = 3740; studies = 17; I^2 = 24%, GRADE: moderate-quality evidence) and heart failure-related hospitalisations (RR 0.71, 95% CI 0.60 to 0.83; participants = 2148; studies = 8; I^2 = 20%, GRADE: moderate-quality evidence). Structured telephone support reduced all-cause mortality (RR 0.87, 95% CI 0.77 to 0.98; participants = 9222; studies = 22; I^2 = 0%, GRADE: moderate-quality evidence) and heart failure-related hospitalisations (RR 0.85, 95% CI 0.77 to 0.93; participants = 7030; studies = 16; I^2 = 27%, GRADE: moderate-quality evidence).

Neither structured telephone support nor telemonitoring demonstrated effectiveness in reducing the risk of all-cause hospitalisations (structured telephone support: RR 0.95, 95% CI 0.90 to 1.00; participants = 7216; studies = 16; I^2 = 47%, GRADE: very low-quality evidence; non-invasive telemonitoring: RR 0.95, 95% CI 0.89 to 1.01; participants = 3332; studies = 13; I^2 = 71%, GRADE: very low-quality evidence).

Seven structured telephone support studies reported length of stay, with one reporting a significant reduction in length of stay in hospital. Nine telemonitoring studies reported length of stay outcome, with one study reporting a significant reduction in the length of stay with the intervention. One telemonitoring study reported a large difference in the total number of hospitalisations for more than three days, but this was not an analysis of length of stay per hospitalisation. Nine of 11 structured telephone support studies and five of 11 telemonitoring studies reported significant improvements in health-related quality of life. Nine structured telephone support studies and six telemonitoring studies reported costs of the intervention or cost effectiveness. Three structured telephone support studies and one telemonitoring study reported a decrease in costs and two telemonitoring studies reported increases in cost, due both to the cost of the intervention and to increased medical management. Adherence was rated between 55.1% and 98.5% for those structured telephone support and telemonitoring studies which reported this outcome. Participant acceptance of the intervention was reported in the range of 76% to 97% for studies which evaluated this outcome. Seven of nine studies that measured these outcomes reported significant improvements in heart failure knowledge and self-care behaviours.

Authors' conclusions

For people with heart failure, structured telephone support and non-invasive home telemonitoring reduce the risk of all-cause mortality and heart failure-related hospitalisations; these interventions also demonstrated improvements in health-related quality of life and heart failure knowledge and self-care behaviours. Studies also demonstrated participant satisfaction with the majority of the interventions which assessed this outcome.

PLAIN LANGUAGE SUMMARY

Structured telephone support and non-invasive telemonitoring in the management of people with heart failure

Review question

We reviewed the evidence about the effect of structured telephone support and non-invasive telemonitoring in the management of people with heart failure. We found 41 studies. Two of the included studies trialled both structured telephone support and telemonitoring compared to usual care, therefore 43 comparisons are evident. The evidence is current to January 2015.

Background

In the context of limited health funding and a rapidly expanding population of older people, it is increasingly difficult for healthcare systems to provide high-quality care to those with heart failure. Multidisciplinary specialist heart failure clinics are available only to a minority of people and do not have the capacity for frequent patient review. Patients may be unwilling or unable to make frequent clinic attendance due to cost, difficulty with transport or disability and frailty. Structured telephone support and telemonitoring can provide specialised heart failure care to a large number of people with limited access to healthcare services.

Study characteristics

We include 41 full-text peer-reviewed studies of either structured telephone support or home telemonitoring in this review. Twenty-five studies evaluate structured telephone support (eight new studies, plus one previously included study now classified as telemonitoring; total of 9332 participants), 18 evaluated telemonitoring (nine new studies; total of 3860 participants) and two studies evaluated both interventions (included in listed counts).

Key results

This review demonstrates that supporting people with heart failure at home using information technology can reduce the rates of death and heart failure-related hospitalisation. It can improve people's quality of life and knowledge about heart failure and self care. Most patients, even those who are elderly, learn to use the technology easily and are satisfied with these interventions.

Quality of the evidence

We assessed the quality of the evidence for the primary outcomes in this review (all-cause mortality, all-cause hospitalisation and heart failure-related hospitalisation) according to GRADE criteria. We rated it from very low (all-cause hospitalisations) to moderate (all-cause mortality and heart failure-related hospitalisations).

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Impact of structured telephone support and telemonitoring in heart failure on all-cause mortality[2]

Patient or population: people with heart failure
Setting:
Intervention: structured telephone support or telemonitoring
Comparison: usual care

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with usual care	Risk with Impact of structured telephone support and telemonitoring in CHF on all-cause mortality				
All-cause mortality: Structured telephone support versus usual care	Study population		RR 0.87 (0.77 to 0.98)	9222 (22 RCTs)	MODERATE [1]	
	116 per 1000	101 per 1000 (89 to 113)				
	Moderate risk population					
	109 per 1000	94 per 1000 (84 to 106)				
All-cause mortality: Telemonitoring versus usual care	Study population		RR 0.80 (0.68 to 0.94)	3740 (17 RCTs)	MODERATE [1]	
	145 per 1000	116 per 1000 (99 to 136)				
	Moderate risk population					
	155 per 1000	124 per 1000 (105 to 145)				

***The risk in the intervention group** (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: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1]Publication bias strongly suspected.
[2] Length of follow-up ranged from 3 months to 18 months for structured telephone support studies and 3 months to 26 months for
telemonitoring studies.

BACKGROUND

A 2010 Cochrane review of structured telephone support or home telemonitoring for people with heart failure (HF) concluded that structured telephone support and telemonitoring were effective in reducing the risk of all-cause mortality and heart failure related-hospitalisations (Inglis 2010). Since then, doubt has been cast on the efficacy of these interventions, due to publication of several neutral studies (Anker 2011; Chaudhry 2010 (Tele-HF); Koehler 2011 (TIM-HF)). Current international heart failure guidelines have so far not recommended widespread implementation of remote monitoring due to these conflicting trial results (National Heart Foundation of Australia 2011; Mant 2011; McMurray 2012; Yancy 2013) and have called for more research before recommending these interventions Ponikowski 2014. This review sought to update the previous version by identifying and classifying all peer-reviewed trials of structured telephone support or non-invasive home telemonitoring published since the Inglis 2010 review.

Description of the condition

Heart failure (HF) 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. Heart failure often results from damage to the myocardium for which the aetiology differs according to the population studied. In high-income countries, hypertension and coronary heart disease are the most important causes of heart failure (Cleland 2011; Gerber 2015; Maggioni 2013; Yusuf 2014). Hypertension is a risk factor for coronary disease, which is the most common direct cause for heart failure with reduced ejection fraction (HFrEF). Hypertension, often associated with atrial fibrillation, is the predominant cause of heart failure with preserved ejection fraction (HFpEF). In low- to middle-income countries, the syndrome is also often the result of longstanding hypertension but cardiomyopathy and rheumatic heart disease are also common. However, the incidence of atherosclerotic disease is increasing in low- to middle-income countries (Callender 2014b). Heart failure exerts a substantial burden on healthcare systems, due to the high consumption of human resources caused predominantly by repeated and lengthy admissions to hospital (Dunlay 2014).

Ageing of populations will drive up the prevalence of heart failure internationally, making it increasingly difficult to maintain the quality of care. Switching resources from crisis management (by hospitalising people) to health maintenance (through structured telephone support or home telemonitoring) may be an affordable method to maintain and improve the quality of care for heart failure.

Pharmacological treatments, including angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers, an-giotensin-receptor neprilysin inhibitors beta-blockers, aldosterone antagonists and ivabradine, and devices such as implantable defibrillators and cardiac resynchronisation therapy, can improve symptoms and prolong survival in those with heart failure with reduced left ventricular ejection fraction (LVEF) (McMurray 2012). In people who are stable, mildly symptomatic (NYHA I - II) and optimally treated, annual mortality is 1.6% (Linde 2008), but it rises up to 12% for those with moderate to severe symptoms (Cleland 2006a; Kjekshus 2007). Several projection models predict an increase in the prevalence of HF and the number of HF hospitalisations by more than 20% in the next 20 years (Heidenreich 2013; Stewart 2013).

Fewer RCTs of medicines or devices have been conducted in people with heart failure with preserved LVEF (HFpEF) and none have been conclusively positive (Cleland 2014b). RCTs in participants with stable HFpEF suggest an annual mortality of 5% to 13% (Cleland 2006b; MAGGIC 2012; Zile 2002) and a similar rate of hospitalisations for worsening heart failure (Massie 2008).

For acute heart failure, no new treatments have been identified in the last 40 years and much of clinical practice is opinion- rather than evidence-based (Mebazaa 2015). In RCTs, six-month mortality ranges from 11% to 24%, depending on age (Metra 2015). Most trials of telemonitoring have focused on people with a recent history of heart failure hospitalisation and have shown a high mortality in those assigned to usual care, which is consistent with the above.

The worse outcome of participants in epidemiological studies compared to RCTs (Jhund 2009; Levy 2002) may reflect the strict inclusion/exclusion criteria of randomised controlled trials, with selection of better-educated participants with fewer comorbidities and a lower likelihood that older and sicker people will agree to be researched (Cleland 2007; Jhund 2009; Lenzen 2005). Also, participants in trials are likely to be much more closely monitored, and this may have a favourable influence on prognosis, consistent with the evidence from trials of telemonitoring. However, perhaps the most important reason why people in surveys have an outcome similar to those in trials of acute heart failure is because that is the point at which most people in surveys of heart failure are enrolled (Cleland 2001). Surveys suggest that about 20% of participants 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 people. Using National Audit data for England and Wales, which captures an even broader population admitted with heart failure, inpatient mortality ranges from less than 5% in those aged under 65 years to almost 15% in those aged over 84 years. Rates of death and readmission in the following weeks are also high; 30-day mortality after discharge ranges from under 10% in people aged less than 65 years to more than 25% in those aged over 84 years, whilst 30-day rates for readmission regardless of age run at about 15%, although only one-third are primarily due to heart failure (Cleland 2003; Cleland 2011). In

contrast to clinical trials, in epidemiological studies LVEF does not appear to be a major determinant of prognosis, possibly because people with heart failure with preserved ejection fraction are often older and have more comorbidities (Bhatia 2006; Cleland 2007; Cleland 2011; Owan 2006).

Description of the intervention

The effectiveness of multidisciplinary approaches to managing people with heart failure has been demonstrated by meta-analyses (Holland 2005; McAlister 2004) and specialist heart failure disease management programmes are recommended in best practice guidelines (Mant 2011; McMurray 2012; National Heart Foundation of Australia 2011; Yancy 2013).To date, trials of specialist, multidisciplinary heart failure 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 heart failure populations who have difficulty accessing multidisciplinary heart failure 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; Inglis 2010).

In this review, we classified programmes a priori as being 'structured telephone support' if the monitoring or self-care management or both were 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 blue-tooth transmission of physiological and other non-invasive data. This review focuses only on non-invasive remote monitoring of people with heart failure. We consider that there is significant heterogeneity in monitoring of people using non-invasive and invasive technologies, in particular monitoring using implanted therapeutic devices such as defibrillators; this will form a part of future reviews.

We consider that structured telephone support and telemonitoring are two similar but distinctly different interventions, and 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 heart-failure 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 criterion.

How the intervention might work

Some studies have demonstrated a beneficial effect of remote monitoring on mortality and morbidity in people with heart failure. The mechanisms by which improvements in outcomes with these interventions is achieved are not clear, but may include enhanced self care by improving the person's knowledge and adherence through education and monitoring, higher prescription rates of guideline-based medication by clinicians, or earlier intervention when heart failure worsens. It might also be that recipients find the presence of remote monitoring comforting and that it reduces their anxiety and need for formal contact with healthcare providers. A common finding is that participants in the active arm of studies showing a benefit from telemonitoring are more likely to be on higher doses of disease-modifying agents, which probably mediates benefit (Abraham 2011; Antonicelli 2010; Cleland 2005 (Struct Tele) (TENS-HMS)). This makes sense; simply monitoring a person will not modify the course of the disease unless action results.

Structured telephone support and home telemonitoring are more likely to be effective when delivery of care by conventional means is deficient. Trials that select participants carefully and ensure that treatment is optimal prior to randomisation may be less likely to show a benefit from intervention. Thus, trials that randomly assign individual participants to different strategies may place structured telephone support and home telemonitoring at a disadvantage, since care is likely to improve in those assigned to conventional care.

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. Results from earlier systematic reviews and meta-analyses (Clark 2007a; Inglis 2010; Klersy 2009; Louis 2003; McAlister 2004) supported the beneficial effect of non-invasive home telemonitoring or structured telephone support or both within heart failure disease management programmes on mortality and hospitalisation. In the 2010 Cochrane review, participants assigned to telemonitoring had lower all-cause mortality and heart failure-related hospitalisations, while structured telephone support mainly reduced heart failure-related hospitalisations (Inglis 2010). However several large trials of remote monitoring interventions have since been published, and some have shown a lack of clinical benefit. Also, one criticism of the previous Cochrane review (Inglis

2010) was that it accepted the study by Kielblock 2007 as an RCT while others considered it to be a cohort study (Anker 2011). A more recent systematic review and meta-analysis included some (but not all) of the newer trials and excluded the Kielblock study, and again provided support for remote monitoring interventions in reducing all-cause mortality. However, only trials that focused on people with a recent discharge diagnosis of heart failure were included (Pandor 2013b).

Remote monitoring interventions have often been more effective in reducing all-cause mortality rather than heart failure-related hospitalisations, and some trials have even reported an increase in the number of hospitalisations (Cleland 2005 (Struct Tele) (TENS-HMS); Cleland 2005 (Telemon) (TENS-HMS); Steventon 2012a; Steventon 2013a). This may reflect the effect of overcautious, risk-averse health professionals increasing participant anxiety. Alternatively, appropriate expert review and timely hospitalisation can be life-saving and improved survival means that more people are alive and at risk of hospitalisation. Given the conflicting evidence on this topic and the interests of the European Society of Cardiology and the American Heart Association heart failure guideline committees, an updated systematic review incorporating recent results is appropriate at this time.

OBJECTIVES

To review randomised controlled trials (RCTs) of structured telephone support or non-invasive home telemonitoring compared to standard practice for people with heart failure, in order to quantify the effects of these interventions over and above usual care.

This is an update of previous versions (Clark 2007a; Inglis 2010).

METHODS

Criteria for considering studies for this review

Types of studies

We include randomised controlled trials (RCTs) comparing heart failure management delivered via structured telephone support or non-invasive home telemonitoring with usual post-discharge care for people with heart failure living within the community. We include only RCTs that have been published in full in the peer-reviewed literature. We excluded any studies that did not report data for any of our outcomes of interest in an extractable format (we contacted authors of each primary study in an attempt to obtain data).

Types of participants

Adults (aged 18 years and over) of either sex, any age or ethnic group, with a definitive diagnosis of heart failure. Participants may have been recently discharged from an acute-care setting (including emergency departments and acute assessment units) 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. We excluded studies dealing with general cardiac disorders rather than specifically with heart failure.

Types of interventions

Structured telephone support or non-invasive telemonitoring interventions needed to be scheduled, as opposed to offering telephone follow-up on an 'as needed' basis. The intervention must have been initiated by a healthcare professional (medical, nursing, social work, pharmacist) and delivered to people with heart failure living in the community as the only aftercare intervention, without protocol-driven home visits or intensified clinic follow-up. The intervention had to be targeted at the person and intended to address their concerns and problems, not those of caregivers. The participant must not have been visited at home by a specialised heart failure healthcare professional or study personnel for the purpose of education or clinical assessment other than as an initiation visit to set up equipment. 'Usual care' consisted of standard post-discharge care without intensified attendance at cardiology clinics or clinic-based heart failure disease management programme, or home visiting as described above. We excluded studies if there was any previous exposure to telemonitoring or structured telephone support for the usual care or intervention arms prior to the start of the study.

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)
- All-cause hospitalisations (calculated as the proportion of participants readmitted to hospital at least once during the period of follow-up)
- Heart failure-related hospitalisations (calculated as the proportion of participants readmitted to hospital at least once during the period of follow-up due to heart failure)

Secondary outcomes

- Length of stay (number of days for hospitalisations)
- Health-related quality of life as assessed by validated questionnaires
- Healthcare costs and cost effectiveness (reduction in healthcare costs, cost of care)

- Adherence to the intervention
- Participant acceptance of the intervention
- Heart failure knowledge and self care as assessed by validated questionnaires

Search methods for identification of studies

This review updates a previously published Cochrane review which examined the period 2006 to November 2008 (Inglis 2010); that in turn had updated a previously published review examining the period January 1966 to May 2006 (Clark 2007a).

For this update, we searched all databases from 2008 until January 2015, without any language restrictions. If we found an abstract or thesis reporting an eligible RCT in the searches, then we included the study as long as a full-text peer-reviewed publication was available (online or in print) by 1 June 2015.

Electronic searches

We searched the following databases on 12 January 2015:

1. Cochrane Central Register of Controlled Trials (CENTRAL) (Issue 12 of 12, 2014, Cochrane Library);
2. Database of Abstracts of Reviews of Effects (DARE) (Issue 4 of 4, 2014, Cochrane Library);
3. Health Technology Assessment Database (HTA) (Issue 4 of 4, 2014, Cochrane Library),
4. MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, MEDLINE Daily and OLDMEDLINE (OVID, 1946 to 12 January 2015);
5. EMBASE (OVID, 1980 to 2015 week 2);
6. CINAHL Plus with Full text (EBSCO, 1937 to 12 January 2015);
7. Science Citation Index Expanded (SCI-EXPANDED, 1970 to 12 January 2015) - and Conference Proceedings Citation Index- Science (CPCI-S, 1990 to 12 January 2015) on Web of Science (Thomson Reuters);
8. AMED (to 31 December 2014).

The search strategies are listed in Appendix 1 (for this version of the review) and Appendix 2 (for the 2010 version of the review (Inglis 2010)).

Searching other resources

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

1. IEEE Xplore (2008 to 31 December 2014);
2. TROVE (2008 to 31 December 2014);
3. Proquest Digital Dissertations (2008 to 31 December 2014).

We handsearched bibliographies of identified studies and published systematic reviews relevant to this topic area. We also handsearched abstracts and conference proceedings from the following international conferences for relevant studies:

1. European Society of Cardiology Congress (2009, 2010, 2011, 2012, 2013, 2014);
2. American College of Cardiology Congress (2009, 2010, 2011, 2012, 2013, 2014);
3. American Heart Association (2009, 2010, 2011, 2012, 2013, 2014);
4. World Congress of Cardiology (2010, 2012, 2014);
5. Heart Failure Society of America (2009, 2010, 2011, 2012, 2013, 2014);
6. European Society of Cardiology Heart Failure Congress (2009, 2010, 2011, 2012, 2013, 2014);
7. European Society of Cardiology Annual Spring Meeting of Cardiovascular Nursing (2009, 2010, 2011, 2012, 2013, 2014).

Data collection and analysis

Two review authors (from SCI, RAC or RD) checked all identified abstracts and results from database searches for relevance to the review topic. If the reference appeared to be relevant, we obtained a full copy of the reference for detailed review, to determine inclusion/exclusion of the study.

Selection of studies

Two review authors (SCI and RAC) independently reviewed the results of each search according to exclusion and inclusion criteria. We excluded studies 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 participants in the intervention or control groups. A third review author (JGFC) adjudicated in cases of disagreement between the first two review authors.

Data extraction and management

Two review authors (RD and SA) abstracted the data from the included studies in a blinded manner, and a third review author (either SCI or RAC) checked all extracted data.

Assessment of risk of bias in included studies

Two review authors (RD and SA) independently assessed risks of bias for each study, and a third review author (SCI or RAC) checked them, using the Cochrane tool for assessing risk of bias (Higgins 2011).

Measures of treatment effect

Data were dichotomous and the statistical method used for analysis was a fixed-effect analysis model (Deeks 2011). We calculated risk ratios (RRs) and 95% confidence intervals (CIs) for all-cause mortality, and proportions of participants with at least one all-cause and heart failure-related hospitalisation. We conducted all

analyses on an intention-to-treat (ITT) basis, i.e. all participants and their outcomes 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.

We tabulated and described all measured outcomes such as quality of life, using tools such as validated questionnaires, or length of stay.

Dealing with missing data

In the absence of appropriate details regarding the participants, intervention, usual care or outcomes assessed for a study potentially eligible for inclusion, we contacted authors via email to request further details. We contacted authors of studies which we identified as a published abstract, to request a copy of a full-text peer-reviewed publication for the study if one was available. We sent authors a follow-up email if we received no response.

Assessment of heterogeneity

We explored statistical heterogeneity in each outcome of interest using the Chi² test and I² statistic, as recommended in the *Cochrane Handbook* (Deeks 2011).

Assessment of reporting biases

We assessed reporting bias through funnel plots and visual assessment.

Data synthesis

Owing to differences in participant populations, programme characteristics, and length of follow-up, we performed all meta-analyses using a fixed-effect model.

Summary of Findings

We assessed the primary outcomes examined in the review using GRADEPro methodology (Schünemann 2011) to create 'Summary of findings' tables. We performed quality assessment and rated using the measures of very low, low, moderate or high. We assessed only primary outcomes, as these were the most consistently reported outcomes across the included studies.

Subgroup analysis and investigation of heterogeneity

We conducted several subgroup analyses to investigate heterogeneity. These were based on previously published post hoc subgroup analyses from the data included in the 2010 version of this review (Inglis 2014), and in Conway 2014.

Each of the subgroup analyses and their methodology are detailed below:

1. Technology

We categorised included studies according to the following technology types: a) telephone calls; b) videophone; c) interactive voice response (IVR) involving the manual input of data using a telephone keypad in response to questions from a computerised interactive voice response system and computer-assisted telephone interviewing (CATI); d) complex/clinical telemonitoring, involving automatic transmission of physiological data, such as weight, heart rate and rhythm, oxygen saturations and blood pressure, from the measuring device to a central server via telephonic, satellite or broadband capabilities for interpretation by the healthcare team (Conway 2014).

2. Telemonitoring intensity

We categorised included studies of non-invasive telemonitoring according to the level of data monitoring and response, adapted from a categorisation proposed by Anker 2011. Categories included: a) office hours (typically Monday to Friday, 9 - 5 pm); b) 24 hours per day/seven days per week.

3. Publication year

We categorised included studies according to the year that a full-text peer-reviewed publication for that study was published: a) pre-2000; b) 2000 - 2007; c) since 2008. These nominal periods were based on time points of change to heart failure care.

- Pre-2000: era before contemporary pharmacological prescribing (beta-blockers, ACE inhibitors);
- 2000 - 2007: development of several important heart failure treatments (pharmacological and devices) influencing the standard of 'usual care';
- 2008 onwards: revised heart failure guidelines.

4. Mean/median age of study participants

We categorised included studies according to the mean or median age of the study participants. Categories included: a) < 70 years of age; b) ≥ 70 years of age (Inglis 2014).

5. Focus of structured telephone support studies

We categorised included studies of structured telephone support according to the focus of the intervention. Categories included: a) clinical monitoring of heart failure signs and symptoms with clinical support provided (clinical support); b) self-management education.

Meta-regression

In each subgroup analysis we performed a heterogeneity test to investigate whether there was enough evidence that the treatment effect differed between subgroups. We estimated the Q statistics that follows a Chi² distribution and produced a P value using the command 'metabin' from the package 'meta' in R.

To investigate whether the intervention effect depended on variables that were originally recorded as a continuous scale (year of publication and median age), we conducted linear meta-regressions between the logarithm of the RR in the trials and each variable. We performed the meta-regression assuming a fixed-effect model and using the command 'rma.uni' in the package 'metareg' in R.

Sensitivity analysis

We performed a sensitivity analysis for each of the primary outcomes, 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.

RESULTS

Description of studies

Results of the search

We identified 17 new studies for inclusion in the review. Searching the databases and search engines retrieved a total of 5051 new results (Figure 1):

Figure 1.   Study flow diagram for update

- CENTRAL n = 548
- DARE n = 62
- HTA n = 19
- MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, MEDLINE Daily and OLDMEDLINE (OVID) n = 731
- EMBASE (OVID) n = 936
- Science Citation Index Expanded (SCI-EXPANDED) and Conference Proceedings Citation Index- Science (CPCI-S) n = 881
- CINAHL Plus with Full text (EBSCO) n = 306
- AMED n = 21
- IEEE Xplore n = 1524
- TROVE n = 0
- Proquest Digital Dissertations n = 23

We excluded 973 references as duplicates.

Handsearching of conference abstracts identified 52 references. Overall, we identified 265 studies as potentially relevant, and we obtained full-text copies for assessment according to our inclusion and exclusion criteria.

We have identified 34 new studies which are currently ongoing, which includes those identified as conference abstracts but for which a full-text peer-reviewed publication was not available by the census date (Characteristics of ongoing studies).

We have identified seven new references as awaiting classification (Characteristics of studies awaiting classification), as we have con-tacted the study authors but have not received a reply to assist with determining the study eligibility, with several remaining in this category from the 2010 version of this review (Dunlap 2006 (HearT-I); Kulshreshtha 2010; Levine 2006 (Mind My Heart); Yakushin 2006).

We have now excluded one study (Kielblock 2007) which was included in the previous version of this review, since, based on debate and discussion in the literature (Anker 2011) since the publication of the previous version of this review, we consider it not to be a randomised controlled trial.

Included studies

We include 41 full-text peer-reviewed studies of either structured telephone support or home telemonitoring. Two included stud-ies trialled both structured telephone support and telemonitor-ing compared to usual care, therefore 43 comparisons are evident. These include 24 studies published as full-text peer-reviewed pub-lications included in the 2010 Cochrane review (Inglis 2010); (Figure 2 and Characteristics of included studies). Twenty-five studies evaluated structured telephone support (eight new studies, plus one included study previously classified as telemonitoring; total of 9332 participants), 18 evaluated telemonitoring (nine new studies; total of 3860 participants) and two studies evaluated both interventions (included in listed counts).

Figure 2.   Study flowchart.

We have excluded one telemonitoring study (Kielblock 2007) included in the previous version of this review (Inglis 2010). Another study (Capomolla 2004) which used IVR technology and was previously included as a telemonitoring study in the previous version of this review we now classify as structured telephone support.

We have added 17 new studies to the review for this update. These include eight new studies of structured telephone support (Angermann 2012 (INH); Baker 2011; Bento 2009; Brandon 2009; Chaudhry 2010 (Tele-HF); Domingues 2011; Krum 2013 (CHAT); Zamanzadeh 2013) and nine new studies of non-invasive home telemonitoring (Biannic 2012 (SEDIC); Blum 2014 (MCCD); Dendale 2012 (TEMA-HF1); Koehler 2011 (TIM-HF); Lyngå 2012 (WISH); Scherr 2009 (MOBITEL); Seto 2012; Villani 2014 (ICAROS); Vuorinen 2014).

Studies with multiple intervention arms included in this review are: Cleland 2005 (Struct Tele) (TENS-HMS); Cleland 2005 (Telemon) (TENS-HMS); Mortara 2009 (Struct Tele) (HHH); Mortara 2009 (Telemon) (HHH). We have separated out the data from these studies into our two interventions of interest (structured telephone support and telemonitoring). Structured telephone support (Mortara 2009 (Struct Tele) (HHH)) data are from the "Strategy 2" study arm, and telemonitoring data (Mortara 2009 (Telemon) (HHH)) are from the "Strategy 3" study arm. (Wakefield 2008) includes two intervention arms, one using standard telephone equipment and the other a videophone; for the purposes of our analyses, we combined these two intervention arms and classed them as structured telephone support.

Two new structured telephone support studies (Brandon 2009; Zamanzadeh 2013) did not examine the main outcomes of interest (all-cause mortality, all-cause hospitalisations and heart failure-related hospitalisations) but did include data on some secondary outcomes.

Of the newly-included studies, four had been included in the 2010 review as conference abstracts and have now been included in this version of the review as they are now available as full-text peer-reviewed publications. These are: Angermann 2012 (INH); Blum 2014 (MCCD); Krum 2013 (CHAT); Villani 2014 (ICAROS). Two studies identified in the 2010 version of this review as ongoing (Chaudhry 2010 (Tele-HF); Koehler 2011 (TIM-HF)) and one study awaiting assessment in 2010 (Scherr 2009 (MOBITEL)) are now included in this version of the review.

For the structured telephone support studies (n = 25 studies, including two three-armed studies):

- Trials ranged in size from small (34 participants in Barth 2001) to large (1653 participants in Chaudhry 2010 (Tele-HF));
- Mean/median age of participants ranged from 45 years (Ramachandran 2007) to 75 years (Barth 2001);
- Mean percentage of male participants was 63%, which ranged from 45% to 99%. Only five out of the 25 included studies recruited more women than men (Barth 2001; Brandon 2009; DeWalt 2006; Riegel 2002; Riegel 2006);
- 56% (n = 14) of the studies reviewed originated from the USA; other countries were Australia (1), Argentina (1), Brazil (2), Canada (1), Germany (1), India (1), Iran (1), Italy (1) and two studies which were involved several European countries (Germany, Netherlands, UK, Poland, Italy).
- Ethnic groups: Riegel 2006 examined the effect of structured telephone support on a Hispanic population;
- 66% of studies had a length of follow-up less than six months;
- Most studies included participants with symptomatic heart failure, NYHA Class II - III.

For non-invasive home telemonitoring studies (n = 18, including two three-armed studies):

- Trials ranged in size from small (20 participants in De Lusignan 2001) to large (710 participants in Koehler 2011 (TIM-HF));
- Mean/median age of participants ranged from 55 years of age in Seto 2012 to 78 years of age in Antonicelli 2008;
- Mean percentage of male participants was 72%, and ranged from 35% to 85%. Only one of the 18 included studies recruited more women than men (Soran 2008);
- Studies were undertaken in a variety of countries: Italy (3), USA (3), Canada (2), Austria (1), Belgium (1), Finland (1), France (1), Germany (1), Sweden (1), The Netherlands (1), UK (1) and two studies involved several European countries (Germany, The Netherlands and the UK; UK, Poland and Italy)
- Minority populations: Soran 2008 included older minorities (elderly women and non-white men);
- 38% of studies had a length of follow-up less than six months;
- Most studies included participants with symptomatic heart failure, NYHA Class III.

Structured telephone support studies included in the primary meta-analysis for the primary outcomes of interest funded by industry/health insurers (reported in publications):

1. Cleland 2005 (Struct Tele) (TENS-HMS) - Phillips.
2. DeWalt 2006 - Pfizer Inc.
3. Domingues 2011 - FIPE and CNPq.
4. GESICA 2005 (DIAL) - Roche, Boehringer Ingelheim, Bago. Pharmacia, Novartis, Merck Sharp & Dohme.
5. Krum 2013 (CHAT) - National Health and Medical Research Council (NHMRC) and National Heart Foundation of Australia and Medical Benefits Fund.
6. Laramee 2003 - Novartis Pharmaceuticals.
7. Riegel 2002 - Pfizer Inc.
8. Tsuyuki 2004 - Park Davis Canada (Pfizer Canada).

Non-invasive telemonitoring studies included in the primary meta-analysis of the primary outcomes of interest funded by industry (reported in publications):

1. Balk 2008 - Achmea, Philips; provision of the MOTIVA system.
2. Cleland 2005 (Telemon) (TENS-HMS) - Philips.
3. De Lusignan 2001 - Nexan Telemed Ltd, Cambridge.
4. Dendale 2012 (TEMA-HF1) - Belgium Government Health Insurance Institute, Leo Pharma.
5. Goldberg 2003 (WHARF) - Alere Medical, Incorporated.
6. Koehler 2011 (TIM-HF) - German Federal Ministry of Economics and Technology, Robert Bosch Healthcare GmbH, InterComponentWare AG, Aipermon GmbH & Co KG.
7. Scherr 2009 (MOBITEL) - Novartis Pharma Austria, Roche Pharma Australia Mobilkom Austria.
8. Woodend 2008 - Merck-Frost Canada.

Excluded studies

We excluded the majority of studies for the following reasons (Characteristics of excluded studies):

- Not an RCT: n = 54
- Involved home or intensive clinic visits: n = 36
- Review or editorial: n = 35
- Not structured telephone support or telemonitoring: n = 19
- Not heart failure-specific: n = 10
- System design: n = 10
- Invasive telemonitoring: n = 7
- Structured telephone support or telemonitoring exposure in usual care or both arms: n = 4

Risk of bias in included studies

Overall the heterogeneity ranged from "might not be important" to "may represent substantial heterogeneity" according to the rough guide provided by Deeks 2011:

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

- All-cause mortality:
  - Structured telephone support vs usual care: Heterogeneity: Chi² = 13.56, df = 20 (P = 0.85); I² = 0%
  - Telemonitoring vs usual care: Heterogeneity: Chi² = 19.70, df = 15 (P = 0.18); I² = 24%

- All-cause hospitalisation:
  - Structured telephone support vs usual care: Heterogeneity: Chi² = 28.51, df = 15 (P = 0.02); I² = 47%
  - Telemonitoring vs usual care: Heterogeneity: Chi² = 41.72, df = 12 (P < 0.0001); I² = 71%

- Heart failure-related hospitalisation:
  - Structured telephone support vs usual care: Heterogeneity: Chi² = 19.20, df = 14 (P = 0.16); I² = 27%
  - Telemonitoring vs usual care: Heterogeneity: Chi² = 8.71, df = 7 (P = 0.27); I² = 20%

Analysis of the distribution in the funnel plots (Figure 3; Figure 4; Figure 5; Figure 6; Figure 7; Figure 8) demonstrates a strong publication bias in the studies selected for this review.

Figure 3.   Funnel plot of comparison: 1 Impact of structured telephone support and telemonitoring in CHF on all-cause mortality, outcome: 1.1 All-cause mortality: STS vs UC.

Figure 4.   Funnel plot of comparison: 1 Impact of structured telephone support and telemonitoring in CHF on all-cause mortality, outcome: 1.2 All-cause mortality: TM vs UC.
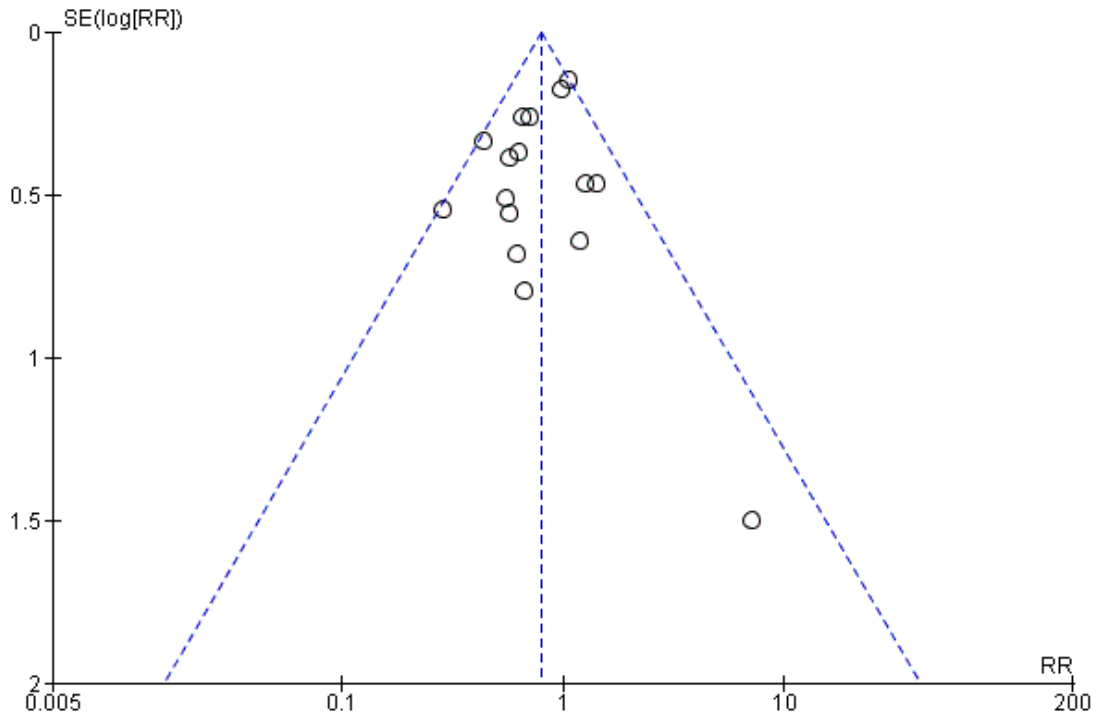
Figure 5. Funnel plot of comparison: 2 Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation, outcome: 2.1 All-cause hospitalisation: STS vs UC.
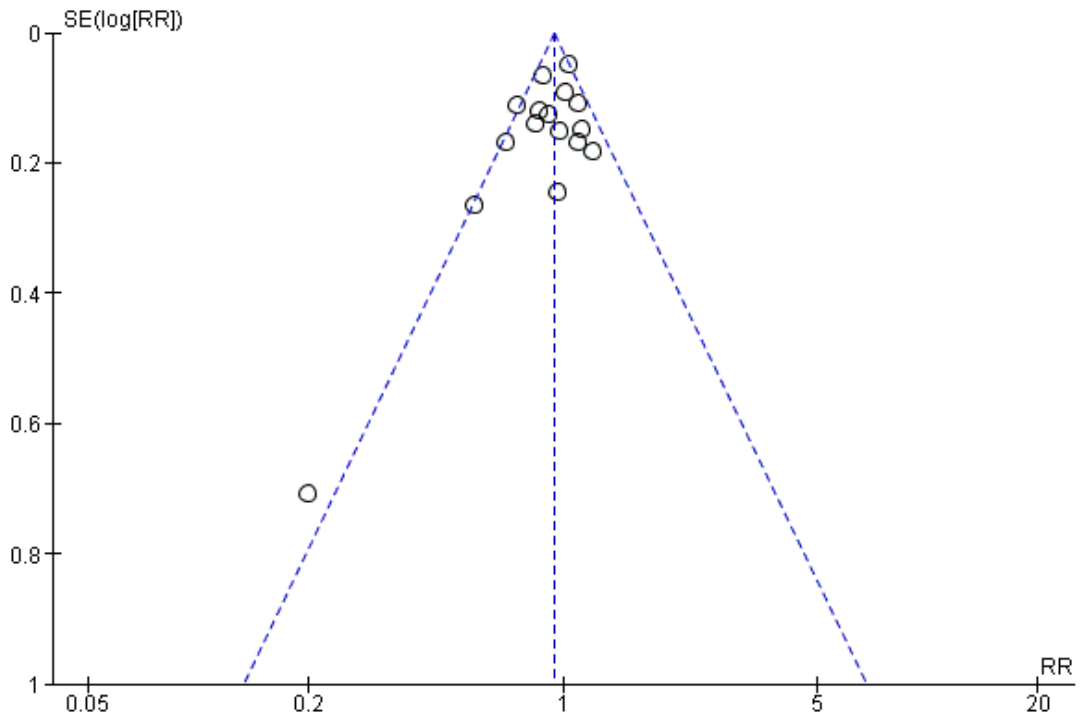
Figure 6. **Funnel plot of comparison: 2 Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation, outcome: 2.2 All-cause hospitalisation: TM vs UC.**
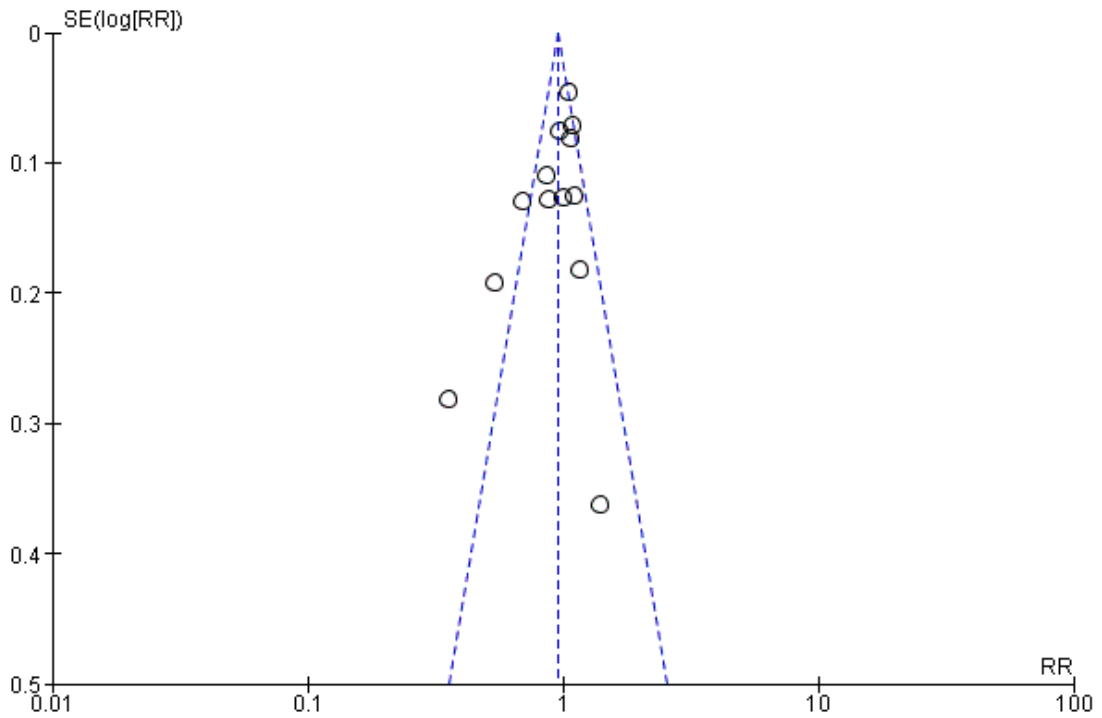
Figure 7. Funnel plot of comparison: 3 Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation, outcome: 3.1 CHF-related hospitalisation: STS vs UC.
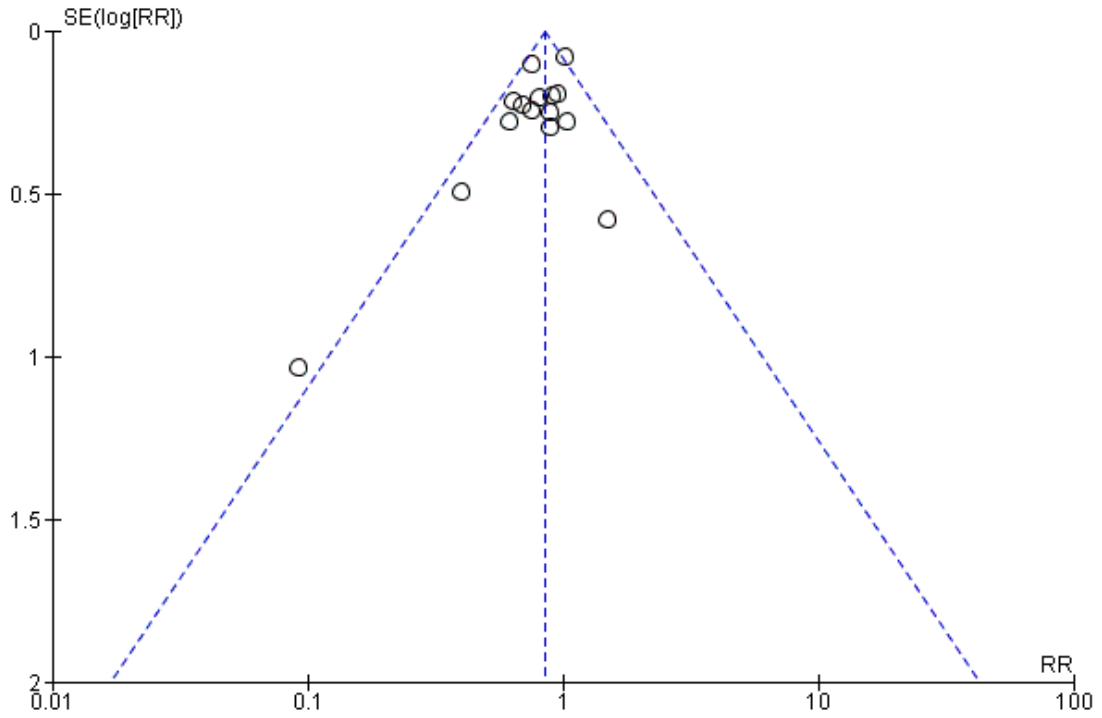
Figure 8. Funnel plot of comparison: 3 Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation, outcome: 3.2 CHF-related hospitalisation: TM vs UC.
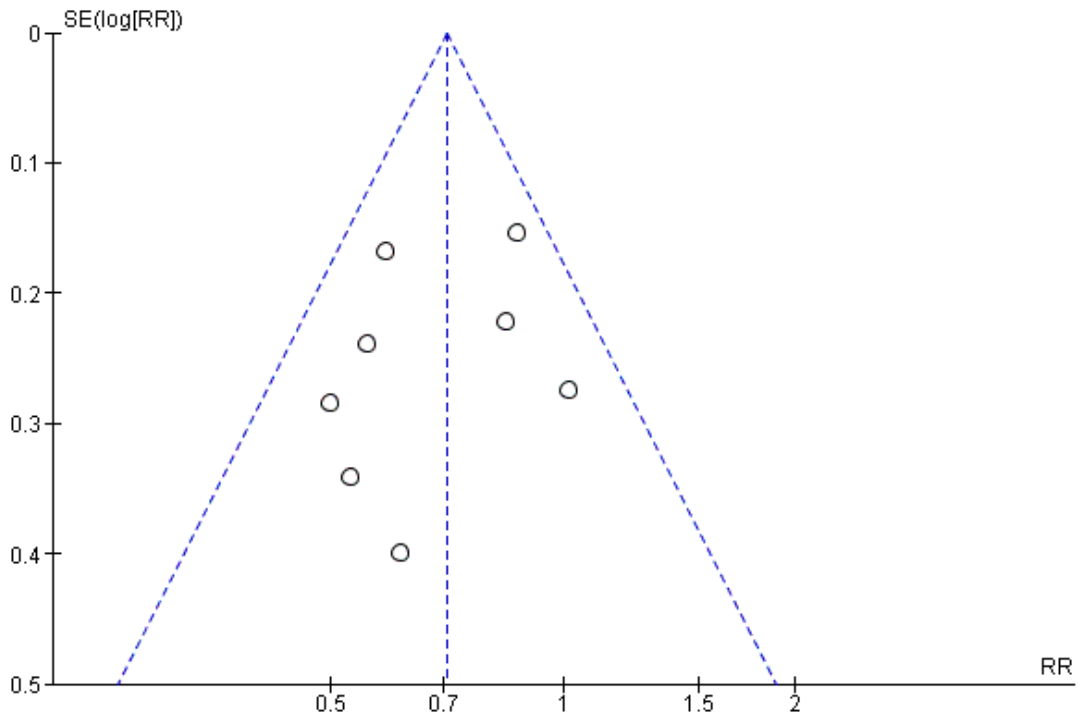
Allocation

We assessed random sequence generation as either low risk of bias (50% of all studies) or unclear for more than 95% of all studies included in this review. Many studies did not report the method of random sequence generation Figure 9; Figure 10.

Figure 9. Risk of bias graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.
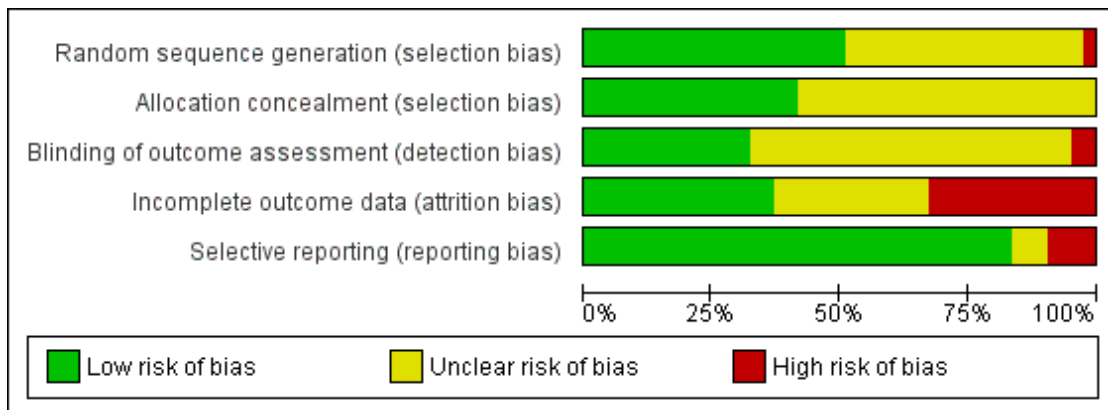
Figure 10. Risk of bias summary: review authors' judgements about each methodological quality item for each included study.

Allocation concealment was not clearly reported for more than 50% of all studies included in the review. We rated those that did report allocation concealment at low risk.

Blinding

We do not consider that blinding of participants and study personnel delivery was possible for these types of interventions. We assessed blinding of outcome assessment, and rated the majority of included studies at unclear risk of detection bias, due to the absence of details in the publications for outcome assessment (Figure 9; Figure 10).

Incomplete outcome data

Several studies reported losses to follow-up without detailing how or whether outcome data for these studies were included in an intention-to-treat analysis (Figure 9; Figure 10).

Selective reporting

We assessed more than 75% of all studies included in this review to be at low risk for selective reporting, with a small number assessed as being at high risk (Figure 9; Figure 10).

Effects of interventions

See: **Summary of findings for the main comparison** Summary of findings - structured telephone support or telemonitoring versus usual care - all-cause mortality; **Summary of findings 2** Summary of findings - structured telephone support or telemonitoring versus usual care - all-cause hospitalisation; **Summary of findings 3** Summary of findings - structured telephone support or telemonitoring versus usual care - heart failure-related hospitalisation

All-cause mortality

All-cause mortality was available for 22 peer-reviewed studies comparing structured telephone support with usual care and for 17 studies comparing telemonitoring with usual care. Both structured telephone support (RR 0.87, 95% CI 0.77 to 0.98; participants = 9222; studies = 22; I² = 0%; Analysis 1.1) and non-invasive telemonitoring (RR 0.80, 95% CI 0.68 to 0.94; participants = 3740; studies = 17; I² = 24%; Analysis 1.2) reduced all-cause mortality in people with heart failure.

GRADE assessment rated all-cause mortality evidence included in the review as of moderate quality, limited by a strong suspicion publication bias (Summary of findings for the main comparison).

Subgroup analyses designed to explore heterogeneity in the included studies found the following:

1. Technology

Heterogeneity tests between groups were not significant (P = 0.34) and therefore it is difficult to conclude that the apparent differences amongst technologies on all-cause mortality are true.

Effective technologies for reducing the risk of all-cause mortality in people with heart failure were telephone (RR 0.81, 95% CI 0.71 to 0.93; participants = 6629; studies = 17; I² = 0%; Analysis 1.3) and complex telemonitoring (RR 0.81, 95% CI 0.68 to 0.96; participants = 2885; studies = 12; I² = 31%; Analysis 1.4).

Technology categories that did not individually demonstrate statistically significant effects on all-cause mortality in people with heart failure included videophone (RR 1.14, 95% CI 0.65 to 1.99; participants = 269; studies = 2; I² = 0%; Analysis 1.5), IVR (RR 1.01, 95% CI 0.80 to 1.28; participants = 2445; studies = 4; I² = 0%; Analysis 1.6), and mobile telephone or person digital assistant (PDA) (RR 0.71, 95% CI 0.46 to 1.11; participants = 734; studies = 4; I² = 25%; Analysis 1.7).

2. Telemonitoring intensity

A heterogeneity test did not show strong statistical evidence of differences between the two groups (P = 0.21) according to the intensity of telemonitoring.

When we categorised telemonitoring studies according to data monitoring intensity, only the first subgroup with monitoring in conventional office hours showed statistically significant evidence of an effect (RR 0.69, 95% CI 0.52 to 0.92; participants = 1548; studies = 10; I² = 0%; Analysis 1.8), while the subgroup of seven days per week/24 hours per day showed no significant effect: (RR 0.86, 95% CI 0.71 to 1.04; participants = 2192; studies = 7; I² = 44%; Analysis 1.9).

3. Publication year

A test came close to identifying significant heterogeneity between the two subgroups (P = 0.0760). The linear meta-regression coefficient for year of publication for telemonitoring studies was 1.0477 (P = 0.0463), providing further support for the view that more recent studies have shown a smaller impact on mortality.

For structured telephone support studies, full-text peer-reviewed publications prior to 2000 reported a reduction in all-cause mortality in people with heart failure, but was not statistically significant. This could be due to the few studies and cases. (RR 0.45, 95% CI 0.14 to 1.40; participants = 219; studies = 2; I² = 0%; Analysis 1.10). For studies published between 2000 and 2007 the effect was smaller, but the larger sample size made it (just) statistically significant (RR 0.86, 95% CI 0.74 to 0.99; participants = 5668; studies = 13; I² = 0%; Analysis 1.11). Studies published after 2007 showed an even smaller effect and were clearly statistically non-significant (RR 0.91, 95% CI 0.75 to 1.10; participants

= 3335; studies = 7; I² = 0%; Analysis 1.12). Heterogeneity tests between these three subgroups were non-significant (P = 0.47) and a meta-regression failed to identify a significant linear trend (slope = 1.008, P = 0.67).

For non-invasive telemonitoring studies, full-text peer-reviewed publications during the period 2000 to 2007 reported a reduction in all-cause mortality in people with heart failure (RR 0.58, 95% CI 0.39 to 0.86; participants = 553; studies = 3; I² = 0%; Analysis 1.13), but for those published after 2008 the effect did not have strong statistically significant evidence (RR 0.85, 95% CI 0.72 to 1.02; participants = 3187; studies = 14; I² = 21%; Analysis 1.14). We did not identify any telemonitoring study published prior to 2000 for inclusion.

4. Mean/median age of participants

Again, a test failed to identify heterogeneity (P = 0.4534) and the linear regression coefficient for median age of participants was 1.0010 (P = 0.9405).

When we categorised structured telephone support studies according to the age of the participants, the benefit of structured telephone support for all-cause mortality was similar for studies where the mean/median age of participants was less than 70 years (RR 0.88, 95% CI 0.77 to 1.01; participants = 6158; studies = 13; I² = 0%; Analysis 1.15) and for those aged 70 years or older (RR 0.84, 95% CI 0.67 to 1.04; participants = 3064; studies = 9; I² = 0%; Analysis 1.16).

Tests for heterogeneity were not significant (P = 0.69).The linear meta-regression coefficient for age of participants for structured telephone support studies was 0.9886 (P = 0.3871) supporting the view that age is not a major determinant of the effect of the intervention.

For non-invasive telemonitoring studies, the effect on mortality was similar to the above, with studies where the mean/median age of participants was less than 70 years (RR 0.84, 95% CI 0.68 to 1.04; participants = 2493; studies = 9; I² = 31%; Analysis 1.17), and for those aged 70 or over (RR 0.74, 95% CI 0.59 to 0.94; participants = 1247; studies = 8; I² = 30%; Analysis 1.18).

5. Focus of structured telephone support studies

The heterogeneity test was non-significant (P = 0.8921).

Structured telephone support which focused on monitoring of signs and symptoms of heart failure and provided clinical support reduced all-cause mortality (RR 0.87, 95% CI 0.77 to 0.98; participants = 8094; studies = 18; I² = 0%; Analysis 1.19), to a similar extent as those that focused on self-management education (RR 0.90, 95% CI 0.55 to 1.45; participants = 1128; studies = 4; I² = 0%; Analysis 1.20).

Sensitivity analyses, performed to explore the influence of length of follow-up greater than six months on all-cause mortality removed the statistically significant effect of structured telephone support (RR 0.88, 95% CI 0.75 to 1.02; participants = 4818; studies = 11; I² = 0%; Analysis 1.21) and telemonitoring (RR 0.89, 95% CI 0.74 to 1.06; participants = 2580; studies = 10; I² = 0%; Analysis 1.22), but reduced heterogeneity for telemonitoring studies. However, meta-regression tests revealed no heterogeneity according to study duration.

All-cause hospitalisation

All-cause hospitalisation data were available for 16 studies comparing structured telephone support with usual care and 13 studies comparing telemonitoring with usual care. Both structured telephone support (RR 0.95, 95% CI 0.90 to 1.00; participants = 7216; studies = 16; I² = 47%; Analysis 2.1), and non-invasive telemonitoring (RR 0.95, 95% CI 0.89 to 1.01; participants = 3332; studies = 13; I² = 71%; Analysis 2.2), showed an average reduction in all-cause hospitalisation of people with heart failure but statistically significant evidence was not strong in either study and heterogeneity between trial effects was important.

GRADE assessment rated the evidence for all-cause hospitalisation as very low, due to serious inconsistency and serious imprecision in this outcome, and a strong suspicion of publication bias (Summary of findings 2).

Subgroup analyses designed to explore heterogeneity in the included studies found the following:

1. Technology

The heterogeneity test between subgroups was not significant (P = 0.25), suggesting that observed effect differences between subgroups may be due to the play of chance.

Effective technologies for reducing the risk of all-cause hospitalisation in people with heart failure was telephone (RR 0.93, 95% CI 0.86 to 0.99; participants = 4756; studies = 12; I² = 51%; Analysis 2.3) and mobile phone/PDA (RR 0.76, 95% CI 0.60 to 0.97; participants = 560; studies = 2; I² = 70%; Analysis 2.4). Technology categories that did not individually demonstrate statistically significant reductions in all-cause hospitalisation in people with heart failure included videophone (RR 0.91, 95% CI 0.80 to 1.04; participants = 269; studies = 2; I² = 92%; Analysis 2.5), IVR (RR 0.99, 95% CI 0.91 to 1.08; participants = 2312; studies = 3; I² = 76%; Analysis 2.6) and complex telemonitoring (RR 0.97, 95% CI 0.90 to 1.04; participants = 2651; studies = 10; I² = 69%; Analysis 2.7). But again, heterogeneity between studies was important in all these analyses.

2. Telemonitoring intensity

The heterogeneity test identified differences between the two subgroups (P = 0.0125) (Figure 11).

Figure 11.
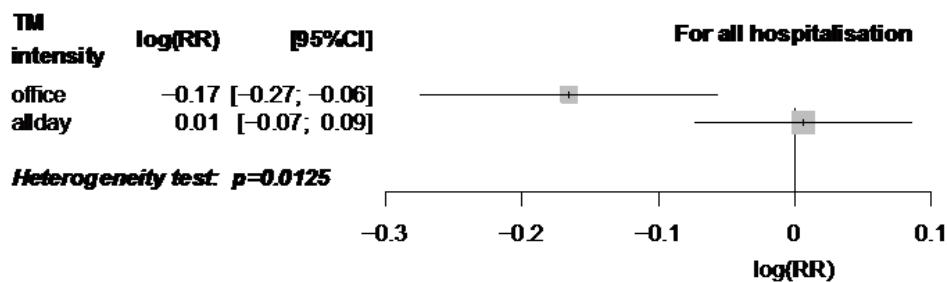
When we categorised telemonitoring studies according to data monitoring intensity (office hours or seven days per week/24 hours per day) only those which operated during standard office hours reduced the risk of all-cause hospitalisation in people with heart failure (RR 0.85, 95% CI 0.76 to 0.94; participants = 1140; studies = 6; I² = 76%; Analysis 2.8), whereas studies that operated telemonitoring seven days per week or 24 hours per day did not (RR 1.01, 95% CI 0.93 to 1.09; participants = 2192; studies = 7; I² = 50%; Analysis 2.9).

3. Publication year

A test did not identify heterogeneity (P = 0.9269) and the linear meta-regression coefficient for year of publication was 1.0000 (P = 0.9992).

For structured telephone support studies, only one study (Gattis 1999 (PHARM)) was published as a full-text peer-reviewed report prior to 2000, and demonstrated a statistically significant effect on reducing the risk of all-cause hospitalisation for people with heart failure (RR 0.57, 95% CI 0.34 to 0.96; participants = 181; studies = 1; Analysis 2.10). Structured telephone support studies published during the period 2000 to 2007 (RR 0.93, 95% CI 0.86 to 1.01; participants = 3700; studies = 8; I² = 0%; Analysis 2.11) and from 2008 onwards (RR 0.98, 95% CI 0.91 to 1.06; participants = 3335; studies = 7; I² = 68%; Analysis 2.12) did not show strong evidence of a reduced risk. However, there was no strong evidence of heterogeneity between the three subgroups (P = 0.1031) and the linear meta-regression coefficient for year of publication was also non-significant (slope = 1.0078, P = 0.3453). For non-invasive telemonitoring studies, we found no statistically significant reduction in all-cause hospitalisation for the period 2000 to 2007: (RR 0.94, 95% CI 0.79 to 1.12; participants = 533; studies = 2; I² = 0%; Analysis 2.13) or for the period from 2008 onward: (RR 0.95, 95% CI 0.89 to 1.02; participants = 2799; studies = 11; I² = 76%; Analysis 2.14).

4. Mean/median age of participants

Heterogeneity tests (P = 0.1990) and linear meta-regression coefficient for age (slope = 0.9983; P = 0.7271) did not provide statistically significant evidence of heterogeneity of effect.

The borderline effect of STS on all-cause hospitalisation was similar for trials with a median/mean participant age above 70 (RR 0.94, 95% CI 0.85 to 1.04; participants = 1923; studies = 6; I² = 36%; Analysis 2.15), or below 70 years of age (RR 0.95, 95% CI 0.89 to 1.01; participants = 5293; studies = 10; I² = 56%; Analysis 2.16). Neither heterogeneity tests (P = 0.88) nor linear meta-regression coefficient for age (slope = 0.9933; P = 0.2369) identified significant heterogeneity amongst studies.

Non-invasive telemonitoring studies with a mean/median participant age above 70 years demonstrated a marginally significant reduction in the risk of all-cause hospitalisation for people with heart failure (RR 0.90, 95% CI 0.82 to 0.99; participants = 1147; studies = 6; I² = 80%; Analysis 2.17) that we did not observe for studies with a mean/median age of participants below 70 years of age (RR 0.98, 95% CI 0.90 to 1.07; participants = 2185; studies = 7; I² = 57%; Analysis 2.18).

5. Focus of structured telephone support studies

Heterogeneity tests did not find important heterogeneity (P = 0.3052).

Neither structured telephone support which focused on monitoring of signs and symptoms of heart failure and providing clinical support (RR 0.94, 95% CI 0.89 to 1.00; participants = 6820; studies = 14; I² = 52%; Analysis 2.19), nor those that focused on self-management education (RR 1.08, 95% CI 0.84 to 1.38; participants = 396; studies = 2; I² = 0%; Analysis 2.20) showed statistically significant reductions in all-cause hospitalisation.

Sensitivity analyses, performed to explore the influence of length of follow-up greater than six months showed slightly better results and less heterogeneity for STS (RR 0.89, 95% CI 0.82 to 0.96; participants = 3451; studies = 7; I² = 37%; Analysis 2.21), but

had no influence on the results of home telemonitoring (RR 0.94, 95% CI 0.87 to 1.01; participants = 2387; studies = 8; I² = 78%; Analysis 2.22).

Heart failure-related hospitalisation

Data on heart failure-related hospitalisations were available for 16 studies comparing structured telephone support with usual care and eight studies comparing non-invasive telemonitoring with usual care.

Both structured telephone support (RR 0.85, 95% CI 0.77 to 0.93; participants = 7030; studies = 16; I² = 27%; Analysis 3.1) and non-invasive telemonitoring (RR 0.71, 95% CI 0.60 to 0.83; participants = 2148; studies = 8; I² = 20%; Analysis 3.2) showed a statistically significant reduction in heart failure-related hospitalisations.

GRADE assessment rated the evidence for heart failure-related hospitalisation evidence as moderate, due to a strong suspicion publication bias.(Summary of findings 3).

Subgroup analyses designed to explore heterogeneity in the included studies found the following:

1. Technology

A heterogeneity test (P = 0.0029) strongly suggested that there are differences in effect for this outcome amongst these technologies (Figure 12).

Figure 12.
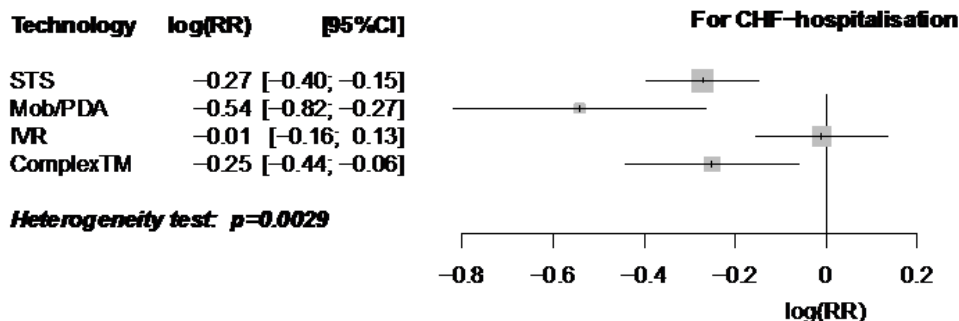
Effective technologies for reducing the risk of heart failure-related hospitalisation included telephone (RR 0.76, 95% CI 0.67 to 0.86; participants = 4718; studies = 13; I² = 2%; Analysis 3.3), mobile phone/PDA (RR 0.58, 95% CI 0.44 to 0.77; participants = 674; studies = 3; I² = 0%; Analysis 3.4) and complex non-invasive telemonitoring (RR 0.78, 95% CI 0.64 to 0.94; participants = 1474; studies = 5; I² = 33%; Analysis 3.5).

IVR was the only technology which did not demonstrate a benefit for reducing the risk of heart failure-related hospitalisation (RR 0.99, 95% CI 0.86 to 1.14; participants = 2312; studies = 3; I² = 0%; Analysis 3.6).

2. Telemonitoring intensity

The heterogeneity test did not find evidence of differences in the effect (P = 0.9907).

When we categorised telemonitoring studies according to data monitoring intensity (office hours or seven days per week/24 hours per day), we found significant reductions in heart failure-related

hospitalisation (office hours: RR 0.71, 95% CI 0.56 to 0.89; participants = 858; studies = 5; I² = 20%; Analysis 3.7; seven days per week/24 hours per day: RR 0.71, 95% CI 0.57 to 0.87; participants = 1290; studies = 3; I² = 46%; Analysis 3.8).

3. Publication year

The heterogeneity tests did not demonstrate heterogeneity (P = 0.3978) and the linear meta-regression coefficient for year of publication was non-significant (0.9694; P = 0.3721).

For structured telephone support studies, the two studies published prior to 2000 demonstrated a large reduction in the risk of heart failure-related hospitalisations (RR 0.24, 95% CI 0.10 to 0.58; participants = 219; studies = 2; I² = 48%; Analysis 3.9). The effect size was smaller with more recent publications: 2000 to 2007 RR 0.78, 95% CI 0.69 to 0.89; participants = 3784; studies = 10; I² = 0%; Analysis 3.10; 2008 onwards RR 0.96, 95% CI 0.84 to 1.11; participants = 3027; studies = 4; I² = 0%; Analysis

3.11. The heterogeneity test strongly suggested differences between these three groups (P = 0.0019) and the linear meta-regression coefficient for year of publication was 1.0360 (P = 0.0177), indicating a reduction in benefit for more recent publications for this outcome (Figure 13; Figure 14).

Figure 13.

Figure 14.

Meta−regression using a fixed effect model
for CHF−related hospitalisations (STS vs UC)
(Dot size is proportional to study precision)
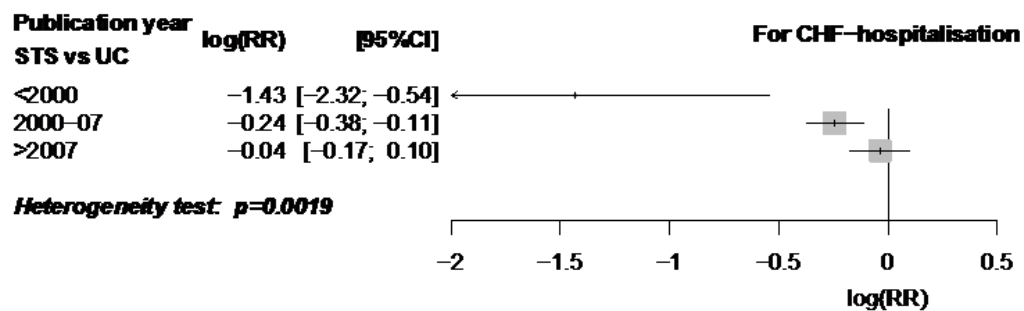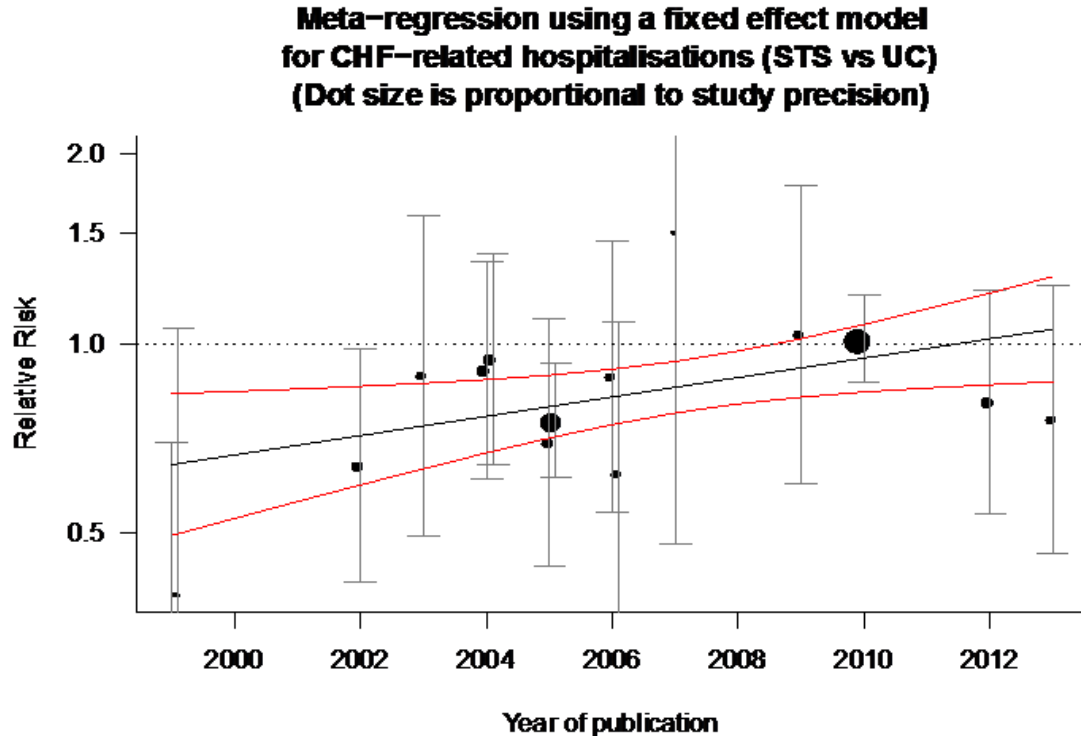
Only one non-invasive telemonitoring study reporting heart failure-related hospitalisations was published during the period 2000 to 2007 (Cleland 2005 (Telemon) (TENS-HMS)), which did not demonstrate a significant benefit for reducing the risk of heart failure-related hospitalisations in people with heart failure (RR 0.84, 95% CI 0.55 to 1.30; participants = 253; studies = 1; Analysis 3.12). Telemonitoring studies published from 2008 onwards did detect a significant reduction in heart failure-related hospitalisations (RR 0.69, 95% CI 0.58 to 0.82; participants = 1895; studies = 7; I^2 = 24%; Analysis 3.13).

4. Mean/median age of participants

A test did not identify heterogeneity between the three groups (P = 0.0952) and the linear meta-regression coefficient for age of participants was 0.9915 (P = 0.4784).

Structured telephone support reduced heart failure-related hospitalisations in studies where the mean/median age of participants was below 70 years (RR 0.86, 95% CI 0.77 to 0.96; participants = 5035; studies = 8; I^2 = 51%; Analysis 3.14) and for those where the mean/median age was 70 years and above (RR 0.81, 95% CI 0.67 to 0.96; participants = 1995; studies = 8; I^2 = 0%; Analysis 3.15). A test did not find evidence of heterogeneity (P = 0.5349). The linear meta-regression coefficient for median age of participants

was 0.9821 (P = 0.0562). This result does not provide strong evidence that studies with an older median age for participant have slightly larger effects.

There were similar findings for non-invasive telemonitoring studies where the mean/median age of participants was below 70 years (RR 0.75, 95% CI 0.63 to 0.89; participants = 1898; studies = 6; I^2 = 14%; Analysis 3.16), and for those where the mean/median age was 70 years and above (RR 0.53, 95% CI 0.37 to 0.76; participants = 250; studies = 2; I^2 = 0%; Analysis 3.17).

5. Focus of structured telephone support studies

A test did not demonstrate heterogeneity (P 0.5607).

Structured telephone support which focused on monitoring of signs and symptoms of heart failure and provided clinical support reduced heart failure-related hospitalisations (RR 0.84, 95% CI 0.76 to 0.93; participants = 6754; studies = 15; I^2 = 31%; Analysis 3.18). There was only one included structured telephone support study (Tsuyuki 2004) which focused on self-management education and the effect on heart failure-related hospitalisations, and did not show a significant effect (RR 0.95, 95% CI 0.64 to 1.39; participants = 276; studies = 1; Analysis 3.19).

The effect was somewhat greater for studies of structured telephone

support with a follow-up greater than six months (RR 0.76, 95% CI 0.66 to 0.88; participants = 3341; studies = 7; I² = 0%; Analysis 3.20), but restricting the analysis to longer duration of follow-up in studies of non-invasive telemonitoring, did not seem to affect the results (RR 0.78, 95% CI 0.65 to 0.94; participants = 1684; studies = 4; I² = 31%; Analysis 3.21).

Length of stay

Of the 25 studies reporting on structured telephone support versus usual care, seven reported length-of-stay data (Chaudhry 2010 (Tele-HF); Galbreath 2004; Laramee 2003; Riegel 2002; Riegel 2006; Tsuyuki 2004; Wakefield 2008). Only Tsuyuki 2004 reported a statistically significant reduction in length of stay in hospital. Nine telemonitoring studies reported length of stay (Balk 2008; Blum 2014 (MCCD); Dendale 2012 (TEMA-HF1); Koehler 2011 (TIM-HF); Lyngå 2012 (WISH); Scherr 2009 (MOBITEL); Soran 2008; Vuorinen 2014; Wakefield 2008). Only Scherr 2009 (MOBITEL) reported a significant reduction in the length of stay with the intervention. One telemonitoring study (Villani 2014 (ICAROS)) reported a large difference in the total number of hospitalisations for longer than three days, but this was not an analysis of length of stay per hospitalisation. Studies which assessed both telemonitoring and structured telephone support (Cleland 2005 (Struct Tele) (TENS-HMS); Cleland 2005 (Telemon) (TENS-HMS); Mortara 2009 (Struct Tele) (HHH); Mortara 2009 (Telemon) (HHH)) reported no significant difference in length of stay for hospital admissions between groups (Table 1).

Health-related quality of life

Health-related quality of life (HRQoL) was a secondary outcome for 22 of the 41 included studies (Table 2). Several different psychometric tools were used for evaluation (Chronic Heart Failure Symptomatology Questionnaire (CHFSQ); Minnesota Living with Heart Failure Questionnaire (MLWHFQ); Kansas City Cardiomyopathy Questionnaire (KCCQ); Short Form 12 Item (SF-12); Short Form 36 Item (SF-36); Health Distress Score (HDS); Improving Chronic Illness Care Evaluation (ICICE); and Heart Failure Symptom Scale (HFSS)). Eleven structured telephone support studies measured HRQoL, of which nine (Angermann 2012 (INH); Baker 2011; Barth 2001; Brandon 2009; Galbreath 2004; Smith 2005; GESICA 2005 (DIAL); Ramachandran 2007; Sisk 2006; Hebert 2008; Wakefield 2008) demonstrated significant improvements in component scores or overall HRQoL measures, and two studies (DeWalt 2006; Riegel 2006) did not. Of the 11 telemonitoring studies that measured HRQoL, five (45%) (Antonicelli 2008; Blum 2014 (MCCD); Koehler 2011 (TIM-HF); Seto 2012; Woodend 2008) reported statistically significant improvements in HRQoL outcomes. Studies which assessed both telemonitoring and structured telephone support (Cleland 2005 (Struct Tele) (TENS-HMS); Cleland 2005

(Telemon) (TENS-HMS); Mortara 2009 (Struct Tele) (HHH); Mortara 2009 (Telemon) (HHH)) have not reported HRQoL outcomes.

Healthcare costs and cost effectiveness

Fifteen studies presented detailed cost analysis (cost of the intervention or cost effectiveness) for these two types of technologies (structured telephone support (Barth 2001; Galbreath 2004 - Smith 2008; Laramee 2003; Ramachandran 2007; Riegel 2002; Riegel 2006; Sisk 2006 - Hebert 2008; Tsuyuki 2004; Wakefield 2008) and telemonitoring (Balk 2008; Blum 2014 (MCCD); Dendale 2012 (TEMA-HF1); Giordano 2009; Soran 2008 - Soran 2010; Villani 2014 (ICAROS)). Costs varied according to the intensity and technologies used in the intervention. Studies which reported reduction in the cost of care per admission or overall cost reduction due to fewer hospitalisations reported cost savings ranging between 14% (Laramee 2003) and 86% (Wakefield 2008). Three structured telephone support studies (Riegel 2002; Tsuyuki 2004; Wakefield 2008) and one telemonitoring study (Giordano 2009) reported a decrease in costs. Two telemonitoring studies (Balk 2008; Villani 2014 (ICAROS)) reported increases in cost, due both to the cost of the intervention and to increased medical management (Table 3).

Adherence to the intervention

Adherence (compliance) was between 55.1% and 65.8% for structured telephone support (Chaudhry 2010 (Tele-HF); Krum 2013 (CHAT) - Clark 2007b) and from 75% to 98.5% for telemonitoring (Capomolla 2004; Cleland 2005 (Struct Tele) (TENS-HMS); Cleland 2005 (Telemon) (TENS-HMS); De Lusignan 2001; Goldberg 2003 (WHARF); Mortara 2009 (Struct Tele) (HHH); Mortara 2009 (Telemon) (HHH), Soran 2008) (Table 4).

Acceptability (satisfaction and usability)

Acceptance (satisfaction and usability) of people receiving health care via technology was rated between 76% and 97% (Balk 2008; Cleland 2005 (Struct Tele) (TENS-HMS); Cleland 2005 (Telemon) (TENS-HMS); Krum 2013 (CHAT) - Clark 2007b; Vuorinen 2014; Woodend 2008).

The only two videophone studies in this review both had low satisfaction (De Lusignan 2001) and statistically non-significant satisfaction ratings (Wakefield 2008) (Table 5).

Heart failure knowledge and self care

Six structured telephone support studies (Baker 2011; Brandon 2009; DeWalt 2006; Domingues 2011; Wakefield 2008; Zamanzadeh 2013) and one telemonitoring study (Balk 2008) evaluated the effects of the intervention on participants' knowledge

of their heart failure. All studies except Wakefield 2008 demonstrated significant improvements in heart failure knowledge, although Wakefield 2008 did report an improvement in medication knowledge. Four structured telephone support (Baker 2011; GESICA 2005 (DIAL); DeWalt 2006; Zamanzadeh 2013) and one telemonitoring study (Seto 2012) reported significant improvements in self-care (Table 6).

ADDITIONAL SUMMARY OF FINDINGS [Explanation]

Impact of structured telephone or telemonitoring in heart failure on risk of all-cause hospitalisation[4]

Patient or population: people with heart failure
Setting:
Intervention: structured telephone or telemonitoring
Comparison: usual care

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with usual care	Risk with Impact of structured telephone or telemonitoring in CHF on risk of all-cause hospitalisation				
All-cause hospitalisation: Structured telephone support verus usual care	Study population		RR 0.95 (0.90 to 1.00)	7216 (16 RCTs)	○○○ VERY LOW [1,2,3]	
	422 per 1000	401 per 1000 (380 to 422)				
	Moderate risk population					
	432 per 1000	411 per 1000 (389 to 432)				
All-cause hospitalisation: Telemonitoring versus usual care	Study population		RR 0.95 (0.89 to 1.01)	3332 (13 RCTs)	○○○ VERY LOW [1,2,3]	
	517 per 1000	491 per 1000 (460 to 522)				
	Moderate risk population					
	541 per 1000	514 per 1000 (482 to 547)				

***The risk in the intervention group** (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: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1]Evidence of serious inconsistency in this outcome, due to moderate to substantial heterogeneity (structured telephone support I^2 =
47%; telemonitoring I^2 = 71%) .

[2]Evidence of serious imprecision in this outcome, due to wide confidence intervals around the effect measure for individual studies.

[3]Publication bias strongly suspected.

[4] Length of follow-up ranged from 3 months to 16 months for structured telephone support studies and from 3 months to 802 days for
telemonitoring studies.

Impact of structured telephone support or telemonitoring in heart failure on risk of heart failure-related hospitalisation[2]						
Patient or population: people with heart failure **Setting:** **Intervention:** structured telephone support or telemonitoring n **Comparison:** usual care						
Outcomes	**Anticipated absolute effects*** (95% CI)		**Relative effect (95% CI)**	**№ of participants (studies)**	**Quality of the evidence (GRADE)**	**Comments**
	Risk with usual care	**Risk with Impact of structured telephone support or telemonitoring in CHF on risk of CHF-related hospitalisation**				
CHF-related hospitalisation: Structured telephone support versus usual care	Study population		RR 0.85 (0.77 to 0.93)	7030 (16 RCTs)	MODERATE [1]	
	214 per 1000	182 per 1000 (165 to 199)				
	Moderate risk population					
	179 per 1000	152 per 1000 (138 to 167)				
CHF-related hospitalisation: Telemonitoring versus usual care	Study population		RR 0.71 (0.60 to 0.83)	2148 (8 RCTs)	MODERATE [1]	
	272 per 1000	193 per 1000 (163 to 225)				
	Moderate risk population					
	299 per 1000	212 per 1000 (179 to 248)				

***The risk in the intervention group** (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: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1]Publication bias strongly suspected.
[2]Length of follow-up ranged from 3 months to 16 months for structured telephone support studies and from 3 months to 26 months for telemonitoring studies.

D I S C U S S I O N

Summary of main results

This review summarises data from 41 trials covering 12,947 participants. Two of the included studies trialled both structured telephone support and telemonitoring compared to usual care, therefore 43 comparisons are evident. This review demonstrates that structured telephone support and non-invasive home telemonitoring programmes for people with heart failure living in the community reduce all-cause mortality by 13% (95% CI .0.77 to 0.98) and 20% (95% CI 0.68 to 0.94) respectively and heart failure-related hospitalisation by 15% (95% CI 0.77 to 0.93) and 29% (95% CI 0.60 to 0.83) respectively relative to usual care, but do not provide evidence of an important effect on all-cause hospitalisations. These results confirm those reported in previous Cochrane reviews (Clark 2007a; Inglis 2010), and place in context recent studies with a neutral outcome that have not materially changed the point estimates for mortality. However, the reduction in all-cause hospitalisation for people with heart failure reported in the previous version of this review (Inglis 2010), was not sustained in this updated analysis. Several studies reported significant improvements in health-related quality of life, as well as heart failure knowledge and self care. There is also evidence to support some reduction in healthcare costs, although this was less consistent across studies.

The first RCTs of structured telephone support (compared to usual care, without home or clinic visits) were published in 1999 (Gattis 1999 (PHARM); Rainville 1999) and the first study of non-invasive telemonitoring was published in 2001 (De Lusignan 2001). In the past 15 or more years, information technology has progressed rapidly alongside the need and demand for chronic disease management for conditions such as heart failure. The first version of this review (Clark 2007a) included just nine studies of structured telephone support and four studies of non-invasive telemonitoring. The first Cochrane review in 2010 (Inglis 2010) included 14 studies of structured telephone support and nine studies of non-invasive telemonitoring. The current review now includes 25 studies of structured telephone support and 18 studies of non-invasive telemonitoring.

Although we found a reduction in the proportion of participants with a heart failure-related hospitalisation, we did not identify a consistent effect 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 affect the care administered in hospital.

Remote monitoring might be most useful in reducing the risk of death if it is implemented when patients are unstable or newly diagnosed, and over a relatively brief period when they need support and education. We therefore performed sensitivity analyses to investigate length of follow-up on outcomes. Restricting the analyses only to studies with more than six months follow-up failed to demonstrate a significant effect of either intervention on all-cause mortality. However, this might reflect the smaller number of trials and participants rather than a true lack of effect.

For all-cause mortality there was little heterogeneity amongst pre-specified subgroups, although we noted a trend of borderline significance for a smaller effect of home telemonitoring in more recent studies. Although some technologies appeared inferior, such as the videophone and IVR, tests for heterogeneity were unable to confirm differences. Meta-regression tests did not identify heterogeneity (P = 0.34) and it is therefore inappropriate to conclude that apparent differences are well founded.

Neither age group, not the intensity of home telemonitoring, nor the nature of the structured telephone support proffered had an influence on the effect of interventions.

For reducing the risks of all-cause hospitalisations, we found no difference for non-invasive telemonitoring, while for structured telephone support the effect became barely statistically significant. When we limited the studies to those with more than six months follow-up the effect did not change for the telemonitoring intervention, but was improved (and reached statistical significance) for the structured telephone support intervention.

Both interventions (structured telephone support and non-invasive telemonitoring) showed a consistent and clear reduction in the risk of heart failure-related hospitalisations. When we used only studies with more than six months of follow-up, the first effect improved and the second remained basically unchanged.

We undertook several subgroup analyses to explore heterogeneity across the included studies. Using data from the previous version of this review (Inglis 2010), two of these subgroup analyses have been published (Conway 2014; Inglis 2014). We used heterogeneity tests to explore differences across the prespecified subgroups and meta-regressions to test whether the intervention effect could depend on the median age of participants or the year of publication of the trial. We found little conclusive evidence of heterogeneity, although in some cases this may have reflected the paucity of data. These analyses indicate that the effect of the intervention might change depending on the technologies involved, the intensity of the telemonitoring regimen and also on the year of publication. For all-cause mortality, only telephone and complex telemonitoring studies demonstrated a significant benefit, with mobile/PDA and IVR shown to be ineffective. For both structured telephone support studies and telemonitoring, studies published over the period 2000 to 2007 were effective in reducing the risk of all-cause mortality, but with this effect absent for more recent studies. Structured telephone support studies focusing on clinical support demonstrated a significant benefit in reducing the risk of

all-cause mortality, whereas those which focused on self-management education did not. For heart failure-related hospitalisations, telephone studies, mobile phone/PDA studies and complex telemonitoring studies were effective in reducing this risk, while IVR interventions were ineffective. For structured telephone support studies, the reduction in the risk of heart failure-related hospitalisations reduced by year of publication. Assessment of this effect was limited for telemonitoring studies, as only one study reporting heart failure-related hospitalisations was published prior to 2008. The differences between the mean/median age of participants was most notable for the outcome of heart failure-related hospitalisations for telemonitoring studies, where studies with a mean/median age of participants of 70 years or older demonstrated a 43% reduction in the risk of this outcome (relative to a 25% reduction for those with a mean/median age below 70 years).

Of the three outcomes included in our primary meta-analysis, we found the greatest heterogeneity in all-cause hospitalisations (structured telephone support I² = 47% and telemonitoring studies I² =71%). Two telemonitoring studies with small numbers of participants (Antonicelli 2008; Biannic 2012 (SEDIC)) reported a substantially lower RR for hospitalisation for all-causes (RRs of 0.36 and 0.54 respectively). These two studies account for a large part of the heterogeneity observed for this outcome, as between the other studies the heterogeneity is much lower (I² = 40%). The methodological reasons for this difference in reported outcomes for these two studies are unclear, but may relate to the intervention and the clinical management of these participants. There are no obvious differences in the study participants or study methodology that we can identify to account for this difference.

This review demonstrated good evidence for cost effectiveness for structured telephone support. The expense of telemonitoring has not been shown to have a cost benefit. Strong evidence is also emerging for the effect of structured telephone support and telemonitoring for improving health-related quality of life, heart failure knowledge and self-care behaviours.

Adherence was good in most studies reporting this outcome, and acceptance was strong among the participants in the studies reviewed. However, it appears that not all technologies are favoured by patients exposed to video and IVR. After a decade and a half of research in this area, what is indisputable from the satisfaction and quality-of-life evidence was that overall participants liked these interventions (structured telephone support and telemonitoring). This is demonstrated by levels of adherence, acceptance, knowledge, self-care behaviours and health-related quality of life. As described in the Background, the majority of people with heart failure do not have access to specialist services. Structured telephone support and telemonitoring can bridge this gap.

People who use non-invasive home telemonitoring are generally very positive about their experience. Structured telephone support and non-invasive home telemonitoring may provide greater benefits when targeting people requiring education about their disease and optimisation of therapy tailored to their needs. Home telemonitoring provides the person with the possibility of taking much more informed responsibility for their own care. Integrating structured telephone support and home telemonitoring into services may increase their benefits. It may be possible to deliver benefits similar to those of structured telephone support and home telemonitoring by intensification of conventional clinic- or community-based interventions. However, structured telephone support or home telemonitoring or both might prove more cost-effective than intensified conventional care. The possibility of additive or synergistic benefit from enhanced conventional services and structured telephone support and home telemonitoring should not be discounted. For geographically isolated people, remote management may be the only feasible means of delivering advice, and providing monitoring and support. The evidence supports the use of these interventions.

Overall completeness and applicability of evidence

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, or only available as a conference abstract or awaiting classification. We were unable to stratify results according to age, functional class or sex, as outcomes were not reported in a manner that allowed us to extract these subgroup-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.

Correctly identifying all of the outcomes available for each included study was challenging because of 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. Often these multiple publications were published with a different order or list of authors and the study was not always clearly identified from the title of the paper or the abstract. Future publications arising from RCTs of structured telephone support and telemonitoring should be published in a manner which permits easy identification of multiple publications.

Krumholz 2006 has outlined a taxonomy for disease management which encourages authors to describe their study intervention under eight domains (patient population; intervention recipient; intervention content; delivery personnel; method of communication; intensity and complexity; environment; and clinical outcomes). We found that studies inconsistently reported these details, which in turn did not allow us to explore differences in these domains as potential explanations for observed heterogeneity between studies. Many of the included studies were published prior to publication of the taxonomy. Similarly, Clark 2009 has called for a more specific evidence base to support the development of

effective programmes for different populations, and 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 us to extract these data. Most studies recruited more men than women. We were also unable to pool outcomes based on age, other than by using mean/median age of the study 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 comorbidities.

A major limitation to the studies conducted so far is that the research study is conducted in parallel with the existing service to patients who are willing to participate in research and by staff that are usually supernumerary 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, the lack of a service means that health professionals will struggle to get experience and training in conducting home monitoring. Ideally, studies should integrate home monitoring into the routine service. However, until home monitoring, and 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. 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); Chaudhry 2010 (Tele-HF); Koehler 2011 (TIM-HF)). However, employing health professionals is by far the largest part of healthcare costs. Technology that can make staff more efficient and effective may well be cost-neutral or cost-saving.

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

Quality of the evidence

We assessed the primary outcomes examined in the review using GRADEPro methodology (Schünemann 2011) to create 'Summary of findings' tables. Quality assessment ranged from very low (all-cause hospitalisation) to moderate (all-cause mortality and heart failure-related hospitalisation). We downgraded all-cause mortality and heart failure-related hospitalisation evidence by one point for strong suspicions of publication bias. We downgraded all-cause hospitalisation evidence by three points because of evidence of serious inconsistency and imprecision in this outcome, as well as a strong suspicion of publication bias.

The strong suspicion of publication bias may in some part be due to the inclusion of only full-text peer-reviewed publications. How-

ever we stand by our decision to exclude studies not yet published as a full-text peer-reviewed publication and have discussed this methodological aspect below in the strengths and weaknesses of this review.

Potential biases in the review process

Our review has adhered to Cochrane methodology, and all review authors and personnel have at all times tried to avoid or minimise any biases in the review process. The introduction of several subgroup analyses in this version of the review was initiated in order to investigate potential heterogeneity across the included studies. We classified studies into these categories adhering to clear definitions and processes; however, minimal details of interventions and participants reported in some studies may lead to some minor inaccuracies in these classifications. Of most concern is that categorisation of studies according to year of publication does not take into account that for a small number of studies there may be a substantial time lag between the start of study recruitment and full-text peer-reviewed publication in a journal.

Publication bias has been noted as an issue in evidence presented in the review. It may be that the exclusion of studies not yet published as a full peer-reviewed publication has given rise to some of this publication bias. The review captures eight studies currently awaiting classification and 25 currently ongoing studies. Some of these currently ongoing studies have not yet reported any study findings and only a study protocol was available, for others, interim results have been presented in the form of conference abstracts, with very little detail provided to clarify the intervention or usual care. Our decision to exclude studies not published as a full peer-reviewed publication was based on research indicating inconsistency between trial findings presented as conference abstracts to those reported in a full, peer-reviewed publication (Toma 2006). Another factor which was important in the decision to exclude studies only available as a conference abstract was the lack of detail provided regarding the intervention and usual care, thereby not providing confidence as to the classification of the study in terms of inclusion/exclusion in the review. Authors of studies available only as a conference abstract or study protocol were contacted in order to identify a full peer-reviewed publication for the study. A response was not received from several studies which are classified as ongoing or awaiting classification despite multiple attempts to contact authors.

Agreements and disagreements with other studies or reviews

This review is novel in that we sought to delineate the benefits of one form of heart failure disease management on patient outcomes while controlling for other disease management interventions which may confound the benefits of structured telephone

support and non-invasive home telemonitoring. It is important to consider the benefits that these specific interventions can deliver, as there are some circumstances where such interventions may be the only option for providing specialised heart failure management. Multidisciplinary heart failure management programmes, designed to improve patient outcomes through structured follow-up with patient education, optimisation of treatment and psychosocial support, are advocated worldwide as a fundamental component to the delivery of care. However, because of conflicting trial results, national and international guidelines have so far not recommended widespread implementation of remote monitoring. The latest European Society of Cardiology Heart Failure Guidelines (McMurray 2012) state that the effect of invasive (implantable devices) and non-invasive telemonitoring, and structured telephone support remain unclear, with insufficient evidence to support a guideline recommendation. Similarly the 2013 ACCF/AHA Guidelines for the Management of Heart Failure (Yancy 2013) acknowledged the problem of the mixed quality of evidence for specific components of heart failure clinical management interventions, such as home-based care, disease management, and remote telemonitoring programmes. The National Institute for Health and Clinical Excellence (NICE) guidelines in the United Kingdom (Mant 2011) summarise that telemonitoring reduces mortality and hospitalisation for any reason but does not seem to improve quality of life or decrease heart failure-related hospitalisations. For this reason again the guideline did not include a recommendation for telemonitoring.

Several systematic reviews and meta-analyses have been published on this topic (Clarke 2011; Kotb 2015; Pandor 2013b; Polisena 2010). Although superficially the recently published reviews appear similar, there are important differences in inclusion criteria from our review, and particularly the inclusion of home visits or invasive haemodynamic monitoring in their definitions of 'remote monitoring'. Our review focuses solely on non-invasive monitoring and structured telephone support, and as such we believe is more relevant for healthcare 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 impair the possibility of directly comparing 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. The previous version of this review included 30 randomised controlled trials (25 peer-reviewed publications and 5 abstracts) comparing telemonitoring or structured telephone support to usual care. Other recently published systematic reviews and meta-analyses have included fewer studies, used different selection criteria, and some have included cohort studies and/or did not systematically exclude intensified follow-up such as home visits (Clarke 2011; Kotb 2015; Pandor 2013b; Polisena 2010). Nonetheless, overall findings have been consistent in confirming that telemonitoring re-

duces all-cause mortality, especially in those situations where the quality of usual care is inferior. However, the effect on all-cause or heart failure-related hospitalisations was more variable.

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 non-invasive telemonitoring in the absence of home visits or intensified clinic follow-up, which identifies for clinicians and healthcare service planners the value of each of the 'building blocks' in contemporary heart failure disease management programmes, allowing them to be better customised to needs. Another strength of our systematic review and meta-analysis is that we have considered and synthesised evidence on many important aspects of heart failure (mortality, hospitalisations, length of stay, quality of life, heart failure knowledge and self care, acceptability, and cost). Weaknesses of this review are due to inadequate reporting by some studies, which has precluded classification of risks of bias as either low or high risk, leading to many studies across the categories being rated as at unclear risk.

Although we have only included studies which were published as a full-text peer-reviewed publication, we consider that this is a strength of this review. We do, however, acknowledge that this has resulted in some studies which are near to reporting final results not being included in this update. Studies which are yet to report final results are listed as Studies awaiting classification, and those which are still ongoing are listed as Ongoing studies.

A U T H O R S ' C O N C L U S I O N S

Implications for practice

Compared to usual conventional care, implementation of structured telephone support and non-invasive home telemonitoring reduces mortality and heart failure-related hospitalisations, improves quality of life, heart failure knowledge and self-care behaviours and therefore should be considered evidence-based strategies to improve the quality of care and outcomes for people with heart failure.

As the equipment for these interventions was in most cases provided as part of the study, the implications for purchase, installation and maintenance of such equipment for use of telemonitoring in particular in the real world needs to be considered as these may be barriers to the use of telemonitoring.

Implications for research

- Patient preference and engagement is a key factor in successful delivery of structured telephone support and non-invasive home telemonitoring services and should be a greater

focus for future research. Patient approval for these services appears to be high.

- Structured telephone support and non-invasive home telemonitoring are a heterogeneous group of interventions. Further RCTs investigating the benefits of these interventions would be valuable, but should take into account many factors including the population to be studied and the intended interventions for both the active and control groups. Structured telephone support and non-invasive home telemonitoring may not be superior to intensive management by conventional means, and this should be taken into account when planning studies. Monitoring alone is unlikely to change outcome; actions as a consequence of monitoring may.

- However, further studies in geographically isolated communities could be considered unnecessary, as there may be no satisfactory alternative to structured telephone support and non-invasive home telemonitoring, and the data in support of this approach are substantial.

- More consideration should be given to the potential advantages of cluster-RCTs when evaluating service models, including structured telephone support and non-invasive home telemonitoring. This allows structured telephone support and non-invasive home telemonitoring to be evaluated alongside other disease management strategies and the 'best' multi-modal strategy identified.

- Although there is a plethora of evidence in well-resourced, high-income countries, consideration should be given to more studies undertaken in low- and middle-income nations where the burden of heart failure may increase in the future (Callender 2014b).

- Standard design and reporting criteria for studies of structured telephone support and non-invasive home telemonitoring should be developed. The published taxonomy (Krumholz 2006) should be developed for this purpose.

- Investigators are encouraged to share data. This will enable individual patient data meta-analysis that can provide insights into overall effect and in subgroups.

- Future research into 'remote monitoring' of people with heart failure should compare the value of remote monitoring using a variety of different non-invasive technologies as well as implanted devices.

- The development of closed-loop systems that integrate physiological measurements into decision-support tools that allow the patient greater participation in their own disease management is an exciting area requiring more research. Patient motivation as well as education may be important.

- More work is required on business models to identify sustainable, cost-effective services, particularly telemonitoring.

High capital acquisition costs with low running costs argue for long-term monitoring of individuals. However, renting equipment argues for monitoring over shorter periods of high risk with intensive monitoring and education. Business models will help define how the clinical community use the technology.

- Stratified implementation of technology should be investigated, according to the severity of illness on the trajectory of heart failure.

- The potential for remote monitoring in end-of-life care for heart failure should be investigated.

- Publications relating to studies of these interventions should clearly identify to which study they relate and where outcomes are reported across multiple publications, all publications for a study should detail all of the outcomes and then indicate which are reported in each publication.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Angermann 2012 (INH)

Methods	Open, randomised, 2-armed, parallel-group, multicentre trial 2 groups: nurse co-ordinated disease management programme (HeartNetCare-HF, HNC) or usual care (UC)
Participants	715 people with heart failure ≥ 18 years of age hospitalised with signs and symptoms of decompensated heart failure (dyspnoea at rest/minimal exercise plus at least 1 the following: raised jugular venous pressure, peripheral oedema, third heart sound or pulmonary congestion on either clinical examination or radiography) and LVEF ≤ 40% Mean age 68.6 years. 71% of participants were men. 2% NYHA class I, 58% NYHA class II, 36% NYHA class III, 4% NYHA class IV, mean LVEF 30% HNC: n = 352, mean age 67.7 years, 71% men, 3% NYHA class I, 54% NYHA class II, 40% NYHA class III, 3% NYHA class IV, mean LVEF 30% UC: n = 363, mean age 69.4 years, 71% men, 2% NYHA class I, 62% NYHA class II, 31% NYHA class III, 5% NYHA class IV, mean LVEF 30% 9 hospitals in Germany.
Interventions	Structured telephone support Electronic scale and BP at participant's home. Intervention included: 1) in-hospital face-to-face education; 2) telephone-based structured monitoring using 19-item questionnaire (assessing indicators of worsening HF, other cardiac symptoms, medication, health care utilisation, state of mood and general health and well-being; 3) up titration of HF medication in co-operation with GPs; 4) needs-adjusted specialist care, which nurses co-ordinated with participant's physician All nurses received supervision by cardiologist (weekly) and a psychologist (bimonthly), and had unrestricted access to their supervisor for questions Professionals involved: skilled nurses, general practitioners and cardiologist Frequency of intervention: weekly during the first month, and then individualised according to NYHA class at discharge (weekly or fortnightly for NYHA III - IV, monthly for NYHA I - II) and participant's needs
Outcomes	Follow-up: 180 days Primary endpoint was time to all-cause rehospitalisation (combined endpoints) Secondary endpoints were cardiovascular and all-cause death or hospitalisation separately, time to, number and duration of readmissions, number of days alive and not hospitalised, changes in NYHA class, HF medication, cardiac function and quality of life
Funding source	German Ministry of Education and Research, German Competence Network Heart Failure, Comprehensive Heart Failure Centre Wurzburg, University of Wurzburg Cardiovascular Centre

Angermann 2012 (INH) *(Continued)*

Comparison Group(s)	Usual care: fixed appointment with GP or cardiologist within 7 - 14 days after discharge. No restrictions were placed on outpatient care Professionals involved: skilled nurses, general practitioners and cardiologist
Notes	New in 2015 review - included as abstract in sensitivity analysis in previous version of review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Central computer-generated block random assignment was used (strata: age (>70 vs. <70 years), sex and type of outpatient care (cardiologist vs. GP)"
Allocation concealment (selection bias)	Low risk	Quote: "Patients were randomly assigned 1:1 to either HNC or UC, using sealed envelopes"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "An independent committee adjudicated the end points (see online-only Data Supplement Appendix), blinded to treatment assignment"
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "More patients withdrew consent in HNC; life status at 180 days was ascertained in dropouts and reported as uncensored survival data" 22 UC (6%) and 45 HNC (12%) participants withdrew consent. No participants were lost to follow-up Comment: There were imbalances between dropouts in the 2 groups. (Uncensored) survival was assessed but unsure about other endpoints
Selective reporting (reporting bias)	Low risk	All prespecified endpoints have been addressed (except for total duration of readmissions; duration of first and second hospitalisation has been reported)

Antonicelli 2008

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	57 people hospitalised for worsening symptoms and signs of CHF with NYHA class II - IV, evidence of pulmonary congestions on chest x-ray and EF < 40%. People with NYHA class II - III with an EF > 40% and diastolic LV dysfunction were also included Mean age 78 years. 61% of participants were men. Italy
Interventions	Telemonitoring Participants 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. Participants were then evaluated and their regimen altered when necessary based on these data. Additionally, clinic visits were performed when required based on the data collected or telephone interviews
Outcomes	Combined rate of mortality and hospitalisation, these rates considered individually, quality of life 12-month follow-up.
Funding source	Italian Ministry of Health
Comparison Group(s)	Usual care involved receiving stand care based on routinely scheduled clinic visits (every 4 months) performed by a team specialised in CHF patient management. These participants 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
Notes	Included previous version of review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not stated.
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No evidence of incomplete outcome data.

Antonicelli 2008   *(Continued)*

Selective reporting (reporting bias)	Low risk	No evidence of selective outcome reporting.

Baker 2011

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	605 people with heart failure from general and internal medicine and cardiology clinics at 4 different sites Inclusion criteria: diagnosis of heart failure, NYHA Class II - IV symptoms in the past 6 months, current use of a loop diuretic, fluency in English or Spanish and adequate cognitive function (based on Mini-Cog screening tool) Mean age 60.7 years. 52% of participants were men. USA
Interventions	Structured telephone support. Intensive education and self-care training which was based on social cognitive theory and adult learning theory. This included specific instruction using daily weights to guide diuretic self adjustment and included an individualised plan developed with the participant's clinician. Over 4 weeks, participants were scheduled to receive 5 - 8 phone calls from the study educator to reinforce education and to guide the participant towards improved self-care skills. Each call lasted about 10 minutes. The calls focused on reviewing the content of the initial education session, assessing the participant's knowledge and behaviour and providing additional information and encouragement
Outcomes	30 days - Heart failure-related quality of life and heart failure knowledge was assessed using the Improving Chronic Illness Care Evaulation Heart Failure Symptom Scale All-cause hospitalisation and mortality at 6 and 12 months.
Funding source	Not reported.
Comparison Group(s)	Control was a brief educational intervention (BEI), duration of 40 minutes which covered daily self assessment and action planning in case of exacerbation, salt avoidance, exercise and medication adherence. Participants received an educational manual and a new digital scale for weighing themselves. All participants in both study arms received this BEI, after which participants were randomised to the control arm where they continued to receive usual care, or the intervention
Notes	New in 2015 review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Allocation to study group is done with concealed, stratified, block randomization by the statistical team at UNC."

Allocation concealment (selection bias)	Low risk	Quote: "Randomization assignments are placed in sets of opaque envelopes and distributed to the health educators at each site. After literacy status is determined and the BEI is delivered, the health educator opens the opaque envelope and learns the intervention status of the patient"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Patients were called by the UNC Survey Research Unit (SRU) on day 30 of the study (with day 1 defined as the day of the initial in-person educational session) and a blinded interview conducted."
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "During the 30-day study period.. .72 (11.7%) patients did not complete the 1-month assessment call (41 in the BEI group and 31 in the TTG group), leaving 259 patients in the BEI group and 272 in the TTG group"
Selective reporting (reporting bias)	Low risk	No evidence of selective outcome reporting.

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 men. The Netherlands.
Interventions	Telemonitoring. Participants 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 participants 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). Participaent guidance followed a personalised plan
Outcomes	288 days - mean follow-up. All-cause hospital days per year, days alive and out of hospital, quality of life, knowledge of disease, self care
Funding source	Study proposed and funded by the healthcare insurance company Achmea Philips- provision of the MOTIVA system.

Balk 2008 (*Continued*)

Comparison Group(s)	Control participants were followed by their cardiologists and HF nurses according to standard local practice All participants recorded all contacts with healthcare professionals and hospital admissions
Notes	Included in previous version of review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "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"
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No evidence of incomplete outcome data.
Selective reporting (reporting bias)	Low risk	No evidence of selective outcome reporting.

Barth 2001

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	34 people discharged from acute care to home with primary diagnosis of CHF Mean age 75 years. 47% of participants were men. USA
Interventions	Structured telephone support. Structured nurse-managed telephonic post-discharge programme involving predischarge education plus post-discharge telephone follow-up. Structured interaction at 72 hours, 144 hours, and then fortnightly
Outcomes	Mortality, rehospitalisation, physician and emergency department visits, quality of life, cost of the intervention 3 months follow-up.
Funding source	Not reported.

Barth 2001 *(Continued)*

Comparison Group(s)	The control group received routine discharge teaching at the time of discharge as per hospital procedure. Participants were contacted at 2 months for collection of data
Notes	Included in previous version of review (Inglis 2010)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not stated.
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not detailed.
Selective reporting (reporting bias)	Low risk	Not evident.

Bento 2009

Methods	Randomised controlled trial. Single-blinded 2 groups: intervention group (nursing consultation and telephone monitoring of educational nature every 15 days) versus usual care (with monthly telephone monitoring of epidemiological and administrative nature)
Participants	40 participants with a diagnosis of heart failure and NYHA class I - IV, treated at a heart failure outpatient clinic with telephone access Mean age (intervention 54 years; control 61 years, P = 0.046) 70% of participants were men. IG: n = 20, mean age 54.3 years, 65% men, 5% NYHA I, 65% NYHA II, 30% NYHA III, 0% NYHA IV CG: n = 20, mean age 60.7 years, 75% men, 5% NYHA I, 50% NYHA II, 45% NYHA III, 0% NYHA IV Brazil
Interventions	Structured telephone support Conventional medical assistance (not otherwise specified), nursing consultation (fortnightly or monthly depending on participants' needs) and telephone monitoring every 15 days (education, recording hospitalisations and emergency treatments). Recomendations on pharmacological treatment, water intake, sodium intake, BP control, body weight control Duration: 6 months Professionals involved: nurses

Bento 2009 *(Continued)*

Outcomes	Follow-up: 6 months. All-cause hospitalisations.
Funding source	No funding received.
Comparison Group(s)	Conventional medical assistance and monthly telephone monitoring of administrative and epidemiological nature, with no education. The phone calls were aimed at recording hospitalisations and emergency treatments Professionals involved: not specified
Notes	New in 2015 review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The groups were created by simple random allocation (drawing lots)..."
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: No dropouts reported.
Selective reporting (reporting bias)	High risk	Comment: Some hospitalisations in the CG might have been underreported due to the fact that some emergency services do not record these cases

Biannic 2012 (SEDIC)

Methods	Randomised controlled trial. 2 groups - classic follow-up group and telemedicine group.
Participants	Telemonitoring Elderly and well-treated population suffering from severe heart failure. Participants older than 65 years of age, recently hospitalised for HF (EF < 45%) 73 participants (99 randomised); 35 in control group (UC) and 38 in the TM group TM: mean age 76; 79% men, mean LVEF 31.9%, NYHA II 45.9%, NYHA III 54% UC: mean age 77.9; 77% men, mean LVEF 31.1%, NYHA II 35.3%, NYHA III 64.7% France

Biannic 2012 (SEDIC) *(Continued)*

Interventions	TM group: TM during 3 months, after which participants all received usual care up until 1 year TM: intensity 3 times per week; variables: symptoms, weight and BP
Outcomes	Follow-up 3 months (preliminary results; main trial will report on follow up of 1 year) Primary outcome: number of days in hospital for acute cardiac reasons:
Funding source	No funding
Comparison Group(s)	Author correspondence: "After an initial consultation with a specialized nurse, all eligible patients participated in therapeutic education sessions, which focused on disease knowledge and dietetic advice and were part of the French I-Care project endorsed by the French Society of Cardiology (14). All investigators were asked to treat patients in accordance with the current guidelines for the management of HF, irrespective of the group assignment. Automated sphygmomanometers were given to all patients. Patients assigned to the SOC group were treated in the same manner as those assigned to the ETM group (including standard therapeutic education), and all subjects were instructed to contact their physician for HF symptom worsening and weight increase."
Notes	New in 2015 review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomized occurred centrally by the Unit of Biostatistics and Clinical Research" in Caen."
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	High risk	Both intention-to-treat and per protocol analysis have been performed. 99 participants were randomized, 11 withdrew consent after inclusion or refused further follow-up, 3 were excluded because of breach of protocol. 4 never used the TM system and in 1 participant it was never installed (because of prolonged hospitalisation). 73 participants completed the 3-month follow-up. Conflict in the report: "34 patients in the telemonitoring arm produced at least 1 alert" (Page 43) is in conflict with the num-

Biannic 2012 (SEDIC) *(Continued)*

		ber of 38 patients reported to be included in the telemonitoring group
Selective reporting (reporting bias)	Low risk	Prespecified endpoints were addressed

Blum 2014 (MCCD)

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	204 people with heart failure. Inclusion criteria: hospital admission in the past year; able to provide informed consent; access to a telephone; systolic or diastolic dysfunction; and enrolled in Medicare Part A and B Mean age 72 years. 71% of participants were men. USA
Interventions	Telemonitoring. All participants 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 Intervention participants were instructed to use the scale, BP cuff/HR monitor and the heart rhythm strip monitor at the same time each day. The transmitted data were then compared to individually assigned parameters based on the participant'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 people with heart failure contacted the participant 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 or consultation with the participant's cardiologist, or both. If no flags were noted over the period of 1 month, the participants were called just to maintain contact, provide encouragement and answer any questions they might have
Outcomes	Mean follow-up 802 ± 430 days. All-cause mortality, hospitalisations (as provided by the authors). Quality of life using SF-36 and Minnesota Living with Heart Failure Questionnaire at 12 months
Funding source	Center for Medicare and Medicaid Services (CMS).
Comparison Group(s)	The usual-care group was not contacted again until time to schedule the 6-month follow-up appointment
Notes	New in 2015 review - included as abstract in sensitivity analysis in previous version of review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement

Blum 2014 (MCCD) *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Quote: "The subject's identification information was entered into the Mathematica Policy Research (MPR) randomisation web site and the designation of participant (tele monitored group) or control (usual care) was returned"; author correspondence
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "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
Selective reporting (reporting bias)	Low risk	No evidence of selective outcome reporting.

Brandon 2009

Methods	Randomised controlled trial using pretest, post-test design. 2 study arms, a control (usual care) and a intervention (advanced-practice nurse-led telephone intervention)
Participants	People with heart failure under the care of 1 cardiologist. Inclusion criteria included living with heart failure for more than 6 months, capable of self care, telephone access Mean age of participants was 60 years. 45% men. USA.
Interventions	Structured telephone support. Advanced Practice Nurse-led intervention was delivered by the same APN throughout the study. The frequency of the APN-led intervention was weekly for 2 weeks and every 2 weeks for the following 10 weeks. There were 7 telephone appointments for each participant in the intervention group. The APN-led intervention included education about the pathophysiology of HF, a low sodium diet, smoking cessation, flu/pneumonia

Brandon 2009 (*Continued*)

	vaccination, when to call the physician with symptoms of exacerbation and medication adherence
Outcomes	Length of follow-up 3 months. HF-related hospital admissions; QoL and self-care behaviours
Funding source	Not reported.
Comparison Group(s)	Participants randomised to the control group received usual care from the cardiologist clinic. This included education by the physician or a registered nurse about exercise recommendations, low sodium intake, medications, and when to call the physician with increased swelling or shortness of breath
Notes	HF-hospitalisation data presented only as ANOVA output and unable to be included in meta-analysis. Authors contacted, but no response received New in 2015 review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not detailed: "...participants were randomly assigned to the intervention or usual care group"
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not detailed.
Selective reporting (reporting bias)	Unclear risk	HF-hospitalisation data presented only as ANOVA output and unable to be included in meta-analysis. Authors contacted, but no response received

Capomolla 2004

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	133 people discharged from specialist CHF unit to home. Mean age 57 years. 88% of participants were men. Italy

Capomolla 2004 (*Continued*)

Interventions	Structured telephone support. Daily communication of vital signs (including weight, systolic BP, HR) and symptoms with review by nurses and physicians. Access to medical staff via phone was available as needed
Outcomes	Mortality, re hospitalisation, emergency department visits, compliance with intervention 12 month follow-up.
Funding source	Ministero della Salute
Comparison Group(s)	Usual care consisted of a referral to the participant's primary care physician or cardiology department at discharge. Post-discharge care was governed by the care provider
Notes	Included in previous version of this review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not stated.
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not detailed.
Selective reporting (reporting bias)	Low risk	No evidence of selective outcome reporting.

Chaudhry 2010 (Tele-HF)

Methods	Randomised controlled trial.
Participants	1653 people who had recently been hospitalised for heart failure enrolled from 2006 through 2009 at 33 cardiology practices across the USA Median age of the participants was 61 years. 58% of participants were men. USA.
Interventions	Structured telephone support. All study participants received educational materials developed by the Heart Failure Society of America, and if needed, a weighing scale Participants in the intervention group were also provided with detailed instructions and

Chaudhry 2010 (Tele-HF)   *(Continued)*

	a demonstration by site co-ordinators of how to use the system, as well as a touch-tone telephone, if needed. The intervention was performed using a commercial system, Tel-Assurance (Pharos Innovations)
	The intervention group was instructed to make daily, toll-free calls to the system. During each call, participants, via an interactive voice response system, heard a series of questions about general health and heart-failure symptoms, and entered responses using the telephone keypad. Validated depression screening questions were included monthly. Information from the system was downloaded daily to a secure Internet site and was reviewed every weekday (except on holidays) by site co-ordinators. All questions had predetermined responses that triggered "variances" to flag clinicians' attention. The protocol required the sites to contact any participant whose response generated variances and document their management of the variances
	Clinicians were instructed to treat participants in accordance with national guidelines for the management of heart failure
Outcomes	Primary endpoint was a composite of readmission for any reason or death from any cause within 180 days after enrolment. Prespecified secondary endpoints included hospitalisation for any reason or death from any cause, hospitalisation for heart failure, number of days in the hospital, number of hospitalisations for any cause, and times to the primary endpoint and its components
Funding source	National Heart, Lung, and Blood Institute.
Comparison Group(s)	All study participants received educational materials developed by the Heart Failure Society of America, and if needed, a weighing scale
	Clinicians were instructed to treat participants in accordance with national guidelines for the management of heart failure
Notes	New in 2015 review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomly assigned to receive usual care or undergo telemonitoring, according to a sequence of computer-generated random numbers, with stratification on the basis of the study site"
Allocation concealment (selection bias)	Low risk	Quote: "All patients provided written informed consent before randomization"
		"Randomization is centralized and performed by telephone. Randomization is stratified by study site, and force randomized within each study site in blocks of 20 (10 intervention, 10 control), to ensure a balance across study arms within each site. The randomization sequence is developed by the coordinating center using a computer random-number generator. The sequence is unknown to the attending cardiologists and nurses.

Chaudhry 2010 (Tele-HF) *(Continued)*

		The study nurses call the coordinating center when they enroll a new patient; the coordinating center personnel then assigns the new patient to intervention or control group according to the randomization list for that study site"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "A committee of physicians, all of whom were unaware of the treatment-group assignments, adjudicated each potential readmission to ensure that the event qualified as a readmission (and not another clinical encounter such as an emergency department visit) and to determine the primary cause of the readmission"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "A total of 21% of the study patients did not complete the final telephone interview at 6 months. This rate is not surprising, given the severity of illness in the study population. Missing data for these patients should have had minimal influence on our assessment of hospitalization and vital status, which were verified through medical-record review and electronic databases."
Selective reporting (reporting bias)	High risk	Comment: The study protocol is available and the primary endpoint has been adequately reported. However, following secondary endpoints are missing: number of office visits with the clinician receiving information from the telemonitoring system; cost of inpatient and outpatient medical care; health status; participants' satisfaction with care; and participants' reported confidence in their self management of HF

Cleland 2005 (Struct Tele) (TENS-HMS)

Methods	Randomised controlled trial; multiple intervention arms and control (usual care) arm 3-armed study with both telephone and telemonitoring.
Participants	426 people with a recent admission for heart failure and LVEF < 40% Mean age 67 years. 77% of participants were men. Germany, Netherlands, UK.
Interventions	Structured telephone support; telemonitoring. Participants 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 Participants assigned to telemonitoring received the nurse telephone support and had their weight, BP and ECG monitored twice daily
Outcomes	Mortality, rehospitalisation, compliance with intervention. 240-day and 450-day follow-up.

Cleland 2005 (Struct Tele) (TENS-HMS)   *(Continued)*

Funding source	Quote: "The study was funded jointly by the European Union's Trans European Network (TEN) Telecom programme, which provided most of the financial support for clinical investigators, data collection, and analysis, and by Philips Medical Systems, which provided information technology systems, telemonitoring solutions, and support engineers and contributed to investigator-site staff costs"
Comparison Group(s)	Usual care consisted of a management plan forwarded to the participant's primary care physician, who was asked to implement it. If the practice involved nurse titration of drugs this was allowed. Participants were assessed at a research clinic every four months; contact with the clinic was discouraged between clinic visits
Notes	Included in previous review (Inglis 2010). Results included in meta-analysis are from 240-day follow-up

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random permuted blocks - correspondence from author.
Allocation concealment (selection bias)	Low risk	After consent and collection of baseline data an independent statistical centre was contacted - correspondence from author
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Investigators were asked to classify hospitalizations as due to heart failure, other cardiovascular, or noncardiovascular. Deaths were classified as sudden, due to circulatory failure, or due to other causes."
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "...Four were lost to follow-up and 12 declined to comply with regular telemonitoring" Quote: "Analyses were conducted by intention-to-treat".
Selective reporting (reporting bias)	Low risk	Selective outcome reporting not evident.

Cleland 2005 (Telemon) (TENS-HMS)

Methods	Randomised controlled trial; multiple intervention arms and control (usual care) arm 3-armed study with both telephone and telemonitoring.
Participants	426 people with a recent admission for heart failure and LVEF < 40% Mean age 67 years. 77% of participants were men.

Cleland 2005 (Telemon) (TENS-HMS) *(Continued)*

	Germany, Netherlands, UK.
Interventions	Structured telephone support; telemonitoring. Participants 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 Participants assigned to telemonitoring received the nurse telephone support and had their weight, BP and ECG monitored twice daily
Outcomes	Mortality, rehospitalisation, compliance with intervention. 240-day and 450-day follow-up.
Funding source	Quote: "The study was funded jointly by the European Union's Trans European Network (TEN) Telecom programme, which provided most of the financial support for clinical investigators, data collection, and analysis, and by Philips Medical Systems, which provided information technology systems, telemonitoring solutions, and support engineers and contributed to investigator-site staff costs"
Comparison Group(s)	Usual care consisted of a management plan forwarded to the participant's primary care physician, who was asked to implement it. If the practice involved nurse titration of drugs this was allowed. Participants were assessed at a research clinic every 4 months; contact with the clinic was discouraged between clinic visits
Notes	Included in previous review (Inglis 2010). Results included in meta-analysis are from 240-day follow-up

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random permuted blocks; correspondence from author.
Allocation concealment (selection bias)	Unclear risk	After consent and collection of baseline data an independent statistical centre was contacted; correspondence from author
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Investigators were asked to classify hospitalizations as due to heart failure, other cardiovascular, or noncardiovascular. Deaths were classified as sudden, due to circulatory failure, or due to other causes."
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "...Four were lost to follow-up and 12 declined to comply with regular telemonitoring" Quote: "Analyses were conducted by intention-to-treat".

Cleland 2005 (Telemon) (TENS-HMS) *(Continued)*

Selective reporting (reporting bias)	Low risk	Selective outcome reporting not evident.

De Lusignan 2001

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	20 people with heart failure confirmed by cardiologist, identified from the database of an academic general practice Mean age 75 years. Number or proportion of men and women not specified. UK.
Interventions	Telemonitoring. Telemonitoring of vital signs (pulse, BP, weight) and clinical status daily assessed daily by nurses along with video consultations with a nurse weekly for 3 months, fortnightly for 3 months, then monthly
Outcomes	Mortality, compliance with intervention and medication, participant satisfaction, quality of life 12 month follow-up.
Funding source	Hewlett Packard now Agilent. MSD Pharmaceuticals, Herts who funded the assessments of the controls
Comparison Group(s)	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 the intervention group
Notes	Included in previous version of review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The first 20 patients identified by random table allocation 10 to the telemedicine and 10 to the control group.. ."
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not detailed.

De Lusignan 2001   (*Continued*)

Selective reporting (reporting bias)	Low risk	No evidence of selective outcome reporting.

DeBusk 2004

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	462 people hospitalised with a provisional diagnosis of CHF from Kaiser Permanente Mean age 72 years. 51% of participants were men. USA.
Interventions	Structured telephone support. Standardised telephonic physician-directed nurse-managed case management, involving CHF lifestyle education and medication management. Participants contacted weekly for 6 weeks, biweekly for 8 weeks and then monthly and bimonthly
Outcomes	Mortality, rehospitalisation, emergency and outpatient department visits, prescription of recommended pharmacotherapy 12 months follow-up.
Funding source	National Heart, Lung, and Blood Institute.
Comparison Group(s)	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)
Notes	Included in previous version of review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Equal numbers of patients were allocated to the 2 groups in each medical center by using the Efron procedure".
Allocation concealment (selection bias)	Low risk	Quote: "Research staff who were not associated with delivering the intervention randomly assigned patients to treatment conditions by using sealed assignments."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Research staff who were not associated with, and were blinded to, the intervention conditions measured health outcomes at 12 months."

DeBusk 2004 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "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)" The analysis was by intention-to-treat.
Selective reporting (reporting bias)	Low risk	No evidence of selective reporting.

Dendale 2012 (TEMA-HF1)

Methods	Multicentre RCT (all centres located in Belgium). Follow-up: 6 months 2 arms: Telemonitoring (TM) versus usual care.
Participants	160 people hospitalised with heart failure. Inclusion criteria included: hospitalisation for fluid overload due to heart failure requiring an increase or initiation of diuretic treatment. All participants had to be treated with an ACE inhibitor or angiotensin II receptor antagonist, and with a beta-blocker in the absence of contraindications. Only people with sufficient cognitive function to operate the telemonitoring equipment Mean age 76 years. 65% of participants were men. All: n = 160, mean age 76 years, 65% men, mean LVEF 35%; NYHA class III TM: n = 80, mean age 77 years, 62% men, mean LVEF 32.5%, mean NYHA class III UC: n = 80, mean age 77 years, 67% men, mean LVEF 35%, mean NYHA class III Belgium.
Interventions	Telemonitoring. Daily measurement of weight, BP and HR for 6 months. Participants were seen at the HF clinic 2 weeks after discharge, and at 3 and 6 months (but were allowed to visit the clinic sooner or more frequently if necessary) Professionals involved: GP, heart failure clinic (HF nurse and cardiologist)
Outcomes	Primary endpoint was all-cause mortality. Secondary endpoints were days lost until death, hospitalisation or dialysis and number of hospitalisations and cost of hospitalisations 6 month follow-up.
Funding source	The Belgian Government Health Insurance Institute; Leo Pharma
Comparison Group(s)	All participants were seen at the HF clinic 2 weeks after discharge. No intervention by the study nurse or HF clinic was done thereafter Professionals involved: GP (who could refer participants to their cardiologist if needed)
Notes	New in 2015 review.

Risk of bias

Dendale 2012 (TEMA-HF1) *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Next, patients were block randomised by sealed envelopes to 6 months of intense follow-up facilitated by TM or usual care"
Allocation concealment (selection bias)	Low risk	Comment: Method of allocation concealment was sealed envelopes
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "To decrease the risk of bias in an unblinded study, the data were collected by a data manager not involved in patient care, and not stationed in one of the participating hospitals. The statistical analysis was done by a statistician not involved in patient care. The reason for hospitalization was determined based on the discharge letter and adjudicated after the end of the study in a blinded way, and the primary endpoint was all-cause mortality, which avoided the difficulty of determining the cause of death."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Four patients dropped out prematurely because of lack of motivation (timing and assigned group not specified). Data from these subjects were included in the analysis (intention to treat)"
Selective reporting (reporting bias)	Low risk	Comment: The study protocol is not available but the results paper reports on all pre-specified outcomes

DeWalt 2006

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	127 people 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 men. USA.
Interventions	Structured telephone support. Intervention participants received self-care education, picture-based educational materials with verbal explanation, a digital scale and scheduled follow-up phone calls (days

DeWalt 2006 (*Continued*)

	3, 7, 14, 21, 28, 56) and monthly during months 3 - 6 for reinforcement of education and revision of individualised care plan
Outcomes	Mortality, all-cause rehospitalisation, HF-related quality of life, HF self efficacy, HF knowledge, reported weight monitoring (self-management behaviour) 12 month follow-up.
Funding source	Pfizer Health Literacy Initiative, the Robert Wood Johnson Clinical Scholars Program, the University of North Carolina Program on Health Outcomes, and the National Institute of Nursing Research, NIH
Comparison Group(s)	Control group participants 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
Notes	Included in previous version of review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "..randomised patients by concealed allocation based on a random number generator"
Allocation concealment (selection bias)	Unclear risk	Comment: Unclear if randomisation performed before or after consent provided
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "We assessed outcomes at 6 and 12 months through in-person interviews and review of the medical record. To be sensitive to low literacy, all interviews were conducted verbally by a trained research assistant. If patients were unable to come to clinic for the interview, it was conducted by phone. The research assistant was not blinded to the patient's study group."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "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

DeWalt 2006   (*Continued*)

		the study. Follow-up was completed for all of the remaining participants (98%)"
Selective reporting (reporting bias)	Low risk	No evidence of selective reporting.

Domingues 2011

Methods	Randomised controlled trial. 2 groups: intervention group (IG): education during hospitalisation followed by telephone monitoring after discharge, and control group (CG): in-hospital education only
Participants	120 people randomised (57 IG and 63 CG). Inclusion criteria included: ≥ 18 years old with HF regardless of the aetiology and LVEF ≤ 45%. Only patients who had a telephone number available for after-discharge contact were included. After randomisation 9 patients were excluded (2 deaths, 1 stopped treatment and 6 patients difficult to contact) Mean age 63 years, 68% male, mean LVEF 29%, NYHA not reported (n = 111) IG: n = 48, mean age 62 years, 67% men, mean LVEF 29% CG: n = 63, mean age 63 years, 51% men, mean LVEF 29% Brazil
Interventions	Education in hospital (3 - 5 visits). Systematic telephone contact (study nurse) for a 3-month period 1 telephone contact per week during the 1st month, followed by 1 every 15 days in the 2nd and 3rd month
Outcomes	Follow-up: 3 months Primary outcome was HF awareness and self-care knowledge scores Secondary outcomes were frequency of visits to the emergency room, rehospitalisations and death at the end of the 3 month follow-up
Funding source	FIPE (Fundação Instituto de Pasquisas Econô micas) and CNPq (Conselho Nacional de Desenvolvimento Cientico e Tecnologico)
Comparison Group(s)	Education in hospital (3 - 5 visits). Follow-up of the participant at the return appointment to the outpatient clinic without any telephone contact in between
Notes	New in 2015 review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "After discharge from the hospital, patients were randomised to receive systematic telephone contacts for a 3-month

Domingues 2011 (*Continued*)

		investigational period (intervention group-IG) or to receive the usual care." Comment: Method of randomisation not specified.
Allocation concealment (selection bias)	Unclear risk	Comment: Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: Not detailed.
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "After randomisation, 9 patients were excluded from the IG (n=2 deaths, n= 1 quit treatment, n= 6 could not contact). At the end of the study, 87 patients completed the study protocol, of which 40 were from the IG and 47 from the CG." Comment: Data for 9 participants excluded after randomisation were not included in the analysis
Selective reporting (reporting bias)	Low risk	Comment: All prespecified outcomes have been addressed.

Galbreath 2004

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	1069 people with symptoms of CHF and documented systolic (mean EF 35%) or diastolic dysfunction (echo confirmed) Mean age 71 years. 71% of participants were men. USA.
Interventions	Structured telephone support. All intervention participants received bathroom scales and were assigned a disease manager who administered the disease management programme 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 participant's 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 participant to the disease manager, but the data were not forwarded to the primary care provider. These participants also wore activity monitors at regular intervals and had 6-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."

Galbreath 2004 *(Continued)*

	Traditional-care participants were managed as usual by their physicians
Outcomes	All-cause mortality, 6-minute walk performance, functional therapeutic class improvement, total healthcare costs. Improvement in ejection fraction and medication adherence were assessed in a subgroup 18-month follow-up.
Funding source	US Department of Defense, US Army Medical Research Acquisition Activity. Clinical space was provided by TEAM Research of Seguin, McKenna. Neighborhood Clinic, and Hill Country Medical Associates.
Comparison Group(s)	Traditional-care participants were managed as usual by their physicians
Notes	Included in previous version of review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Participants were randomised in a 2:1 ratio between the treatment and control groups" Method of randomisation not detailed.
Allocation concealment (selection bias)	Low risk	Randomisation performed after informed consent obtained.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "To assess economic and utilization outcomes, we thoroughly reviewed patient medical records. Records covering the period of a patient's enrollment in the trial were requested from both PCPs and specialty physicians. Records of inpatient and outpatient encounters and emergency department visits were culled from patient self-reported data, reviews of electronic hospital records, and documents received from physician and clinic charts. Reviews were performed by study staff, consisting of physicians, nurses, and ancillary health providers."
Incomplete outcome data (attrition bias) All outcomes	High risk	Some evidence of attrition of study participants but actual numbers not presented
Selective reporting (reporting bias)	Low risk	No evidence of selective reporting.

Gattis 1999 (PHARM)

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	181 people with heart failure being evaluated in cardiology clinic Mean age 67 years. 68% of participants were men. USA.
Interventions	Structured telephone support. Clinical pharmacist-led medication review and patient education. Regularly-scheduled telephone contact (at 2, 12 and 24 weeks) to detect clinical deterioration early
Outcomes	Mortality, rehospitalisation, medication prescription. 6-month follow-up.
Funding source	American Society of Health-System Pharmacists Research and Education Foundation, Bethesda, Md and the Duke Clinical Research Institute
Comparison Group(s)	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 participant. Participant assessment and education were provided by the attending physician and/or physician assistant or nurse practitioner. The participant was contacted by the pharmacist via telephone to identify clinical events
Notes	Included in previous version of review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "...patients were randomised according to a computer-generated randomisation scheme.."
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "...clinical events were adjudicated by a blinded end point committee"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not detailed.
Selective reporting (reporting bias)	Low risk	No evidence of selective reporting.

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 men. Argentina.
Interventions	Structured telephone support. Nurses trained in the management of people with CHF performed structured telephone follow-up based on adherence to diet and treatment, monitoring of symptoms, control of fluid retention and daily physical activity. Participants were contacted 4 times in the first fortnight and then as needed
Outcomes	Mortality, rehospitalisation, quality of life. Mean 16-month follow-up.
Funding source	GESICA (Grupo de Estudio de Sobrevida en la Insuficiencia Cardíaca en la Argentina) Foundation with unrestricted collaboration from the following local companies in Argentina: Roche, Boehringer Ingelheim, Bagó, Pharmacia, Novartis, and Merck Sharp and Dohme
Comparison Group(s)	Participants in the control group were followed by their attending cardiologists and received care similar to the intervention group
Notes	Included in previous version of review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "We then used concealed randomisation lists to do permuted block randomisation stratified by attending cardiologist "
Allocation concealment (selection bias)	Low risk	After provision of consent, patient's cardiologist contacted study centre (BMJ comment)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The clinical events committee, which was blinded to the patients' treatment group assignment, adjudicated all outcomes."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Follow-up was completed in 1511 (99.5%) randomised patients" Quote: "We based all analyses on the intention to treat principle"

GESICA 2005 (DIAL) *(Continued)*

Selective reporting (reporting bias)	Low risk	No evidence of selective reporting.

Giordano 2009

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	460 people with confirmed CHF with LVEF < 40% and at least 1 hospitalisation for acute HF in the prior year Mean age 57 years. 85% of participants were men. Italy.
Interventions	Telemonitoring. Home-Based Telemanagement (HBT) participants received a 1-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 to15 days depending on HF severity discussing symptomology, medications, self care and, if required, the transmission of the ECG trace
Outcomes	Unplanned cardiovascular hospital readmissions, hospitalisation for HF, haemodynamic instability episode occurrence, cardiovascular mortality 12-month follow-up.
Funding source	National Ministry of Health.
Comparison Group(s)	Usual care consisted of participants being referred to their primary care physician (PCP) and cardiologist for clinical management. These participants attended a 2-weeks post-discharge PCP appointment and a structured follow-up outpatient cardiologist appointment at 12 months
Notes	Included in previous version of review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Random permuted blocks for each center were used to allocate patients to treatment groups"
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "The data and the cause of readmission were obtained from the GP and confirmed by hospital records. Episodes of clinical instability were confirmed by the GP. Cardiovascular deaths were ascertained

Giordano 2009 (*Continued*)

		through the GP or hospital records."
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "...one patient in UC group and four in HBT group were lost to follow-up" p196 Quote: "Analyses were conducted according to the intention-to treat approach"
Selective reporting (reporting bias)	Low risk	Selective outcome reporting not evident.

Goldberg 2003 (WHARF)

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	280 people hospitalised with NYHA Class III - IV, with a LVEF < 35% Mean age 59 years. 68% of participants were men. 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
Outcomes	Mortality, rehospitalisation, emergency department visits, quality of life, participant satisfaction, compliance with intervention Mean 6-month follow-up.
Funding source	Alere Medical, Incorporated.
Comparison Group(s)	Participants in the control group were instructed to contact their physician for weight increases of more than a prespecified 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
Notes	Included in previous version of review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: method of randomisation not detailed.
Allocation concealment (selection bias)	Low risk	Quote: "After informed consent was obtained and screening laboratory evaluations were completed, patients were randomized"

Goldberg 2003 (WHARF)   (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "To insure that all hospitalizations, emergency room visits, and deaths were identified, all patients were contacted by telephone on a monthly basis by a non medical surveyor (blinded to patient treatment group randomization), located outside of the enrollment sites and Alere monitoring center. Records were obtained for each of these events, including those occurring outside of the participating health systems."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "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"
Selective reporting (reporting bias)	Low risk	Comment: some nominated outcomes (satisfaction) were not reported

Koehler 2011 (TIM-HF)

Methods	Open, randomised, parallel-group, prospective multicentre clinical trial
Participants	A total of 710 people (354 patients RTM group and 356 to the usual care group) with chronic HF who had signed informed consent were eligible to participate if they were at least 18 years of age, were in NYHA class II or III, and had a LVEF of 35% Mean age 66.9 years 80% men Germany
Interventions	Quote: "The telemonitoring system used in the TIM-HF trial is based on a wireless Bluetooth system with a personal digital assistant (PDA) as the central structural element. The only prerequisite for this system to function once installed is the availability of a mobile phone network connection. Three measuring devices are integrated into the system, namely one to collect electrocardiogram (ECG) measurements, one to collect BP measurements, and one to collect body weight. Each device is equipped with a Bluetooth chip and connected to the PDA. The patient performs the daily self-assessment of health status by using the PDA interface. A subgroup of patients in the intervention group performed a 6-min walk test using a telemedical accelerometer once a month starting 3 months after randomization."

Koehler 2011 (TIM-HF) *(Continued)*

Outcomes	Quote: "The primary endpoint is all-cause mortality. The first secondary endpoint is a composite of the combined rate of cardiovascular death and hospitalization for worsening heart failure. For this composite endpoint, patients will be followed for all hospitalizations for heart failure until death or the end of follow-up thus enabling the possibility to report event rates for each event. Other secondary endpoints include: • days lost due to death or heart failure hospitalization, • cardiovascular mortality, • rate of cardiovascular hospitalization at 6, 12 and 24 months • rate of hospitalization for Heart Failure at 6, 12 and 24 months • hospitalization for any reason, • cardiovascular hospitalization, • hospitalization for heart failure, • duration of all hospitalizations for heart failure, • NYHA functional class at 12 months and 24 months adjusted for baseline, • SF-36 physical functioning score at 12 months and 24 months adjusted for baseline, and • PHQ-9 depression score, 12 months and 24 months adjusted for baseline. As for the first secondary endpoint, patients will be followed for all events until death or the end of follow-up." Quote: "Power Calculation: The sample size calculation was based on the assumption of a mortality rate of 27% in the control group and 17% in the intervention group. This corresponds to a relative risk (RR) of 0.63, which is comparable to the effect of remote patient management reported by Cleland et al (2005) (RR=0.65) and more conservative than the findings of Goldberg et al (2003) (RR=0.44)."
Funding source	Quote: "The technology development as well as the clinical trial was funded in a public-private partnership through a research grant of the German Federal Ministry of Economics and Technology (01MG531) and by the following companies: Robert Bosch Healthcare GmbH, Waiblingen, Germany; InterComponentWare AG, Walldorf, Germany; and Aipermon GmbH & Co KG, Munich, Germany."
Comparison Group(s)	Quote: "Patients randomized to the usual care group were followed by their treating physician who was instructed to ensure that the patients were optimally treated for their heart failure in accordance with the current standards and guidelines for treatment of patients with CHF."
Notes	New in 2015 review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were then assigned to one of the two treatment arms by a central computerized randomization system. In order to achieve a balance of potential risk factors in the treatment arms, Pocock's minimization algorithm5 (with 20% resid-

		ual randomness) was used, with the following variables: NYHA class II or III, hospitalization for heart failure within 2 years prior to randomization, implanted defibrillator, region (Berlin-Brandenburg or Baden-Württemberg), age group (,60 or 60-70 or .70 years), known diabetes mellitus, known cerebrovascular disease, living alone or with partner, gender, presence of CRT, use of statins, and use of aldosterone receptor antagonists."
Allocation concealment (selection bias)	Low risk	Comment: Investigators were unaware of the randomisation sequence
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "A Clinical Endpoint Committee (CEC), blinded to treatment allocation, will classify all deaths and hospitalizations using pre-defined criteria as detailed in the CEC charter"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "The essential features of the planned statistical analyses are as follows: two analysis populations will be distinguished-the full analysis set (FAS) and the per protocol analysis population."
Selective reporting (reporting bias)	Low risk	Comment: Not all data for changes in NYHA class, PHQ-9 and SF-36 are reported (but percentages at 12 and 24 months are reported)

Krum 2013 (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 participants
Participants	405 people 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 73 years. 61% of participants were men. Australia.
Interventions	Structured telephone support. Nurse-led telephone monitoring using the Telewatch System (Baltimore) Participant responded to computer-generated CHF self-monitoring questions by press-

	ing the numbers on the touch-phone key pad Nurse survey incoming calls daily and responded to preset variations to participant's parameters	
Outcomes	The primary endpoint was the change in Packer clinical composite score. HRQOL, BNP. Secondary endpoints included: all-cause death and all-cause hospitalisation as well as heart failure-related death and heart failure-specific hospitalisation Participants were assessed by a blinded reviewer at baseline and then after 6 and 12 months 12 months follow-up.	
Funding source	National Health and Medical Research Council, National Heart Foundation of Australia, and Medical Benefits Fund	
Comparison Group(s)	Usual care discharge follow-up with GP and copy of guidelines	
Notes	New in 2015 review; included as abstract in sensitivity analysis in previous version of review (Inglis 2010).	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random sequence.
Allocation concealment (selection bias)	Unclear risk	Quote: "The study involved cluster randomization at the level of the general practitioner (1:1, usual care, usual care plus intervention, stratified by rural, remote and outer metropolitan area [RRMA] classification). This was to minimize contamination across the two interventions to which patients were randomized."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "All patients regardless of treatment allocation were followed up by an independent reviewer, blinded to treatment allocation, and asked to complete a telephone survey at baseline and at 6 and 12 months. The survey included questions relating to quality of life (Minnesota Living with Heart Failure questionnaire), NYHA class, global health assessment, EQ-5D EuroQOL, and questions regarding utilization of health services." Quote: "All hospitalization data were adjudicated by three cardiologists (blinded

Krum 2013 (CHAT)   (*Continued*)

		to randomization allocation) to determine whether the hospitalizations were related to heart failure."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Intention-to-treat analyses were performed for all endpoints"
Selective reporting (reporting bias)	Low risk	No evidence of selective outcome reporting.

Laramee 2003

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	287 people 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 men. USA.
Interventions	Structured telephone support. Telephonic case management performed by 1 CHF nurse case manager, involving 4 major components: early discharge planning, participant and family CHF education, promotion of optimal CHF medications and 12 weeks of telephone follow-up.
Outcomes	Mortality, rehospitalisation, inpatient and outpatient costs, medication prescription and adherence 3-month follow-up.
Funding source	Novartis Pharmaceuticals.
Comparison Group(s)	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 participant's own local physician, 44% received some home-care services
Notes	Included in previous version of this review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "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 endure an even group allocation

Laramee 2003   (*Continued*)

		across time"
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "Patients who withdrew, died or were otherwise lost before 90 days of follow-up were censored on the day of early attrition"
Selective reporting (reporting bias)	Low risk	One secondary outcome not reported: number of days until first readmission

Lyngå 2012 (WISH)

Methods	A multicentre, randomised controlled trial (RCT) involving 6 hospitals in Sweden
Participants	Quote: "A total of 344 patients were randomized in the study and, of them, 319 were included in the final ITT analysis. Twenty-five patients were, after being randomized, found not to be satisfy the inclusion criteria due to reasons such as having an LVEF . 50%, myocardial infarction within 2 months before inclusion, not being hospitalized before enrolment, or moved to a nursing home just after randomization. These patients were excluded from further analysis." 75% of participants were men. Mean age 73.9 years Sweden
Interventions	Telemonitoring. Quote: "Patients randomized to the IG were given an electronic scale (Zenicor Medical Systems AB) to install in their homes. A few patients required help to install the electronic scale. The scale could be placed anywhere in the patients' home and, after weighing, a wireless signal was sent from the scale to a modem plugged into the patient's telephone. The weight was then automatically transmitted via the telephone network to a central internet-based data server system (Zenicor Medical Systems AB). Hence, the weight could be checked from any computer with internet access. The Zenicor system produces an alarm if patients show a weight gain of .2 kg from the target weight (body weight at discharge from hospital) and also if there is an upward trend with a weight increase of . 2 kg in 3 days."
Outcomes	Quote: "Primary endpoint, i.e. cardiac re-hospitalization. Information on hospitalization, cardiac and other, and death was collected from the medical register at the local health authorities." Quote: "Based on previous research, we assumed a re-admission rate due to a cardiac cause of 40% in the control group (CG)3 and 25% in the intervention group (IG). To detect the difference between the groups, with a power of 80% and an alpha-value of 0. 05, a sample size of 152 patients in each group was needed."

Lyngå 2012 (WISH) (*Continued*)

	12 month follow-up.
Funding source	The Swedish Governmental Agency for Innovation Systems (VINNOVA); the Swedish Heart and Lung foundation
Comparison Group(s)	Quote: "The patients in the CG were informed to contact the HF clinic on a special telephone in the case of a weight gain of .2 kg in 3 days."
Notes	New in 2015 review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: method of randomisation not detailed. Quote: "Patients were then randomized to either the CG or the IG, and both groups were recommended to weigh themselves daily after emptying their bladder but before having breakfast."
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "The study was based on intention to treat (ITT) except that randomized patients not fulfilling the inclusion criteria were excluded from analysis. Baseline characteristics are presented by descriptive statistics." Quote: "One obvious limitation in the present study is that 25 patients were randomized before all inclusion criteria were fully checked (e.g., having an LVEF >50%, myocardial infarction within 2 months before inclusion, not being hospitalized before enrolment, or moved to a nursing home just after randomization). However, these patients were equally distributed between the groups. Also the number of all eligible patients is unknown"
Selective reporting (reporting bias)	Low risk	No evidence of selective outcome reporting.

Mortara 2009 (Struct Tele) (HHH)

Methods	Randomised controlled trial; multiple intervention arms and control (usual care) arm Study arms include structured telephone support and telemonitoring
Participants	461 people with heart failure NYHA class II - IV and LVEF $\leq$ 40% Mean age 60 years. 85% of participants were men. UK, Poland, Italy.
Interventions	Structured telephone support; telemonitoring. Strategy 2 is classed as structured telephone support. Strategy 3 is classed as telemonitoring. Strategy 2 received monthly supportive telephone contacts from a study nurse to check on their clinical status and transmitted their vital signs and other data including details of changes in weight, BP and symptoms weekly by telephone. These participants also performed monthly 24h cardiorespiratory recordings which were not made available to the clinical team Strategy 3 carried out the same measurements as strategy 2 participants, but the monthly 24h cardiorespiratory recordings were made available for clinical management
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.
Funding source	HHH was supported by E.C. grant (Action line 10.1 'Public Health, contract no. QLGA-CT-2001-02424)
Comparison Group(s)	Usual care was only described as usual outpatient care.
Notes	Authors provided additional unpublished data. Included in previous version of this review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The randomisation list was generated by the coordinating centre with separate blocks held in each country"
Allocation concealment (selection bias)	Low risk	Quote: "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"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "All endpoints were adjudicated by an independent, blinded, Endpoint Committee."

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

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "...18 patients dropped out of the study...". No statement asserting that analyses were performed as intention-to-treat
Selective reporting (reporting bias)	Unclear risk	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"

Mortara 2009 (Telemon) (HHH)

Methods	Randomised controlled trial; multiple intervention arms and control (usual care) arm Study arms include structured telephone support and telemonitoring
Participants	461 people with heart failure with NYHA class II - IV and LVEF $\leq$ 40% Mean age 60 years. 85% of participants were men. UK, Poland, Italy.
Interventions	Structured telephone support; telemonitoring. Strategy 2 is classed as structured telephone support. Strategy 3 is classed as telemonitoring. Strategy 2 received monthly supportive telephone contacts from a study nurse to check on their clinical status and transmitted their vital signs and other data including details of changes in weight, BP and symptoms weekly by telephone. These participants also performed monthly 24h cardiorespiratory recordings which were not made available to the clinical team Strategy 3 carried out the same measurements as strategy 2 participants, but the monthly 24h cardiorespiratory recordings were made available for clinical management
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.
Funding source	HHH was supported by E.C. grant (Action line 10.1 'Public Health, contract no. QLGA-CT-2001-02424)
Comparison Group(s)	Usual care was only described as usual outpatient care.
Notes	Authors provided additional unpublished data. Included in previous version of this review (Inglis 2010).

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

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The randomisation list was generated by the coordinating centre with separate blocks held in each country"
Allocation concealment (selection bias)	Low risk	Quote: "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"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "All endpoints were adjudicated by an independent, blinded, Endpoint Committee."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"...18 patients dropped out of the study...". No statement asserting that analyses were performed as intention-to-treat
Selective reporting (reporting bias)	Unclear risk	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"

Rainville 1999

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	38 people aged ≥ 50 years discharged from hospital with heart failure Mean age 70 years. 50% of participants were men. 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
Outcomes	Mortality, rehospitalisation, functional assessment score. NYHA Functional Class 12-month follow-up.

Rainville 1999 *(Continued)*

Funding source	Not reported.
Comparison Group(s)	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 participant with computer-generated drug information sheets. Participants were contacted by a pharmacist at 30 days, 90 days and 12 months to determine readmissions
Notes	Included in previous version of this review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not detailed.
Allocation concealment (selection bias)	Low risk	Quote: "Qualified patients were randomly assigned to a control group or an intervention group, with the patients, nurses, and physicians blinded to the randomisation results"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	Low risk	38 participants randomised; 2 participants in intervention group and 1 in control group were excluded during the initial hospitalisation because test results showed normal LVF, long-term dialysis was initiated or because the participant was moving out of state after DC. 1 control participant was lost to follow-up within the first 30 days after discharge and was excluded from the analysis Final sample included 34 participants equally divided between the 2 groups
Selective reporting (reporting bias)	Low risk	Selective outcome reporting not evident.

Ramachandran 2007

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	50 people attending heart failure clinic with symptoms of CHF and LVEF < 40% Mean age 44.5 years. 78% of participants were men. India.
Interventions	Structured telephone support. Intervention group participants 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
Outcomes	Functional status, quality of life, hospitalisation rates, quality of care, drug usage, cost effectiveness. NYHA Functional Class. 6-month follow-up
Funding source	Not reported.
Comparison Group(s)	The control group was managed as per usual care in the heart failure clinic
Notes	Included in previous version of this review (Inglis 2010). Mortality not reported. No response from authors for further detail

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "An investigator, unaware of the patients' demographic and clinical profile, using a computer-generated list, initiated randomisation"
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not detailed.
Selective reporting (reporting bias)	Low risk	No evidence of selective outcome reporting.

Riegel 2002

Methods	Cluster randomised controlled trial; intervention arm and control (usual care) arm
Participants	358 people discharged from hospital with heart failure. Mean age 74 years. 49% of participants were men. 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. Participants were telephoned within 5 days of discharge and thereafter at a frequency guided by the software and case manager (mean 17 calls)
Outcomes	Mortality, rehospitalisation, physician and emergency department visits, inpatient costs, participant satisfaction 6-month follow-up.
Funding source	Pfizer.
Comparison Group(s)	Usual care was not standardised, and no formal telephonic case management was in existence at these institutions. These participants presumably received some education regarding HF management prior to hospital discharge
Notes	Included in previous version of this review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not stated. (Physicians were the unit of randomisation)
Allocation concealment (selection bias)	Low risk	Quote: "Physicians were not informed of the group to which they were assigned"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not detailed.
Selective reporting (reporting bias)	Low risk	Selective outcome reporting not evident.

Riegel 2006

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	135 hospitalised Hispanic people with CHF. Mean age 72 years. 46% of participants were men. 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. Participants 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 participants and 8.4 additional calls to families). Printed educational material was provided monthly and upon request in the relevant language
Outcomes	Mortality, re hospitalisation, cost of care, self-reported health-related quality of life and depression 6-month follow-up.
Funding source	American Heart Association.
Comparison Group(s)	Usual care was not standardised and no formal disease management programme existed at these institutions. The standard of usual care was that participants were educated regarding HF management before discharge, assuming that the nurse spoke the participant's language or someone bilingual was available to translate. In reality, only a small proportion of staff were bilingual
Notes	Included in previous version of review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "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" Method of randomisation not detailed.
Allocation concealment (selection bias)	Low risk	See above.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "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."

Riegel 2006 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	For intervention arm, only 69 participants were included in analysis as 1 outlier excluded from analysis Quote: "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"
Selective reporting (reporting bias)	Low risk	Selective outcome reporting not evident.

Scherr 2009 (MOBITEL)

Methods	A prospective, randomised, open-label study. Recruitment started on October 1, 2003 - April 29, 2008.
Participants	Quote: "Inclusion criteria: acute worsening of heart failure (acute cardiac decompensation) with hospital admission lasting > 24 hours within the last 4 weeks, treatment according to the guidelines of the European Society of Cardiology (ESC) with an angiotensin converting enzyme (ACE) inhibitor or an angiotensin receptor blocker (ARB), diuretic, and beta-blocker (except in cases with documented intolerance to beta-blockers). Initially, patients older than 18 years and younger than 75 years were eligible; the latter was amended to 80 years after 4 months of recruitment. For the definition of CHF, we adopted the ESC guidelines" Austria.
Interventions	Telemonitoring Quote: "Tele group patients were asked to measure vital parameters (blood pressure, heart rate, body weight) on a daily basis at the same time, preferably in the morning after emptying the bladder and before dressing and taking medication. Thereafter, patients were advised to enter these values as well as their dosage of heart failure medication into the mobile phone's Internet browser and send them to the monitoring center provided by the Austrian Institute of Technology (AIT) - Information Management & eHealth, Graz. Study physicians had access to a secure website providing both numerical and graphical depiction of data for each patient."
Outcomes	Quote: "The combined primary endpoint of this study was cardiovascular mortality or re-hospitalization for worsening heart failure. Besides evaluation of patients' functional status according to the NYHA classification and length of stay during re-hospitalizations, further secondary endpoints focused on technical parameters: system availability, cumulative transmissions, and transmissions per patient." Quote: "For statistical planning, we assumed that patients in the control arm would show an event rate of 30% over 6 months. For the telemedicine arm, we expected a 50% reduction of the event rate. To show a statistically significant difference at an error of .05 with a power of 80%, a sample size of 240 subjects was calculated." 6 month follow-up.
Funding source	Quote: "This study was partly funded by restricted research grants from Novartis Pharma Austria, Roche Pharma Austria, and Mobilkom Austria."

Scherr 2009 (MOBITEL)   *(Continued)*

Comparison Group(s)	Quote: "Baseline demographics and medication were recorded for all patients, and an appointment for the 6-month follow-up was made. There was no planned interaction between study site and patients in the control group within the follow-up period of 6 months."
Notes	New in 2015 review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: method of randomisation not detailed. Quote: "Patients were allocated randomly to pharmacological treatment (control group) or pharmacological treatment plus telemedical surveillance (tele group). The adaptive randomization procedure was stratified by patient age, New York Heart Association (NYHA) class, gender, and study center."
Allocation concealment (selection bias)	Unclear risk	Not detailed
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: Baseline demographics data not presented for intention-to-treat sample
Selective reporting (reporting bias)	Low risk	Selective outcome reporting not evident.

Seto 2012

Methods	Quote: "The primary intent of the trial was to pilot the telemonitoring system in order to determine the impact of the system on self-care and clinical management."
Participants	Quote: "Eligible participants were ambulatory patients diagnosed with heart failure. Other eligibility criteria included 18 years of age or older, ability to speak and read in English, not on the heart transplantation list, an expected survival of greater than one year, and a left ventricular ejection fraction (LVEF) less than 40%." Mean age 55.1 SD(13.7) years 82% male Canada

Seto 2012 *(Continued)*

Interventions	Telemonitoring Quote: "The participants in the telemonitoring group received the telemonitoring system in addition to standard care. They were asked to use the telemonitoring system for 6 months to take daily morning weight and blood pressure readings as well as weekly single-lead electrocardiograms (ECGs) if provided with an ECG recorder. They were also asked to answer daily morning symptom questions on a mobile phone. Only the 17 patients who did not have an implantable cardioverter defibrillator (ICD) were provided with an ECG recorder because the recorder was not certified for use with ICDs. Patients were also told to report their symptoms through the mobile phone if they did not feel well during the day. The patients in the telemonitoring group were given an individual training session on how to use the system during the recruitment session, and were provided with technical support by telephone throughout the study. The daily measurements took about 5 minutes each morning."
Outcomes	Quote: "The primary outcomes of this study included a surrogate for heart failure prognosis, specifically brain natriuretic peptide (BNP), self-care as measured by the SCHFI, and quality of life as measured by the MLHFQ. Hospital readmissions, number of nights in hospital, and mortality were secondary outcome measures because the study was underpowered to detect differences between groups for these metrics. Other secondary outcome measures included number of emergency department visits and number of Heart Function Clinic visits. In addition, LVEF, NYHA class, medication prescriptions, and blood test results (specifically creatinine, sodium, potassium, hemoglobin, and urate values) were also subsequently analyzed." Quote: "A sample size calculation was based on the Self-Care of Heart Failure Index (SCHFI), using a population standard deviation of 20 and an effect size of 10 (effect size represents a clinically significant change of more than half a standard deviation) as determined in previous studies (alpha = 0.05, power = 0.8) [7,8]. We calculated the required sample size per group to be 34, and recruited 50 participants for the intervention group and 50 for the control group to compensate for the patients estimated as lost to follow-up, including due to mortality, over the six-month trial." 6 month follow-up.
Funding source	Quote: "Funding for this work was in part provided by the Toronto General Hospital Foundation and the Natural Sciences and Engineering Research Council of Canada Strategic Research Network Grant entitled Healthcare Support through Information Technology Enhancements (hSITE)."
Comparison Group(s)	Quote: "The standard care group received standard care at the UHN Heart Function Clinic, which includes visiting the clinic between once every 2 weeks to once every 3 to 6 months, depending on the severity of the patient's heart failure condition and the need for optimizing their medication. Standard care also includes heart failure education during preliminary visits at the Heart Function Clinic and the ability to telephone the clinic as necessary. Participants in the standard care group were not contacted again regarding the study until the end of the trial."
Notes	New in 2015 review.

Risk of bias

Seto 2012 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The 100 participants were randomized into the telemonitoring (TM) group and standard care (SC) group using stratified four-block randomization. Stratification was based on NYHA classification (NYHA class II-III and NYHA class IV). There were no participants in NYHA class I. An online computer-generated randomization tool, Research Randomizer was used to determine the order of participants in the telemonitoring and standard care groups."
Allocation concealment (selection bias)	Low risk	Quote: "The study coordinator was blinded to which group the patient would be assigned until each patient consented to participate in the trial."
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote from author contact: "We had to rely on self-reported indications of hospitalization and tried to confirm with charts because it was possible that patients would be admitted to hospital outside of the clinical setting where the study took place. Therefore, the denominators are smaller than the number of participants."
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote from author contact: "We had to rely on self-reported indications of hospitalization and tried to confirm with charts because it was possible that patients would be admitted to hospital outside of the clinical setting where the study took place. Therefore, the denominators are smaller than the number of participants."
Selective reporting (reporting bias)	Low risk	Selective outcome reporting not evident.

Sisk 2006

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	406 non-Hispanic and Hispanic people with documented systolic dysfunction Mean age 59 years. 54% of participants were men. USA.

Sisk 2006   *(Continued)*

Interventions	Structured telephone support. An in-person appointment was arranged for each intervention participant, which included symptom and disease education and referral to additional patient services (if required). Follow-up telephone calls consisted of participant 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 participants). Intervention nurses co-ordinated flow of information between participant and clinician and arranged medication adjustment and required examinations
Outcomes	Mortality, hospitalisations, functional status (including quality of life). Cost 12-month follow-up.
Funding source	The Agency for Healthcare Research and Quality.
Comparison Group(s)	Usual care participants received guidelines for managing systolic dysfunction, but no other care information was specified
Notes	Included in previous version of this review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "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"
Allocation concealment (selection bias)	Low risk	See above.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "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."
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up in the first 12 months of follow-up.

Sisk 2006   (*Continued*)

Selective reporting (reporting bias)	Low risk	Selective outcome reporting not evident.

Soran 2008

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	315 people with HF diagnosis secondary to systolic dysfunction (LVEF ≤ 40%) Mean age 76 years. 35% of participants were men. USA.
Interventions	Telemonitoring. Participants randomised to the Heart Failure Monitoring System (HFMS) cohort received a disease management programme using telecommunication equipment including an electronic scale and individualised symptom response system linked to a database staffed by nurses. Participants weighed themselves and answered questions related to their heart failure. Participants were contacted if any changes were observed in symptoms or weight
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 participant costs, quality of life 6-month follow-up.
Funding source	Centers for Medicare & Medicaid Services Baltimore, Maryland
Comparison Group(s)	Participants 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 participants were telephoned 30 days and 3 months post-randomisation for blinded clinical data collection (vital signs, hospital visits, quality of life questionnaires)
Notes	Number of participants hospitalised calculated from reported % with any hospital admission Included in previous version of this review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "...patients were randomised in a 1:1 ratio..". Method of randomisation not detailed.
Allocation concealment (selection bias)	Unclear risk	Not detailed.

Soran 2008 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The HFHC Trial was a multi-center, randomized controlled clinical trial with blinded end point evaluation..."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "Eight patients refused to be re contacted after randomisation and were considered lost to follow-up" Quote: "The intention-to-treat principle was used to compare HFMS to SC"
Selective reporting (reporting bias)	Low risk	No evidence of selective outcome reporting.

Tsuyuki 2004

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	276 people discharged from hospital with heart failure. Mean age 72 years. 58% of participants were men. Canada.
Interventions	Structured telephone support. Early discharge planning with provision of adherence aids, patient education, regularly scheduled telephone contact with local research co-ordinator at 2 and 4 weeks then monthly thereafter for 6 months. Recommendations to see primary care physician if not on target dose ACE inhibitor or deterioration
Outcomes	Mortality, rehospitalisation, medication adherence, physician and emergency department visits, cost analysis 6-month follow-up.
Funding source	Parke Davis Canada (now Pfizer Canada) and the University of Alberta Hospital Foundation
Comparison Group(s)	Participants assigned to usual care received a general heart disease pamphlet before discharge, but no formal counselling beyond what was routine at the hospital. Participants were contacted monthly for 6 months to ascertain clinical events
Notes	Included in previous version of this review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was conducted by a computer-generated sequence using

Tsuyuki 2004 (*Continued*)

		block randomisation (block size of 4), stratified by study site (hospital)"
Allocation concealment (selection bias)	Unclear risk	Quote: "...patients were randomised via a telephone call to the project office"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "...the primary outcome was medication adherence, as measured by pharmacy records." Quote: "Clinical events, the secondary outcome, were recorded by patient report and through examination of hospital records"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Intervention: early withdrawal n = 5; lost to follow-up n = 3 Control: early withdrawal n = 2; lost to follow-up n = 4.
Selective reporting (reporting bias)	Low risk	Selective outcome reporting not evident.

Villani 2014 (ICAROS)

Methods	Quote: "A randomized, parallel open study was conducted on patients with chronic heart failure leaving hospital after being treated for clinical instability." Power Calculation: No sample size calculation was detailed.
Participants	Quote: "...80 agreed to participate and were randomized to the two groups (40 in each Inclusion criteria (1) NYHA class III/IV during hospital stay (2) Left ventricular systolic dysfunction (ejection fraction 40%) (3) High risk of early re-hospitalization at discharge (at least two of): age>70 years, >2 hospitalizations for heart failure in the last 6 months, >1 co-pathologies (diabetes, COPD, cerebrovascular disease, renal failure)" Mean age 72 (SD 3) years. 73.7% men. Italy.
Interventions	Telemonitoring. Quote: "Integrated Management group, patients and their caregivers had specific training in the use of the dedicated PDA described above. Each day, the PDA acted as a reminder of the correct timing for the pills. At a predefined time patients were asked to send their body weight, blood pressure and heart rate data via the PDA. In some cases patients were asked to monitor their diuresis. Each month, a psychological assessment was performed through the PDA software about anxiety (STAI-6; Spielberger's State Trait Anxiety Inventory, depression (PHQ-9; Patient Health Questionnaire)18 and perceived well being (PGWBI; Perception of General Well-Being Inventory)."
Outcomes	Quote: "Cardiovascular death or hospitalization for heart failure lasting more than 3 days were considered major adverse effects. We considered the following as minor adverse effects: (1) any hospital stay of less than three days, including Emergency Department

Villani 2014 (ICAROS)   *(Continued)*

	visits; (2) any unplanned investigation and/or blood testing; (3) any unplanned clinical visit (4) cost." 12 month follow-up
Funding source	The research received a grant from the Italian Ministry of Research and Public Instruction (FIRB RBNE01KYE4 2003)
Comparison Group(s)	Quote: "In the Usual Care group, patients were discharged with appointments for follow-up every three months at our Heart Failure clinic, in accordance with guidelines for fragile patients."
Notes	New in 2015 review - included as abstract in sensitivity analysis in previous version of review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomized 1:1 either to an Integrated Management group or to a Usual Care group, using a computerised random number generator."
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Not evident.
Selective reporting (reporting bias)	Low risk	No evidence of selective outcome reporting.

Vuorinen 2014

Methods	Quote: "Two-arm randomized controlled trial conducted at the Cardiology Outpatient Clinic of HUCH in 2010-2012."
Participants	94 people were randomised. 1 from each pair was randomly assigned to receive the usual care, and the other was assigned to the telemonitoring group (47 per group) Quote: "The inclusion criteria were (1) diagnosis of systolic heart failure, (2) age of 18-90 years, (3) NYHA class ≥2 (an interview-based classification by the New York Heart Association concerning limitations to physical activity), (4) left ventricular ejection fraction ≤35% as measured during hospital visits, (5) need for a regular check-up visit, and (6) time from the last visit of less than 6 months." 83% of participants were men.

	Mean age 58 years. Finland
Interventions	Telemonitoring. Quote: "Patients regularly reported their most important health parameters to the nurse using a mobile phone app. At the beginning of the study, the patients were given a home-care package including a weight scale, a blood pressure meter, a mobile phone, and self-care instructions. The patients were advised to carry out and report the measurements together with the assessment of symptoms once a week."
Outcomes	Quote: "The primary outcome was the number of HF-related hospital days during the follow-up. The data were obtained from the electronic health record system of HUCH. Secondary outcomes included clinical outcomes, use of health care resources, and user experience. death from any cause, heart transplant operation or listing for transplant operation, left ventricular ejection fraction (LVEF, %) measured by echocardiography, plasma concentration of N-terminal of the prohormone brain natriuretic peptide (NT-proBNP, ng/l), creatinine (μmol/l), sodium (mmol/l), and potassium (mmol/l). Self-care behavior was measured using the European Heart Failure Self-Care Behaviour Scale (EHFSBS). Patients' acceptance and experience towards home telemonitoring were evaluated using a questionnaire delivered to patients in the telemonitoring group at the end-point visit." Quote: "The study was designed to have a power of 90%, an alpha level of .05, and an effect size of 0.5 determined as the expected difference of 3 HF-related hospital days between the study groups (SD 6). A t test was used as a calculation framework. With these parameters, we calculated that 44 patients per treatment arm needed to be recruited" 6 month follow-up.
Funding source	Quote: "The Finnish Funding Agency for Technology and Innovation and VTT Technical Research Centre of Finland are acknowledged for funding the study."
Comparison Group(s)	Quote: "A multidisciplinary care approach including patient guidance and support for self-care has been adopted at the clinic. In the care of these HF patients, the cardiac team plays a central role in monitoring and interpreting patient symptoms, optimizing medication, and providing education."
Notes	New in 2015 review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "Matched pair design was used in the randomization. The eligible patients, who were similar in left ventricular ejection fraction, NYHA classification, age, and gender, respectively, were matched in pairs. One was randomized to the control group and the other to the intervention group."

Vuorinen 2014 (*Continued*)

		The first 30 intervention participants and 29 control participants started stepwise from November 2010 to February 2011. After the first 59 participants had finished their follow-up, the second group (17 intervention participants and 18 control participants) started in May to August 2011. The nominal follow-up time was 6 months. The study was completed in February 2012
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "There was one dropout in the intervention group. The patient withdrew from the study shortly after the beginning, and no endpoint measurements were available. The patient was excluded in the endpoint analyses."
Selective reporting (reporting bias)	Low risk	No evidence of selective outcome reporting.

Wakefield 2008

Methods	Randomised controlled trial; intervention arm and control (usual care) arm Telephone and videophone intervention arms were combined and classed as structured telephone support for this review
Participants	148 people hospitalised for HF exacerbation. Mean age 69 years. 99% of participants were men. USA.
Interventions	Structured telephone support. Participants allocated to the intervention group were allocated to 1 of 2 interventions: telephone follow-up or videophone follow-up. Intervention participants were contacted by a nurse 3 times in the first week then weekly for 11 weeks. Symptoms and the participant's discharge plan were 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
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.

Wakefield 2008 (*Continued*)

Funding source	Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development (VA HSR&D) Service (#NRI 99-345), a VA HSR&D Career Development Award to Dr. Wakefield, the VA HSR&D Center for Research in the Implementation of Innovative Strategies in Practice (CRIISP) at the Iowa City VA Medical Center, Iowa City, IA, and by the Harry S. Truman Memorial Veterans Hospital
Comparison Group(s)	Usual care was not specified except to state that "subjects contacted their primary care nurse case manager by telephone if needed"
Notes	Included in previous version of this review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The project coordinator prepared sealed envelopes containing group assignments in blocks of 24"
Allocation concealment (selection bias)	Low risk	Quote: "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"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Qoute: "At 3 months, 85% (n = 126) completed follow-up; at 6 months, 74% (n = 109) completed follow-up". Quote: "All data analyses were conducted using an intent-to-treat approach"
Selective reporting (reporting bias)	Low risk	Selective outcome reporting not evident.

Woodend 2008

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	121 people with symptomatic heart failure (NYHA Class II or greater) Mean age 68 years. 74% of participants were men. 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 and tapered over the 3 months
Outcomes	Mortality (3 months), rehospitalisation, quality of life, emergency department visits, participant satisfaction 12-month follow-up.
Funding source	The Richard Ivey Foundation, The Change Foundation and an unrestricted educational grant from Merck-Frosst Canada
Comparison Group(s)	Usual care was not described.
Notes	Included in the previous version of this review (Inglis 2010).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not detailed.
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not detailed.
Selective reporting (reporting bias)	High risk	Some nominated outcomes not reported (morbidity).

Zamanzadeh 2013

Methods	Prospective, randomised trial of a supportive-educational intervention
Participants	Quote: "Participants who were included were of 18 years age and older, diagnosed with New York Heart Association class III or IV HF, had an ejection fraction less than 40%, agreed to predischarge education and follow-up care, and would be available by phone after discharge." Mean age 65.82 ± 9.87 years 57.9 % men. Iran

Interventions	Quote: "HF participants randomized to the intervention group received a two-part intervention aimed at improving self-care behaviours. The first phase consisted of a one-hour, nurse-led, in-person HF education session that was customized by the nurse according to the participant's level of education. An individualized education booklet was reviewed with literate patients,while for illiterate patients this booklet was reviewed with the participant as well as a family member The second phase of the intervention included postdischarge telephone followup. The objective of this phase was to reiterate and review information covered during the initial education session and improve the participant's ability to cope with the disease, as well as enhance self-care behaviours.The first followup telephone call was made by a nurse two days after hospital discharge to verify participant information and determine the next date of contact. The nurse then contacted the participant by phone every two weeks for 3 months. During these phone calls the nurse asked the participant whether they were experiencing any signs or symptoms that would suggest worsening HF.The nurse also reviewed the recommended self-care behaviours and provided support in the form of advice and encouragement when deemed necessary. These follow-up telephone calls typically lasted 15 minutes."
Outcomes	Self-care (SCHFI) Quote: "A sample size of 80 (40 individuals in the intervention group and40 in the control group)was deemed sufficient based on a preliminary analysis of self-care scores of 5HF patients. The following parameters guided the present study; the optimal self-care behaviour score in the study was 70, the mean and standard deviation of self-care behaviours scores were estimated (Mean = 25, SD= 6.15), alpha = 0.05 and power = 0. 9 were chosen, and no attrition during followup was anticipated"
Funding source	Nil disclosed.
Comparison Group(s)	Quote: "Participants who were randomized to the control group received usual care provided by the hospital and attending physician (nonsystematic and informal teaching) ."
Notes	New in 2015 review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote:"The participants were randomized into the control and experimental groups using random number software"
Allocation concealment (selection bias)	Unclear risk	Not detailed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not detailed.

Zamanzadeh 2013 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: 2 participants from the intervention group lost to follow-up in intervention arm, analyses not performed as intention-to-treat
Selective reporting (reporting bias)	High risk	Comment: No evidence of selective outcome reporting.

ACE: angiotensin-converting enzyme
BNP: brain natriuretic peptide
CHF: congestive heart failure
CNPq: Conselho Nacional de Desenvolvimento Cientico e Tecnologico
ECG: electrocardiograph
EF: ejection fraction

FIPE: Fundação Instituto de Pesquisas Econǒ micas
HF: heart failure
HR: heart rate
LVEF: left ventricular ejection fraction
LVSD: left ventricular systolic dysfunction
NYHA: New York Heart Association
SD: standard deviation

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

Study	Reason for exclusion
Abu-Awwad 2012	System design paper.
Akosah 2005	Contra to protocol: intervention included frequent clinic visits
Al Khateeb 2012	Contra to protocol: not an RCT.
Albanese 2001	Contra to protocol: invasive impedence monitoring (SCOOP II Trial Evaluating CRT/ICD/Impedence Monitoring)
Albert 2007	Contra to protocol: intervention was an education video.
Aliti 2007	Discussion paper.
Alluhaidan 2015	System design paper.
Alnosayan 2014	Review paper.

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Anderson 2005	Contra to protocol: intervention was a heart failure clinic.
Andrikopoulou 2014	Review paper.
Ansinelli 2013	Contra to protocol: not an RCT.
Archelrod 2014	Review paper.
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.
Austin 2012	Contra to protocol: not an RCT.
Baden 2007a	Contra to protocol: not an RCT.
Baden 2007b	Contra to protocol: not an RCT.
Baer 1999	Asessment of correlation between electronic patient measurements and manual nurse measurements
Bakhshi 2011	Contra to protocol: not an RCT.
Baldauf 2008	Contra to protocol: not an RCT.
Baldonado 2013	Review paper.
Barber 1999	Contra to protocol: not an RCT, quasi experimental design.
Bekelman 2013	Contra to protocol: telemonitoring was offered to usual care patients
Ben Gal 2013	Contra to protocol: not an RCT.
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
Bennett Milburna 2014	Review paper.
Berkley 2010	Review paper.
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

(Continued)

Bocchi 2013	Contra to protocol: intervention involved intensive group education sessions and face-to-face individual/group communication
Bohacik 2014	Contra to protocol: invasive monitoring.
Bohmer 2011	Contra to protocol: intensive clinic follow-up in intervention (monthly)
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.
Boriani 2013	Home visits.
Bourge 2008 (COMPASS-HF)	Contra to protocol: invasive implantable haemodynamic monitoring
Bowles 2007	Reivew paper.
Bowles 2008	Systematic review.
Bowles 2009	Contra to protocol: home visits in intervention and usual care arms
Bowles 2011	Home visits.
Brennan 2006	Contra to protocol: not an RCT.
Brennan 2010	Contra to protocol: not HF patients.
Browning 2011	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
Brunetti 2014	Contra to protocol: not an RCT.
Byrnes 2012	Contra to protocol: not HF patients.
Caldwell 2005	Contra to protocol: education session with one follow-up telephone call
Call 2010	Contra to protocol: not an RCT.

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
Calò 2013	Contra to protocol: invasive monitoring.
Capomolla 2002	Contra to protocol: intervention was a day hospital.
Chen 2010	Not an RCT
Chen 2014	Contra to protocol: not an RCT.
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.
Cleland 2012	Not an RCT.
Cleland 2014a	Not an RCT.
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.
Coll 2011	Not heart failure-specific.
Conway 2014	Review paper.
Copeland 2010	Home visits.
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.
Crundall-Goode 2014	Review paper.
Cruz 2010	Contra to protocol: intensive face to face education sessions

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.
Dansky 2009	Contra to protocol: both groups had telemonitoring exposure. Home visits
Dar 2009 (HOME-HF)	Contra to protocol: both study groups received a home visit from study nurse
De Feo 2002	Contra to protocol: not an RCT.
De Vries 2011a	Contra to protocol: not an RCT.
De Vries 2011b	Not an RCT.
Deckwart 2011	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
Delaney 2013	Previous exposure to telemonitoring.
Demarzo 2006	Contra to protocol: invasive haemodynamic monitoring.
Dickens 2012	Contra to protocol: not an RCT.
Dickerson 2011	Contra to protocol: not an RCT.
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.
Dracup 2012	Contra to protocol: face-to-face education and telephone counselling for intervention and control groups

Ducharme 2005	Contra to protocol: intervention was an outpatient clinic.
Duffy 2005	Contra to protocol: intervention included home visits.
Duffy 2008	Discussion paper.
Duffy 2010	Contra to protocol: home visits.
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
Dwinger 2013	Contra to protocol: education intervention (no monitoring data)
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.
Enemuoh 2013	Contra to protocol: not an RCT.
Enjuanes 2013a	Contra to protocol: usual care is a HF disease management program
Erich 2013a	Contra to protocol: not an RCT.
Erich 2013b	Contra to protocol: not an RCT.
Esposito 2008	Not heart failure-specific.
Evangelista 2004	Contra to protocol: web-based education and counselling for patients with heart failure
Fairbrother 2014	Contra to protocol: not an RCT.
Falces 2008	Not structured telephone support or telemonitoring.
Fan 2010	Not an RCT.
Feldman 2004	Contra to protocol: intervention was email-communication to nurses
Feldman 2005	Contra to protocol: intervention was email-communication to nurses
Ferguson 2010	Contra to protocol: not an RCT.
Finkelstein 2004	Contra to protocol: intervention included home visits.
Finkelstein 2006	Contra to protocol: intervention included home visits.

Finkelstein 2010a	System design paper.
Finkelstein 2010b	System design paper.
Finkelstein 2011	System design paper.
Florea 2011	Editorial.
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.
Fursse 2008	Contra to protocol: not an RCT.
Gambetta 2007	Contra to protocol: not an RCT.
Garcia 2009	Review paper.
Gellis 2012	Contra to protocol: home visits.
Gellis 2014	Not structured telephone support or telemonitoring.
Giamouzis 2012	Review paper.
Giordano 2013	Contra to protocol: not an RCT.
Goldstein 2014	Contra to protocol: medication adherence only.
Grancelli 2007	Editorial for previous version of this review.
Granger 2013	Not structured telephone support or telemonitoring.
Graves 2013	Review paper.
Gregory 2006 (SPAN-CHF)	Contra to protocol: intervention included home visits.
Grustam 2014	Review paper.
Gund 2008	Contra to protocol: not an RCT.
Gurne 2012	Review paper.
Gámez-López 2012	Contra to protocol: home visits in intervention.
Hall 2010	Review paper.

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.
Hayes, 2008	Contra to protocol: health technology assessment.
Hayes, 2011	Contra to protocol: health technology assessment.
Heidenreich 1999	Contra to protocol: not an RCT.
Heisler 2007	Contra to protocol: not an RCT.
Helms 2007	Discussion / review paper.
Helms 2010	Contra to protocol: not an RCT.
Hennrikus 2012	Contra to protocol: not an RCT.
Hindricks 2014	Contra to protocol: invasive monitoring.
Hinterbuchner 2010	Contra to protocol: not an RCT.
Ho 2007	Contra to protocol: intervention included home visits.
Hoban 2013	Contra to protocol: home visits.
Holland 2014	Contra to protocol: not telemonitoring or telephone support.
Holly 2011	Review paper.
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.
Hoover 2009	Contra to protocol: not an RCT.
Howlett 2011	Contra to protocol: usual care in a HF clinic.
Hudson 2005	Contra to protocol: not an RCT.
Huynh 2006	Contra to protocol: intensive education session; not structured telephone support or telemonitoring

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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.
Jones 2014	Review paper.
Juan 2011	Not heart failure-specific.
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.
Kastner 2010	Contra to protocol: not an RCT.
Khoury 2008	Contra to protocol: invasive haemodynamic monitoring.
Kielblock 2007	Not an RCT.
Kimmelsteil 2004	Contra to protocol: intervention included home visits.
Kirschner 2006	Discussion paper.
Kitsiou 2013	Review paper.
Kleet 2013	Contra to protocol: not an RCT.
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
Konstam 2012	Review paper.

Kottmair 2005	Discussion paper.
Koutkias 2003	Contra to protocol: not an RCT.
Kraal 2014	Contra to protocol: cardiac rehabilitation.
Kropf 2014	Contra to protocol: not an RCT.
Krumholz 2002	Contra to protocol: frequent clinic and home visits.
Krumholz 2011	Editorial
Kurtz 2011	Contra to protocol: not an RCT.
Kutzleb 2006	Contra to protocol: not an RCT.
Kwok 2008	Contra to protocol: intervention included home visits.
LaFramboise 2003	Contra to protocol: not an RCT.
Lagido 2014	System design paper.
Lavenberg 2012	Contra to protocol: health technology assessment.
Lehmann 2006	Contra to protocol: not an RCT.
Lemay 2013	Chart review paper.
Leventhal 2011	Contra to protocol: home visit in the intervention.
Lind 2013	System design paper.
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.
Madigan 2013	Contra to protocol: home visits.
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.
Maric 2010	Contra to protocol: not an RCT.
Martensson 2005	Contra to protocol: intervention included home visits.
Martín-Lesende 2011	Contra to protocol: home visits when required.
Martín-Lesende 2013	Contra to protocol: home visits when required.
Masterson Creber 2014	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
McEntee 2010	Contra to protocol: not an RCT.
McKinstry 2014	Editorial.
McManus 2004	Contra to protocol: not an RCT.
Mendoza 2002	Contra to protocol: not an RCT.
Meriggi 2009	System development paper.
Metten 2011	Contra to protocol: not an RCT.
Mistiaen 2006	Review paper.
Mitchell 2011	Contra to protocol: health technology assessment.
Mitchell 2014	Contra to protocol: not an RCT.
Moore 2013	Not an RCT.
Morales-Ascencio 2008	Contra to protocol: not an RCT.

Morcillo 2005	Intervention was a single, home-based educational intervention
Morgan 2014	Contra to protocol: invasive monitoring.
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.
Muller 2013	Contra to protocol: invasive monitoring.
Murtaugh 2005	Contra to protocol: intervention was email-communication to nurses
Myers 2006	Contra to protocol: not an RCT.
Nanevicz 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 participants to talk to a nurse)
O'Reilly 1999	Contra to protocol: not an RCT.
Oddone 1999	Contra to protocol: not an RCT.
Odeh 2013	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 participants to contact clinic staff
Oliveira 2013	Contra to protocol: invasive monitoring.
Opasich 2005	Review paper.
Page 2012	Contra to protocol: not an RCT.
Pandor 2013a	Review paper.
Pascual 2011	Contra to protocol: education, not monitoring, intensive clinic visits
Pasqualini 2006	Contra to protocol: not an RCT.
Patja 2012	Contra to protocol: education, not monitoring (outcomes of interest not assessed)
Peikes 2009	Review paper.
Philbin 2000	Report on a quality improvement intervention.
Phillips 2008	Report of a 24-hour telephone support programme for patients and caregivers at the end of life
Picard 2008	Review paper.
Piepoli 2006	Contra to protocol: not an RCT.
Pinto 2014	Contra to protocol: not an RCT.
Piorkowski 2006	Contra to protocol: invasive haemodynamic monitoring.
Piotrowicz 2012	Contra to protocol: cardiac rehabilitation, not an RCT.
Pugh 2001	Contra to protocol: nurse visits were part of the intervention
Purcell 2014	Review paper.
Quinn 2006	Contra to protocol: not an RCT.
Quinn 2008	Contra to protocol: not an RCT.
Rabelo 2007	Contra to protocol: not an RCT.
Raborn 2012	Contra to protocol: not an RCT.
Rahimpour 2008	Contra to protocol: not an RCT.

Ramaekers 2009	Contra to protocol: home visits in usual care.
Raman 2008	Review paper.
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.
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.
Schwamm 2014	Review paper.
Schwarz 2008	Contra to protocol: intervention involved caregivers as well as the person with heart failure
Scott 2004	Contra to protocol: not an RCT.
Seibert 2008a	Contra to protocol: not an RCT.
Sen 2014	Contra to protocol: diabetes not HF

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.
Smolis-Bak 2012	Contra to protocol: not an RCT.
Sonntag 2009	Contra to protocol: not an RCT.
Sousa 2014	Review paper.
Spaeder 2006	Contra to protocol: very frequent clinic visits.
Sprenger 2007	Contra to protocol: not an RCT.
Stampehl 2012	Contra to protocol: not an RCT.
Steckler 2008	Contra to protocol: not an RCT.
Steventon 2013	Contra to protocol: not an RCT.
Stoerk 2013	Contra to protocol: not an RCT.
Stone 2009	Editorial.
Stone 2012	Contra to protocol: not an RCT.
Stork 2009	Review paper.
Stromberg 2003	Contra to protocol: intervention based in clinic.
Stromberg 2006	Contra to protocol: intervention based in clinic.
Stut 2011	System development paper.

Sullivan 2006	Contra to protocol: not an RCT.
Takagawa 2013	System development paper.
Takahashi 2010	Not heart failure-specific.
Takahashi 2012	Not heart failure-specific.
TEHAF Study	Contra to protocol: not an RCT, pre- and post-test study design
Terschuren 2007	Contra to protocol: not an RCT.
Thokala 2013a	Cost-effectiveness modelling.
Thokala 2013b	Not an RCT.
Thompson 2005	Contra to protocol: intervention included home and clinic visits
Thompson 2008	Review of Woodend 2003.
Tompkins 2010	Home visits.
Tramarin 2005	Collection of abstracts, not relating to structured telephone support or telemonitoring in heart failure
Tran 2008	Review paper.
Trudel 2007	Study included participants with diabetes and hypertension. Intervention not specific to heart failure
Tsuji 2013	Contra to protocol: not an RCT.
Umeda 2014	Contra to protocol: invasive monitoring.
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 participant and family, prescribed diet and guideline-based pharmacotherapy and did not include structured telephone support or telemonitoring
Vallina 2008	Contra to protocol: not an RCT.
Vallina 2010	Contra to protocol: not an RCT.
van den Bussche 2004	Contra to protocol: not an RCT, observation study.

Varon 2014	Contra to protocol: not an RCT.
Vasoncelos 2013	Contra to protocol: not an RCT.
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 participants with coronary artery disease, intervention not specific to heart failure
Walsh 2005	Contra to protocol: not an RCT.
Wang 2010	Contra to protocol: not an RCT.
Wang 2012	Not heart failure.
Waywell 2007	Contra to protocol: not an RCT.
Weintraub 2005	Contra to protocol: intervention included home-visits.
West 2013	Editorial paper.
West-Frasier 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.
Wierzchowiecki 2006a	Contra to protocol: intervention included home visits.
Wierzchowiecki 2006b	Contra to protocol: intervention included home visits.
Willyard 2006	Contra to protocol: not an RCT.
Wong 2005	Intervention for people with chronic obstructive pulmonary disease
Wongpiriyayothar 2008	Contra to protocol: intervention included home visits.
Woodside 2011	Contra to protocol: not an RCT.
Wright 2003	Contra to protocol: intervention consisted of symptom diary, attended three education session and clinic visits

(Continued)

Wu 2006	Comparison of internet-based technology.
Xiao 2010	Contra to protocol: not telemonitoring or telephone support.
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 participants to date (NYHA Class II or greater). Mean age no data. % of participants were male - no data. USA.
Interventions	Structured Telephone Support 3 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 symptoms
Outcomes	All-cause hospitalisation; unscheduled outpatient visits. KCCQ; satisfaction; adherence to medications; knowledge of self care and heart failure 12-month follow-up.
Notes	Unable to contact authors to determine or clarify intervention and usual care arms

Kulshreshtha 2010

Methods	Randomised controlled trial.
Participants	150 eligible participants from Massachusetts General Hospital USA.
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"
Notes	Authors contacted to clarify study methods, but no response received

Levine 2006 (Mind My Heart)

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	234 participants. Mean age not reported. % of participants were male not reported. USA.
Interventions	Telemonitoring. Intervention group transmitted to monitoring centre via modem vital signs, BP SpO$_2$ Usual care no further contact with project staff.
Outcomes	Technology use and Satisfaction Survey
Notes	No primary outcomes reported. Unable to contact authors.

Suh 2010

Methods	"The WANDA B. wireless health technology leverages sensor technology and wireless communication to monitor heart failure patient activity and to provide tailored guidance. Patients who have cardiovascular system disorders can measure their weight, blood pressure, activity levels, and other vital signs in a real-time automated fashion. The system was developed in conjunction with the UCLA Nursing School and the UCLA Wireless Health Institute for use on actual patients. It is currently in use with real patients in a clinical trial."
Participants	
Interventions	
Outcomes	
Notes	Authors contacted requesting details of clinical trial, no details provided

Wade 2011

Methods	Randomised clinical trial.
Participants	High-risk people with heart failure.
Interventions	Telehealth system with case management (THCM) versus case management (CM) alone
Outcomes	Composite of all-cause hospitalisation, ED visit, or death.
Notes	Unable to locate valid author contact details.

Wongpiriyayothar 2011

Methods	2-group pretest-post-test experimental research design with random assignment to groups
Participants	22 people with heart failure.
Interventions	Coaching using telephone programme. "The experimental group received the coaching by telephone program (CTP) from the researcher who is a cardiac nurse practitioner; the control group received the usual care from the hospital (routine hospital or clinic assessment and education)."
Outcomes	Self management of heart failure symptoms, dyspnoea, physical functioning
Notes	Authors contacted, no response received.

Wootton 2010

Methods	Randomised controlled trial.
Participants	People with heart failure.
Interventions	
Outcomes	"An evaluation was undertaken on the effectiveness and efficiency of care coordination as a means of delivering health services to Australian veterans with a diagnosis of congestive heart failure."
Notes	Authors contacted, no response received.

Yakushin 2006

Methods	Randomised controlled trial; intervention arm and control (usual care) arm
Participants	78 participants 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.

BP: blood pressure
KCCQ: Kansas City cardiomyopathy questionnaire

SpO_2 : Pulse oximetry

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

Andrei 2011

Trial name or title	
Methods	Randomised controlled trial.
Participants	45 people that have been followed 1 year. All these participants had established diagnosis of chronic congestive heart failure
Interventions	"Two groups: group 1 - patients with worsening CCFH hospitalized for treatment and monitories and group 2 - patients with worsening chronic congestive heart failure treated and monitories at home."
Outcomes	Cost
Starting date	
Contact information	
Notes	Published as conference abstract. Unable to locate contact details for authors.

Black 2014

Trial name or title	
Methods	Multicentre, randomised controlled trial.
Participants	"1,500 patients aged 50 years and older will be enrolled during a hospitalization for treatment of heart failure."
Interventions	"Patients in the intervention group will receive intensive patient education using the 'teach-back' method and receive instruction in using the telemonitoring equipment. Following hospital discharge, they will receive a series of nine scheduled health coaching telephone calls over 6 months from nurses located in a centralized call center. The nurses also will call patients and patients' physicians in response to alerts generated by the telemonitoring system, based on predetermined parameters."
Outcomes	"The primary outcome is readmission for any cause within 180 days. Secondary outcomes include 30-day readmission, mortality, hospital days, emergency department (ED) visits, hospital cost, and health-related quality of life."
Starting date	
Contact information	
Notes	Study protocol only.

Boxer 2010

Trial name or title	
Methods	Randomised controlled trial.
Participants	
Interventions	
Outcomes	
Starting date	
Contact information	
Notes	Published as conference abstract. Authors emailed, no response received.

Cavusoglu 2013 Hit-Point

Trial name or title	Hit-Point
Methods	Multicentre, randomised, controlled trial.
Participants	"Patients who carried the diagnosis of HF secondary to systolic dysfunction, had been hospitalized for HF within six months of randomization, and had symptoms despite optimal medical therapy."
Interventions	"Enhanced HF education with a 6 month phone follow-up program (EHFP) vs routine care (RC). Education included information on the adherence to treatment, symptoms recognition, diet and fluid intake, weight monitoring, activity, exercise training and when to contact cardiologist. Patients were contacted by phone at 1, 3 and 6 month."
Outcomes	"The primary study endpoint was cardiovascular death."
Starting date	
Contact information	
Notes	Conference abstract, authors contacted, full-text peer-reviewed publication not yet available

De Vries 2011 IN TOUCH

Trial name or title	IN-TOUCH
Methods	Randomised controlled trial.
Participants	220 participants will be included after worsening of CHF.
Interventions	Telemonitoring added to ICT-guided disease management.

De Vries 2011 IN TOUCH (*Continued*)

Outcomes	"The primary endpoint of this study is a composite score of: 1: death from any cause during the follow-up of the study, 2: first readmission for HF and 3: change in quality of life compared to baseline, assessed by the Minnesota Living with Heart failure Questionnaire."
Starting date	2009
Contact information	
Notes	Study protocol only.

Dwinger 2013a

Trial name or title	
Methods	Prospective randomised controlled trial.
Participants	
Interventions	Telephone-based health coaching with usual care.
Outcomes	"Patients are selected based on one of the following chronic conditions: diabetes, coronary artery disease, asthma, hypertension, heart failure, COPD, chronic depression or schizophrenia"
Starting date	
Contact information	
Notes	Study protocol only.

Enjuanes 2013b

Trial name or title	
Methods	Prospective, randomised, controlled trial.
Participants	
Interventions	"Strategies of high risk HF patients: HFP (heart failure programme) or HFP+T heart failure programme based on telemedicine). Telemedicine management consisted in daily telemonitoring of weight, blood pressure, heart rate and symptoms that were transmitted to a central station controlled by HF nurses. Teleintervention was carried out replacing the physical appointments by videoconference, promoting self-care and performing therapeutic optimization."
Outcomes	"The determination of direct costs was performed using cost accounting methodology. Primary endpoint: non-fatal HF events by requiring hospital attention at 6 months of inclusion (decompensations requiring parenteral treatment)."

Enjuanes 2013b *(Continued)*

Starting date	
Contact information	
Notes	Conference abstract only, authors contacted, full-text peer-reviewed publication not yet available

Gupta 2013

Trial name or title	
Methods	Randomised controlled trial.
Participants	40 participants with advanced heart failure.
Interventions	"Usual in-hospital care versus telemonitoring-facilitated discharge. Interventions made on the basis of telemonitoring data were limited to telephonically communicated advice to adjust medication and to arrange domiciliary blood samples to monitor renal function and electrolytes."
Outcomes	
Starting date	
Contact information	
Notes	Published as conference abstract. Unable to locate contact details for authors.

Janssen 2010

Trial name or title	
Methods	Controlled trial
Participants	People with heart failure.
Interventions	Telemonitoring.
Outcomes	
Starting date	
Contact information	
Notes	Published as conference abstract. Unable to locate contact details for authors.

Kalowes 2012

Trial name or title	
Methods	Multi-site randomised, controlled trial (RCT)
Participants	"Recently hospitalized HF patients".
Interventions	"post-discharge, telephone intervention" compared to "usual care group receiving outpatient care by their primary care physician."
Outcomes	"...self-care/adherence...incidence of all cause mortality or hospital readmissions (30-day /overall)". "A secondary aim is to assess the impact of the intervention on patient self-care/adherence by examining the effect on QoL and the role of multiple variables (socioeconomic, HC setting/system related, condition related, treatment and patient related)"
Starting date	
Contact information	
Notes	Published as conference abstract. Authors emailed, no response received.

Karanam 2012

Trial name or title	
Methods	Unclear.
Participants	61 participants.
Interventions	"Mobile phone based case management program for patients with Heart Failure (HF) to monitor, educate, and improve self-care efficacy."
Outcomes	"Knowledge, behavior, self care efficacy, and quality of life(QoL) at baseline and 12 weeks."
Starting date	
Contact information	
Notes	Published as conference abstract. Unable to locate contact details for authors.

Kessing 2011 Telemed-HF

Trial name or title	TELEMED-HF
Methods	Randomised controlled trial.
Participants	People with chronic, systolic HF presenting to the outpatient clinic

Kessing 2011 Telemed-HF (*Continued*)

Interventions	Medication support device for 6 months in addition to usual care
Outcomes	"The efficacy and cost-efficiency of an electronic medication adherence support system in improving and monitoring HF patients' medication adherence; (2) the effect of medication adherence on hospitalizations and health care consumption; as well as on (3) clinical characteristics, and Quality of Life (QoL); and (4) clinical, sociodemographic, and psychological determinants of medication adherence."
Starting date	
Contact information	
Notes	Study protocol.

Kotooka 2013 Homes-HF

Trial name or title	
Methods	Multicentre RCT (Japan). 2 groups: Telemonitoring versus usual care. Follow-up: 12 months.
Participants	n = 420 participants planned.
Interventions	"Weight and blood pressure measurements to be performed at least once daily for 12 months Professionals involved: nurses who monitor the data 7 days a week and patient's physician who is responsible for acting on the information."
Outcomes	"Primary endpoints are all-cause death or HF hospitalisation. Secondary endpoints are all-cause death, cardiac death, all-cause rehospitalisation, CV rehospitalisation, HF rehospitalisation, worsening of symptoms, cost of care, LVEF, NTpro-BNP, high sensitive CRP, PTX3, high sensitive troponine, high molecular weight adiponectin, changes in MMSE score, GSES, MLWHF score, PHQ-9 score and adherence to medications."
Starting date	
Contact information	
Notes	Study protocol only.

Lambrinou 2013 MEETTinCy

Trial name or title	MEETTinCy.
Methods	Randomised controlled trial, 4 arms.
Participants	People hospitalised with HF, NYHA I - IV, were recruited from 4 general hospitals in Cyprus

Lambrinou 2013 MEETTinCy   (*Continued*)

Interventions	"Patients were randomly assigned to receive pre-discharge education or telephone support for 3 months after discharge or both, while patients in the control group received the usual care."
Outcomes	"Measures of self-care (using the European Heart Failure Selfcare Behavior Scale) and QoL (using the Minnesota Living in Heart Failure Questionnaire) were collected at baseline and 3 months."
Starting date	
Contact information	
Notes	Published as conference abstract. Authors emailed, no response received.

Mareev 2010 CHANCE-AND

Trial name or title	CHANCE-AND
Methods	"The aim of this trial was to determine whether a special multidisciplinary, non-pharmacological, intervention (including pre-discharge patient education and active follow-up with regular bi-lateral telephone contact) could reduce prevalence of anxiety and depression and morbidity and mortality of patients with heart failure depending on severity of concomitant anxiety and depression."
Participants	
Interventions	
Outcomes	
Starting date	
Contact information	
Notes	Authors contacted, a full-text peer-reviewed publication not yet available

McCall 2011

Trial name or title	Medicare Health Support Pilot Program
Methods	Randomised study of 8 commercial programmes for disease management that used nurse-based call centres
Participants	People with heart failure, diabetes, or both to the intervention or to usual care (control)
Interventions	
Outcomes	"Quality of clinical care, acute care utilization, and Medicare expenditures for Medicare fee-for-service beneficiaries."

McCall 2011 (*Continued*)

Starting date	
Contact information	
Notes	Authors emailed to clarify methods, no response received.

Mizukawa 2014

Trial name or title	
Methods	Multicentre randomised controlled trial.
Participants	People with heart failure.
Interventions	"Three groups: A) TM group with a device of noninvasive blood pressure, heart rate, body weight measurements that automatically send data to the monitor center. Nurses gave patients tele-consultation when the data were out of the optimal values. Patients also received a DM program to gain self-management skills. B) DM group with the DM program. Patients write the value of blood pressure, heart rate, and body weight to monitor their conditions. C) UC group with standard self-management education once from a nurse, and the patients visited the physicians as usual."
Outcomes	Primary outcome was hospital readmissions for heart failure.
Starting date	January 2013 and April 2014
Contact information	
Notes	Conference abstract, authors contacted, full-text peer-reviewed publication not yet available

Moye 2012

Trial name or title	
Methods	Randomised controlled trial.
Participants	Primary or secondary diagnosis of heart failure.
Interventions	"Pharmacist-lead education intervention program. The control group received standard of care. The intervention included one-on-one medication/disease management discharge counseling from a pharmacist, patients were given individualized information regarding their disease state, patients were called on days 14 and 28 post discharge."
Outcomes	Hospital re-admissions
Starting date	August 1, 2011
Contact information	

Moye 2012   (*Continued*)

Notes	Published as a conference abstract. Authors emailed, no response received.

Papadopoulou 2010

Trial name or title	
Methods	Randomised controlled trial.
Participants	100 outpatients with stable chronic HF (NYHA III and IV) and optimal drug treatment
Interventions	"Telephone intervention (a liaison nurse telephoned within seven days of hospital discharge and then at least weekly for one year).vs. usual care."
Outcomes	Mortality, hospitalisations.
Starting date	
Contact information	
Notes	Published as a conference abstract. Unable to locate author contact details.

Persson 2011

Trial name or title	
Methods	Randomised controlled clinical study.
Participants	n = 139
Interventions	"Patients were invited to meet with a specially trained nurse/care manager for a one-hour structured interview investigating possible causes of frequent rehospitalizations. Gaps within the patients' care were identified and specific actions to alleviate the patient's situation (e.g. establishing a primary care contact, booking a specialist or a heart failure nurse appointment, securing home care) were completed. Thereafter regular medical telephone support (structured and planned phone calls) by the same nurse was offered to the patients with the aim to coach and support patients."
Outcomes	Quality of life and hospitalisations.
Starting date	
Contact information	
Notes	Published as a conference abstract. Authors emailed, no response received.

Ritchie 2012 E-coach

Trial name or title	E-Coach
Methods	Randomised controlled trial.
Participants	People with congestive heart failure and chronic obstructive pulmonary disease
Interventions	"Interactive voice response (IVR)-enhanced care transition intervention that monitors patients at home using their personal phone."
Outcomes	
Starting date	
Contact information	
Notes	Study protocol. Authors emailed, no response received.

Voon 2013

Trial name or title	
Methods	Unclear.
Participants	"79 consecutive patients with HF deemed high-risk (hospital admission for acute decompensated HF/IV diuretic outpatient treatment within 6 months, euvolemic BNP .300pg/mL, non-compliance to therapy)."
Interventions	"TM was defined as daily body weight (BW) remote home monitoring using Bluetooth-enabled weighing scale via mobile phone software to a remote web server. DMP was defined as 24-hour outpatient access via phone contact with adhoc review. In addition, structured physician review at 2, 6 and 12 weeks post-discharge and concurrent weekly phone-contacts by nurse, was available."
Outcomes	"Patients were monitored for clinical deterioration (CD), defined as evidence of HF decompensation requiring diuretic therapy or hospitalization as per guidelines."
Starting date	
Contact information	
Notes	Published as a conference abstract. Authors contacted, no response received.

Whole Systems Demonstrator

Trial name or title	Whole System Demonstrator
Methods	Cluster-randomised trial
Participants	79 general practices in 3 areas of England
Interventions	"Telehealth or usual care to eligible patients. Telehealth included remote exchange of vitals signs and symptoms data between patients and healthcare professionals as part of the continuing management of patients. Usual care reflected the range of services otherwise available in the sites, excluding telehealth"
Outcomes	
Starting date	
Contact information	
Notes	Authors contacted to assess if intervention tailored for people with heart failure and if data available for them. Authors did not respond

Zhang 2009

Trial name or title	
Methods	Randomised study
Participants	181 participants with heart failure
Interventions	"Nurse 24 hours telephone services group (24h-telephone, n=91) and non-24 hours telephone services (non-24h-telephone, n=90) group. Telephone services must tell patients how to do next step when patients have any questions."
Outcomes	"The primary end point of the study was the total number of hospital readmission and dead in the one year follow-up period"
Starting date	
Contact information	
Notes	Conference abstract, unable to locate author contact details

Zugck 2010 HiTel

Trial name or title	HiTel
Methods	Randomised controlled trial; intervention arm and control (usual care) arm

Zugck 2010 HiTel *(Continued)*

Participants	88 participants recruited from hospital, mean LVEF was 24 ± 7%. Inclusion criteria NYHA II - IV on optimum therapy and telephone at home Mean age 58.1 years. 82% of participants were men. Germany.
Interventions	Telemonitoring. Intervention group transmitted to monitoring centre via modem vital signs, BP SpO$_2$ and 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. 12-month follow-up.
Starting date	
Contact information	
Notes	

BP: blood pressure

SpO$_2$: pulse oximetry

DATA AND ANALYSES

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

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All-cause mortality: STS vs UC	22	9222	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.77, 0.98]
2 All-cause mortality: TM vs UC	17	3740	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.68, 0.94]
3 Subgroup technology: all-cause mortality STS vs UC	17	6629	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.71, 0.93]
4 Subgroup technology: all-cause mortality Complex TM vs UC	12	2885	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.68, 0.96]
5 Subgroup technology: all-cause mortality Videophone vs UC	2	269	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.65, 1.99]
6 Subgroup technology: all-cause mortality IVR vs UC	4	2445	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.80, 1.28]
7 Subgroup technology: all-cause mortality Mobile/PDA vs UC	4	734	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.46, 1.11]
8 Subgroup TM intensity: all-cause mortality Office hours vs UC	10	1548	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.52, 0.92]
9 Subgroup TM intensity: all-cause mortality 24/7 or 7 days/week vs UC	7	2192	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.71, 1.04]
10 Subgroup Publication year: all-cause mortality STS vs UC < 2000	2	219	Risk Ratio (M-H, Fixed, 95% CI)	0.45 [0.14, 1.40]
11 Subgroup Publication year: all-cause mortality STS vs UC 2000 - 2007	13	5668	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.74, 0.99]
12 Subgroup Publication year: all-cause mortality STS vs UC ≥ 2008	7	3335	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.75, 1.10]
13 Subgroup Publication year: all-cause mortality TM vs UC 2000 - 2007	3	553	Risk Ratio (M-H, Fixed, 95% CI)	0.58 [0.39, 0.86]
14 Subgroup Publication year: all-cause mortality TM vs UC ≥ 2008	14	3187	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.72, 1.02]
15 Subgroup Participant age: all-cause mortality: STS vs UC < 70 years of age	13	6158	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.77, 1.01]
16 Subgroup Participant age: all-cause mortality STS vs UC ≥ 70 years of age	9	3064	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.67, 1.04]
17 Subgroup Participant age: all-cause mortality: TM vs UC < 70 years of age	9	2493	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.68, 1.04]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
18 Subgroup Participant age: all-cause mortality TM vs UC ≥ 70 years of age	8	1247	Risk Ratio (M-H, Fixed, 95% CI)	0.74 [0.59, 0.94]
19 Subgroup STS focus: all-cause mortality STS (clinical support) vs UC	18	8094	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.77, 0.98]
20 Subgroup STS focus: all-cause mortality STS (education) vs UC	4	1128	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.55, 1.45]
21 Sensitivity analysis follow-up period (> 6 months), all-cause mortality: STS vs UC	11	4818	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.75, 1.02]
22 Sensitivity analysis follow-up period (> 6 months), all-cause mortality: TM vs UC	10	2580	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.74, 1.06]

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

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All-cause hospitalisation: STS vs UC	16	7216	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.90, 1.00]
2 All-cause hospitalisation: TM vs UC	13	3332	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.89, 1.01]
3 Subgroup technology: all-cause hospitalisation STS vs UC	12	4756	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.86, 0.99]
4 Subgroup technology: all-cause hospitalisation Mobile/PDA vs UC	2	560	Risk Ratio (M-H, Fixed, 95% CI)	0.76 [0.60, 0.97]
5 Subgroup technology: all-cause hospitalisation Videophone vs UC	2	269	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.80, 1.04]
6 Subgroup technology: all-cause hospitalisation IVR vs UC	3	2312	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.91, 1.08]
7 Subgroup technology: all-cause hospitalisation Complex TM vs UC	10	2651	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.90, 1.04]
8 Subgroup TM intensity: all-cause hospitalisation Office hours vs UC	6	1140	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.76, 0.94]
9 Subgroup TM intensity: all-cause hospitalisation 24/7 or 7 days vs UC	7	2192	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.93, 1.09]
10 Subgroup Publication year: all-cause hospitalisation STS vs UC < 2000	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
11 Subgroup Publication year: all-cause hospitalisation STS vs UC 2000 - 2007	8	3700	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.86, 1.01]
12 Subgroup Publication year: all-cause hospitalisation STS vs UC ≥ 2008	7	3335	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.91, 1.06]
13 Subgroup Publication year: all-cause hospitalisation TM vs UC 2000 - 2007	2	533	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.79, 1.12]
14 Subgroup Publication year: all-cause hospitalisation TM vs UC ≥ 2008	11	2799	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.89, 1.02]
15 Subgroup Participant age: all-cause hospitalisation STS vs UC ≥ 70 years of age	6	1923	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.85, 1.04]
16 Subgroup Participant age: all-cause hospitalisation: STS vs UC < 70 years of age	10	5293	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.89, 1.01]
17 Subgroup Participant age: all-cause hospitalisation TM vs UC ≥ 70 years of age	6	1147	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.82, 0.99]
18 Subgroup Participant age: all-cause hospitalisation: TM vs UC < 70 years of age	7	2185	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.90, 1.07]
19 Subgroup STS focus: all-cause hospitalisation: STS (clinical support) vs UC	14	6820	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.89, 1.00]
20 Subgroup STS focus: all-cause hospitalisation: STS (education) vs UC	2	396	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.84, 1.38]
21 Sensitivity analysis follow-up period (> 6 months), all-cause hospitalisation: STS vs UC	7	3451	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.82, 0.96]
22 Sensitivity analysis follow-up period (> 6 months), all-cause hospitalisation: TM vs UC	8	2387	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.87, 1.01]

Comparison 3. Impact of structured telephone support or telemonitoring in heart failure on risk of heart failure-related hospitalisation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 CHF-related hospitalisation: STS vs UC	16	7030	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.77, 0.93]
2 CHF-related hospitalisation: TM vs UC	8	2148	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.60, 0.83]

3 Subgroup technology: CHF-related hospitalisation STS vs UC	13	4718	Risk Ratio (M-H, Fixed, 95% CI)	0.76 [0.67, 0.86]
4 Subgroup technology: CHF-related hospitalisation Mobile/PDA vs UC	3	674	Risk Ratio (M-H, Fixed, 95% CI)	0.58 [0.44, 0.77]
5 Subgroup technology CHF-related hospitalisation Complex TM vs UC	5	1474	Risk Ratio (M-H, Fixed, 95% CI)	0.78 [0.64, 0.94]
6 Subgroup technology: CHF-related hospitalisation IVR vs UC	3	2312	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.86, 1.14]
7 Subgroup TM intensity: CHF-related hospitalisation Office hours vs UC	5	858	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.56, 0.89]
8 Subgroup TM intensity: CHF-related hospitalisation 24/7 or 7 days vs UC	3	1290	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.57, 0.87]
9 Subgroup Publication year: CHF-related hospitalisation STS vs UC < 2000	2	219	Risk Ratio (M-H, Fixed, 95% CI)	0.24 [0.10, 0.58]
10 Subgroup Publication year: CHF-related hospitalisation STS vs UC 2000 - 2007	10	3784	Risk Ratio (M-H, Fixed, 95% CI)	0.78 [0.69, 0.89]
11 Subgroup Publication year: CHF-related hospitalisation STS vs UC ≥ 2008	4	3027	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.84, 1.11]
12 Subgroup Publication year: CHF-related hospitalisation TM vs UC 2000 - 2007	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
13 Subgroup Publication year: CHF-related hospitalisation TM vs UC ≥ 2008	7	1895	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.58, 0.82]
14 Subgroup Participant age: CHF-related hospitalisation: STS vs UC < 70 years of age	8	5035	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.77, 0.96]
15 Subgroup Participant age: CHF-related hospitalisation: STS vs UC ≥ 70 years of age	8	1995	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.67, 0.96]
16 Subgroup Participant age: CHF-related hospitalisation: TM vs UC < 70 years of age	6	1898	Risk Ratio (M-H, Fixed, 95% CI)	0.75 [0.63, 0.89]
17 Subgroup Participant age: CHF-related hospitalisation: TM vs UC ≥ 70 years of age	2	250	Risk Ratio (M-H, Fixed, 95% CI)	0.53 [0.37, 0.76]
18 Subgroup STS focus: CHF-related hospitalisation: STS (clinical support) vs UC	15	6754	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.76, 0.93]
19 Subgroup STS focus: CHF-related hospitalisation: STS (education) vs UC	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected