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Which components of heart failure programmes are effective? A systematic review and meta-analysis of the outcomes of structured telephone support or telemonitoring as the primary component of chronic heart failure management in 8323 patients: Abridged Cochrane Review

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## Abstract

**Aims** Telemonitoring (TM) and structured telephone support (STS) have the potential to deliver specialized management to more patients with chronic heart failure (CHF), but their efficacy is still to be proven. The aim of this meta-analysis was to review randomized controlled trials (RCTs) of TM or STS for all-cause mortality and all-cause and CHF-related hospitalizations in patients with CHF, as a non-invasive remote model of a specialized disease-management intervention.

**Methods and results** We searched all relevant electronic databases and search engines, hand-searched bibliographies of relevant studies, systematic reviews, and meeting abstracts. Two reviewers independently extracted all data. Randomized controlled trials comparing TM or STS to usual care in patients with CHF were included. Studies that included intensified management with additional home or clinic-visits were excluded. Primary outcomes (mortality and hospitalizations) were analysed; secondary outcomes (cost, length of stay, and quality of life) were tabulated. Thirty RCTs of STS and TM were identified (25 peer-reviewed publications (n= 8323) and five abstracts (n= 1482)). Of the 25 peer-reviewed studies, 11 evaluated TM (2710 participants), 16 evaluated STS (5613 participants) with two testing both STS and TM in separate intervention arms compared with usual care. Telemonitoring reduced all-cause mortality {risk ratio (RR) 0.66 [95% confidence interval (CI) 0.54–0.81], P< 0.0001 }and STS showed a similar, but non-significant trend [RR 0.88 (95% CI 0.76–1.01), P= 0.08]. Both TM [RR 0.79 (95% CI 0.67–0.94), P= 0.008], and STS [RR 0.77 (95% CI 0.68–0.87), P< 0.0001] reduced CHF-related hospitalizations. Both interventions improved quality of life, reduced costs, and were acceptable to patients. Improvements in prescribing, patient-knowledge and self-care, and functional class were observed.

**Conclusion** Telemonitoring and STS both appear effective interventions to improve outcomes in patients with CHF. Systematic Review Number: Cochrane Database of Systematic Reviews. 2008:Issue 3. Art. No.: CD007228. DOI: 10.1002/14651858.CD007228.

## Introduction

Chronic heart failure (CHF) specialized disease management programmes improve survival and quality of life, reduce rehospitalization, and increase the implementation of evidence-based practice.<sup>1,2</sup> However, most of the successful CHF disease management programmes have been built around close clinical follow-up. The need for intense face-to-face follow-up strategies limits the number of patients who can participate in these programmes.

Structured telephone support (STS) is monitoring and/or self-care management delivered using simple telephone technology (data may have been collected and stored by a computer). Telemonitoring (TM) is digital/broadband/satellite/wireless, or blue-tooth transmission of physiological data e.g. electrocardiogram, blood pressure, weight, pulse oximetry, respiratory rate, and other data (self-care, education, lifestyle modification, and medicine administration). Both models of care have the potential to provide access to specialist care for a much larger number of patients across a much greater geography and might reduce the costs of care. These systems can assist directly in patient management, transferring the burden of care from health professionals and involve the patient in supported self-care.<sup>3,4</sup> However, it is still not clear as to whether or not these interventions when delivered as the sole disease management intervention improve patient outcomes.<sup>5,6</sup>

This review, published in the Cochrane Database of Systematic Reviews 2010<sup>7</sup> updates a previously published review of remote monitoring strategies for CHF that included 10 trials of STS and five of TM.<sup>5</sup> Since the first review, a number of large trials have been published reporting outcomes on both STS and TM. We have focused on the same primary outcomes (all-cause mortality, CHF-related hospitalization, and all-cause hospitalization) and secondary outcomes: length of stay, health-related quality of life, healthcare costs, and acceptability of the intervention to patients with CHF. Specifically, we have examined the benefits of STS or TM on a number of important outcomes in patients with CHF when compared with standard care, where STS or TM is the primary model of specialized disease-management intervention.

**Methods** As per our protocol<sup>8</sup> we applied the Cochrane methodology<sup>9</sup> for this review.<sup>7</sup> The specific eligibility criteria of included studies are presented in Table 1.

**Table 1 Inclusion and exclusion criteria.**

<b>Inclusion criteria</b>	
Study type	Randomized controlled trials
Publication	Full peer-reviewed publication (primary meta-analysis of primary outcomes)
Participants	Participants with a definitive diagnosis of heart failure, aged $\geq 18$ years Recently discharged from an acute care setting to home (excluding nursing homes or convalescent homes) or recruited while managed in the community setting
Intervention	Structured scheduled telephone support or telemonitoring (daily, weekly, and monthly) Initiated by a healthcare professional (medical, nursing, social work, pharmacist). Delivered as the only heart failure disease management intervention, without home-visits or intensified clinic follow-up Targeted towards the patient, and not caregivers Did not include any visits at home by a specialized CHF healthcare professional or study personnel for the purpose of education or clinical assessment other than an initial visit to set-up equipment
Comparison	Consisted of standard post-discharge care without intensified attendance at cardiology clinics or clinic-based CHF disease management programme or home-visits
Outcomes	All-cause mortality, CHF-related or all-cause hospitalizations, length of stay, cost of the intervention or cost reductions, quality of life, acceptability, and adherence
<b>Exclusion criteria</b>	
No primary or secondary outcomes of interest reported or available from the study authors	
Not specific to heart failure	
Studies could not include any home-visits by specialized CHF health professionals or study personnel for the purpose of education or clinical assessment or include intensified clinic follow-up	

## **Inclusion and exclusion criteria.**

### **Information sources and search strategies**

As per the Cochrane Heart Group protocol,<sup>9</sup> all known relevant search engines and electronic databases were utilized for the review update period from January 2006 to November 2008. These included CENTRAL; MEDLINE; EMBASE; CINAHL; AMED; Science Citation Index Expanded; DARE; no date limit: National Research Register; IEEE Xplore; OAlster; Google Scholar; Informit; Vivisimo; Australian Digital Theses Programme, and Proquest Digital Dissertations. Bibliographies of relevant studies and systematic reviews were hand-searched. Abstracts from the following conferences were also hand-searched for the years 2006, 2007, and 2008: European Society of Cardiology (ESC) Congress; American College of Cardiology Annual Scientific Sessions; American Heart Association Scientific Sessions; Heart Failure Society of America Annual Scientific Meeting; ESC Heart Failure Congress; ESC Spring Meeting of Cardiovascular Nursing; World Congress of Cardiology (2006, 2008); and the Asia-Pacific Heart Failure Congress (2008). Keywords included: heart failure, cardiac failure, telehealth, telephone, telemonitoring and disease-management. Language restrictions were not applied. Full details of search strategies are available.<sup>7</sup>

### **Study selection**

Randomized controlled trials (RCT) of STS or TM compared with usual care were eligible to be included in the meta-analysis if they were published in full in a peer-reviewed journal.<sup>9</sup> Studies that were published as abstracts only were included in sensitivity meta-analyses.<sup>9</sup> This decision was supported by a publication, co-authored by a member of this review team, which demonstrated that substantial potential discrepancies between results presented in meeting abstracts compared with final peer-reviewed publications.<sup>10</sup>

### **Data collection process**

Two expert reviewers (S.C.I. and R.A.C.) independently reviewed the results of each search according to the inclusion and exclusion criteria with a standardized data extraction tool and also applied standard scales to judge study quality and risk of bias.<sup>9</sup> A third reviewer (J.G.F.C.) adjudicated.<sup>9</sup>

### **Data and analysis**

Meta-analyses of the primary outcomes (all-cause mortality, CHF-related, and all-cause hospitalizations) were performed according to Mantel–Haenzel methods, using a fixed effects model, risk ratios (RR), intention-to-treat, and assessment of statistical heterogeneity using the I<sup>2</sup> statistic.<sup>9</sup> All analyses were performed using Review Manager (RevMan) Version 5.0 (Copenhagen: The Nordic Cochrane Centre, Cochrane Collaboration, 2008).<sup>9</sup> Secondary outcomes such as quality of life, cost effectiveness and adherence and acceptance were measured using multiple tools across the studies. To summarize these outcomes results have been tabulated and described. Due to variances in the way length of stay was calculated and reported in the included studies, this outcome was tabulated as opposed to pooled into a meta-analysis.

### **Sensitivity analysis**

Data from included studies published only as abstracts were added to the meta-analyses of the primary outcomes to assess whether publication status made any difference to the result, including the level of heterogeneity. A second sensitivity analysis was performed to assess the impact of length of follow-up on

the primary outcomes for full peer-reviewed publications only, excluding studies with a follow-up period of 6 months or less.

## Results

### Study selection

Overall, 322 publications from 7952 citations were identified as potentially relevant studies and full copies were retrieved and assessed. Exclusions are detailed in Figure 1.

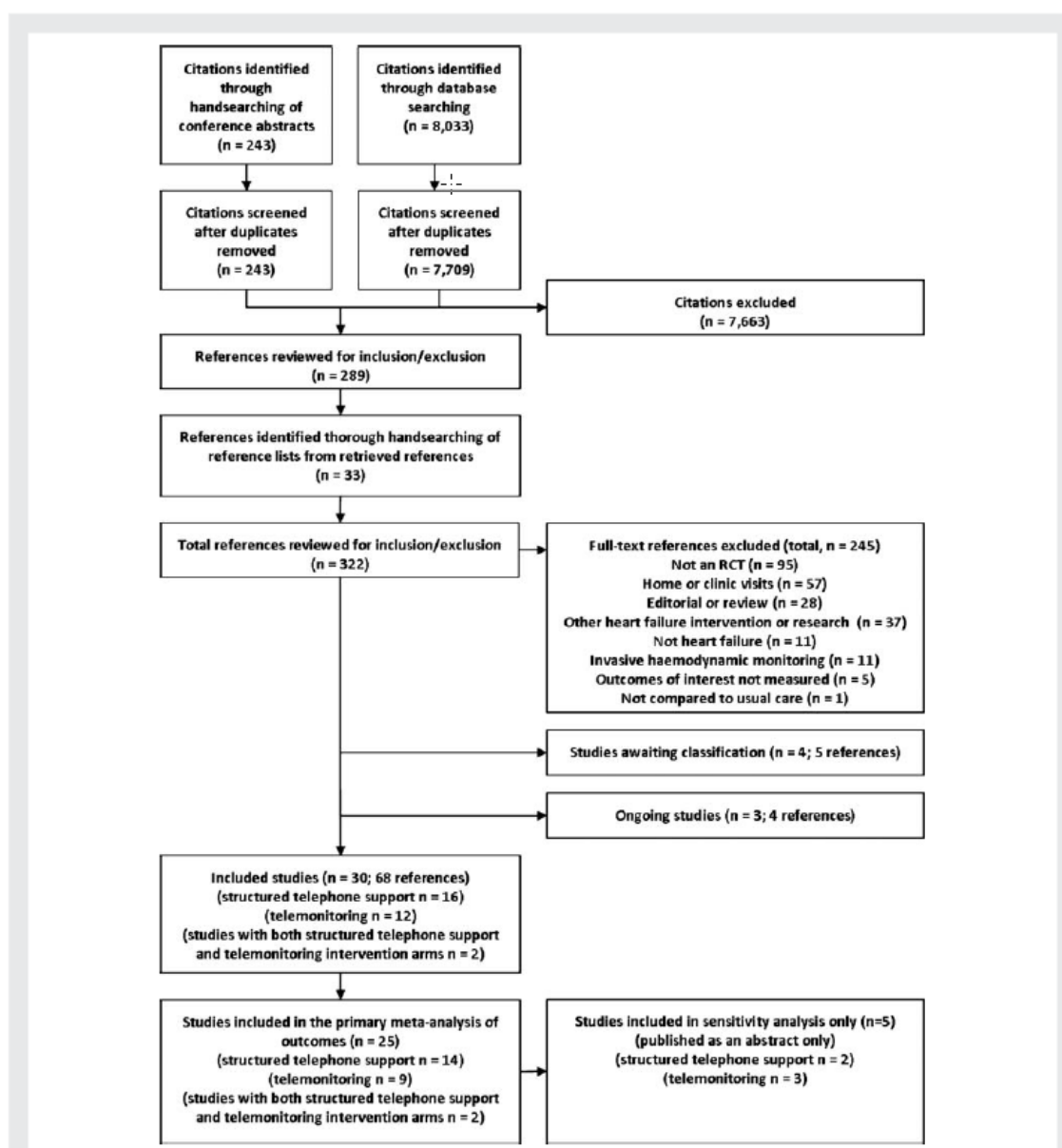


Figure 1 Study selection flowchart.<sup>7</sup> Copyright Cochrane Collaboration, reproduced with permission.

### Study characteristics

Thirty RCTs of STS and TM were identified, which included 9560 participants (Table 2). These include 16 studies of STS<sup>14–18,21–23,25–30,32,33</sup> (two of which were published abstracts<sup>14,23</sup>) 12 studies of TM<sup>34–36,38–45,47</sup> (three

of which were published abstracts<sup>36,43,47</sup>), and two studies with both STS and TM intervention arms compared with usual care.<sup>11,13</sup> The included populations were from seven countries (Table 2).

**Table 2** Description of included studies.

Study	Intervention	Country	Duration of follow-up	Number of patients	Mean age (year)	Male sex (%)	Outcomes
Structured telephone support vs. usual care; telemonitoring vs. usual care							
Cleland et al. (2005) TEN-HMS study <sup>11,12</sup>	STS: education and monitoring.  TM: weight, BP, ECG	Germany, Netherlands, UK	240 days; 15 months	426	67	77	Mortality, hospitalizations, length of stay, adaptation, and acceptance of the intervention
Mortara et al. (2009) HHH study <sup>13</sup>	STS: education and monitoring  TM: weight, BP and symptoms	UK, Poland, Italy	11.6 months (mean)	461	60	85	Mortality, hospitalizations, bed-days, adherence to the intervention
Structured telephone support vs. usual care							
Angermann et al. (2007) INH study [Abstract] <sup>14</sup>	Education and monitoring	Germany	6 months	708	68	71	Mortality, days alive and out of hospital, NYHA functional class, and quality of life
Barth (2001) <sup>15</sup>	Education and monitoring	USA	3 months	34	75	47	Mortality, unexpected visits, hospitalizations, cost, and quality of life
DeBusk et al. (2004) <sup>16</sup>	CHF lifestyle education and medication management	USA	12 months	462	72	51	Mortality, hospitalizations, emergency and outpatient visits, prescription of recommended pharmacotherapy
DeWalt et al. (2006) <sup>17</sup>	Education and monitoring	USA	12 months	127	62.5	47	Mortality, hospitalizations, quality of life, heart failure self-efficacy, heart failure knowledge, weight monitoring
Galbreath et al. (2004) <sup>18-20</sup>	Education and monitoring	USA	18 months	1069	71	71	Mortality, 6-min walk test, NYHA functional class, quality of life, and cost. Subgroup: ejection fraction and medication adherence
Gattis et al. (1999) PHARM study <sup>21</sup>	Pharmacist-led medication review and education	USA	6 months	181	67	68	Mortality, hospitalization and medication prescription
GESICA Investigators (2005) DIAL trial <sup>22</sup>	Education and monitoring	Argentina	16 months (mean)	1518	65	71	Mortality, hospitalizations, quality of life, and medication prescription
Tonkin et al. (2009) CHAT study <sup>23,24</sup> [Abstract]	Telewatch system (Baltimore)	Australia	12 months	405	NR	NR	Mortality, hospitalizations, adherence to, adaptation, and acceptance of intervention
Laramie et al. (2003) <sup>25</sup>	Education and monitoring	USA	3 months	287	71	54	Mortality, hospitalizations, costs, medication prescription, and adherence
Rainville (1999) <sup>26</sup>	Pharmacist-led medication review, education, medication management	USA	12 months	38	70	50	Mortality, hospitalizations, and NYHA functional class
Ramachandran et al. (2007) <sup>27</sup>	Education, monitoring, and medication management	India	6 months	50	44.5	78	Hospitalizations, NYHA functional class, quality of life, medication prescription, and cost
Riegel et al. (2002) <sup>28</sup>	Education and counselling	USA	6 months	358	74	49	Mortality, hospitalizations, hospital days, physician and emergency department visits, cost, and patient satisfaction
Riegel et al. (2006) <sup>29</sup>	Education, monitoring, and guidance	USA	6 months	135	72	46	Mortality, hospitalizations, cost, quality of life, and depression
Sisk et al. (2006) <sup>30,31</sup>	Patient assessment and education	USA	12 months	406	59	54	Mortality, hospitalizations, cost, and quality of life
Telemonitoring vs. usual care							
Tsuyuki et al. (2004) <sup>32</sup>	Education and monitoring	Canada	6 months	276	72	58	Mortality, hospitalizations, medication adherence, physician and emergency department visits, and cost
Wakefield et al. (2008) <sup>33</sup>	Education and monitoring	USA	12 months	148	69	99	Mortality, hospitalizations, hospital days, time to first readmission, urgent care clinic visits, quality of life, satisfaction, and cost
Telemonitoring vs. usual care							
Antoniceili et al. (2008) <sup>34</sup>	BP, HR, weight and 24h urine output, ECG	Italy	12 months	57	78	61	Mortality, hospitalizations, and quality of life
Balk et al. (2008) <sup>35</sup>	MOTIVA system	The Netherlands	288 days (mean)	214	66	70	Hospital days, days alive and out of hospital, quality of life, heart failure knowledge, cost, acceptance, and self-care
Blum et al. (2007) [Abstract] <sup>36,37</sup>	Weight, BP, HR, rhythm	USA	12 months	204	72	71	Hospitalizations, quality of life, mortality, and BNP
Capomolla et al. (2004) <sup>38</sup>	Weight, systolic BP, HR	Italy	12 months	133	57	88	Mortality, hospitalizations, adherence, and emergency department visits
de Lusignan et al. (2001) <sup>39</sup>	Pulse, BP, weight	UK	12 months	20	75	NR	Mortality, satisfaction, adherence, and quality of life
Giordano et al. (2009) <sup>40</sup>	One-lead ECG	Italy	12 months	460	57	85	Mortality, hospitalizations, haemodynamic instability episode occurrence, and cost
Goldberg et al. (2003) WHARF trial <sup>41</sup>	Weight and symptoms	USA	6 months (mean)	280	59	68	Mortality, hospitalizations, emergency department visits, quality of life, and adherence to the intervention
Kielblock et al. (2007) <sup>42</sup>	Weight	Germany	12 months	502	74	51	Mortality, length of stay, hospital and drug costs, total costs per patient, satisfaction, hospitalizations, and medication prescription
Villani et al. (2007) ICARUS [Abstract] <sup>43</sup>	Weight, urine output, fluid intake, BP, HR	Italy	12 months	77	69	75	Mortality, hospitalizations, emergency room visits, and hospital days per patient
Soran et al. (2008) <sup>44</sup>	Weight and symptoms	USA	6 months	315	76	35	Mortality, hospitalizations, length of hospital stay, emergency room visits, quality of life, and adherence to the intervention
Woodend et al. (2008) <sup>45,46</sup>	Weight, ECG, BP	Canada	3 and 12 months	121	68	74	Mortality, hospitalizations, quality of life, emergency department visits, hospital days, and patient satisfaction
Zugck et al. (2008) HiTel trial [Abstract] <sup>47</sup>	Weight, BP, 12-lead ECG	Germany	12 months	88	58	82	Mortality, hospitalizations, and length of stay

**Table 3 Assessment of bias of included studies.**

Study	Adequate sequence generation	Adequate allocation concealment	Adequate blinding of outcome assessors	Incomplete outcome data assessed	Free of selective outcome reporting
Structured telephone support vs. usual care; telemonitoring vs. usual care					
Cleland <i>et al.</i> (2005) TEN-HMS study <sup>11</sup>	Yes	Yes	Unclear	Yes	Yes
Mortara <i>et al.</i> (2009) HHH study <sup>13</sup>	Unclear	Yes	Yes	Unclear	Unclear
Structured telephone support vs. usual care					
Angermann <i>et al.</i> (2007) INH study [Abstract] <sup>14</sup>	Unclear	Unclear	Unclear	Unclear	Unclear
Barth (2001) <sup>15</sup>	Unclear	Unclear	Unclear	Unclear	Unclear
DeBusk <i>et al.</i> (2004) <sup>16</sup>	Yes	Yes	Yes	Yes	Yes
DeWalt <i>et al.</i> (2006) <sup>17</sup>	Yes	Unclear	No	Yes	Yes
Galbreath <i>et al.</i> (2004) <sup>18</sup>	Unclear	Yes	No	No	Yes
Gattis <i>et al.</i> (1999) PHARM study <sup>21</sup>	Yes	No	Yes	Unclear	Yes
GESICA Investigators (2005) DIAL trial <sup>22</sup>	Yes	Yes	Yes	Yes	Yes
Tonkin <i>et al.</i> (2009) CHAT study <sup>23</sup> [Abstract]	Unclear	Unclear	Unclear	Unclear	Unclear
Laramée <i>et al.</i> (2003) <sup>25</sup>	Unclear	Unclear	Unclear	Unclear	No
Rainville (1999) <sup>26</sup>	Unclear	Yes	Unclear	Yes	Yes
Ramachandran <i>et al.</i> (2007) <sup>27</sup>	Yes	Unclear	Unclear	Unclear	Unclear
Riegel <i>et al.</i> (2002) <sup>28</sup>	Unclear	Yes	Unclear	Unclear	Yes
Riegel <i>et al.</i> (2006) <sup>29</sup>	Unclear	Yes	Yes	Yes	Yes
Sisk <i>et al.</i> (2006) <sup>30</sup>	Yes	Yes	Unclear	Yes	Yes
Tsuyuki <i>et al.</i> (2004) <sup>32</sup>	Unclear	Unclear	Unclear	Unclear	Yes
Wakefield <i>et al.</i> (2008) <sup>33</sup>	Yes	Yes	Unclear	Yes	Yes
Telemonitoring vs. usual care					
Antonicelli <i>et al.</i> (2008) <sup>34</sup>	Unclear	Unclear	Unclear	Yes	Yes
Balk <i>et al.</i> (2008) <sup>35</sup>	Yes	Unclear	Unclear	Yes	Yes
Blum <i>et al.</i> (2007) [Abstract] <sup>36</sup>	Yes	Yes	Unclear	Yes	Unclear
Capomolla <i>et al.</i> (2004) <sup>38</sup>	Unclear	Unclear	Unclear	Unclear	Yes
de Lusignan <i>et al.</i> (2001) <sup>39</sup>	Yes	Unclear	Unclear	Unclear	Yes
Giordano <i>et al.</i> (2009) <sup>40</sup>	Unclear	Unclear	Unclear	Yes	Yes
Goldberg <i>et al.</i> (2003) WHARF trial <sup>41</sup>	Unclear	Yes	Yes	Yes	Unclear
Kielblock <i>et al.</i> (2007) <sup>42</sup>	No	Unclear	Unclear	Unclear	Unclear
Villani <i>et al.</i> (2007) ICARUS [Abstract] <sup>43</sup>	Yes	Unclear	Unclear	Unclear	Unclear
Soran <i>et al.</i> (2008) <sup>44</sup>	Unclear	Unclear	Yes	Unclear	Yes
Woodend <i>et al.</i> (2008) <sup>45</sup>	Unclear	Unclear	Unclear	Unclear	No
Zugck <i>et al.</i> (2008) HiTel trial [Abstract] <sup>47</sup>	Unclear	No	Unclear	Unclear	Unclear

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**Description of included studies.**

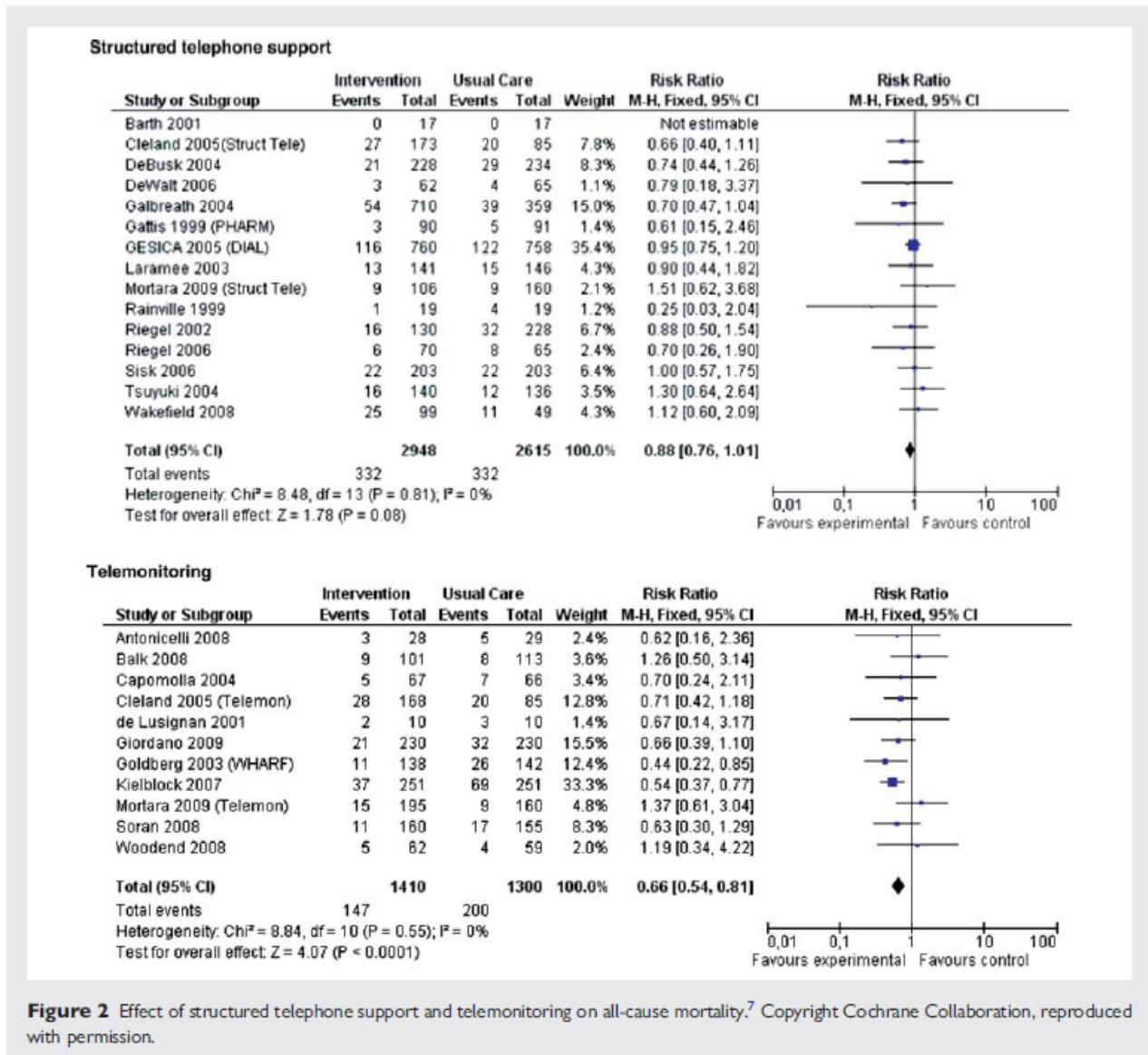
Twenty-five studies were published as full peer-reviewed publications (16 STS, n = 5613 and 11 TM, n = 2710). Two studies<sup>11,13</sup> had two separate intervention arms (STS vs. TM vs. usual care) and each was considered as a separate comparison with usual care (and are included in the aforementioned counts). One study included two STS arms, one of which used standard telephone equipment and the other a videophone; for our analyses these two intervention arms were combined as STS.<sup>33</sup>



## Risk of bias

Analysis of the distribution in the funnel plots (not shown) demonstrated a strong publication bias towards positive outcomes in the included studies.<sup>7,9</sup> A summary of the risk of bias analysis is presented in Table 3. The heterogeneity within the studies ranged from low (for all-cause mortality,  $I^2 = 0\%$ ) to substantial (for all-cause hospitalizations, STS  $I^2 = 24\%$ ; TM  $I^2 = 78\%$ ) (Figures 2–4) ( $I^2$  statistic low = 0–40%; moderate = 30–60%; substantial = 50–90%, considerable = 75–100%).<sup>9</sup>

## Assessment of bias of included studies.



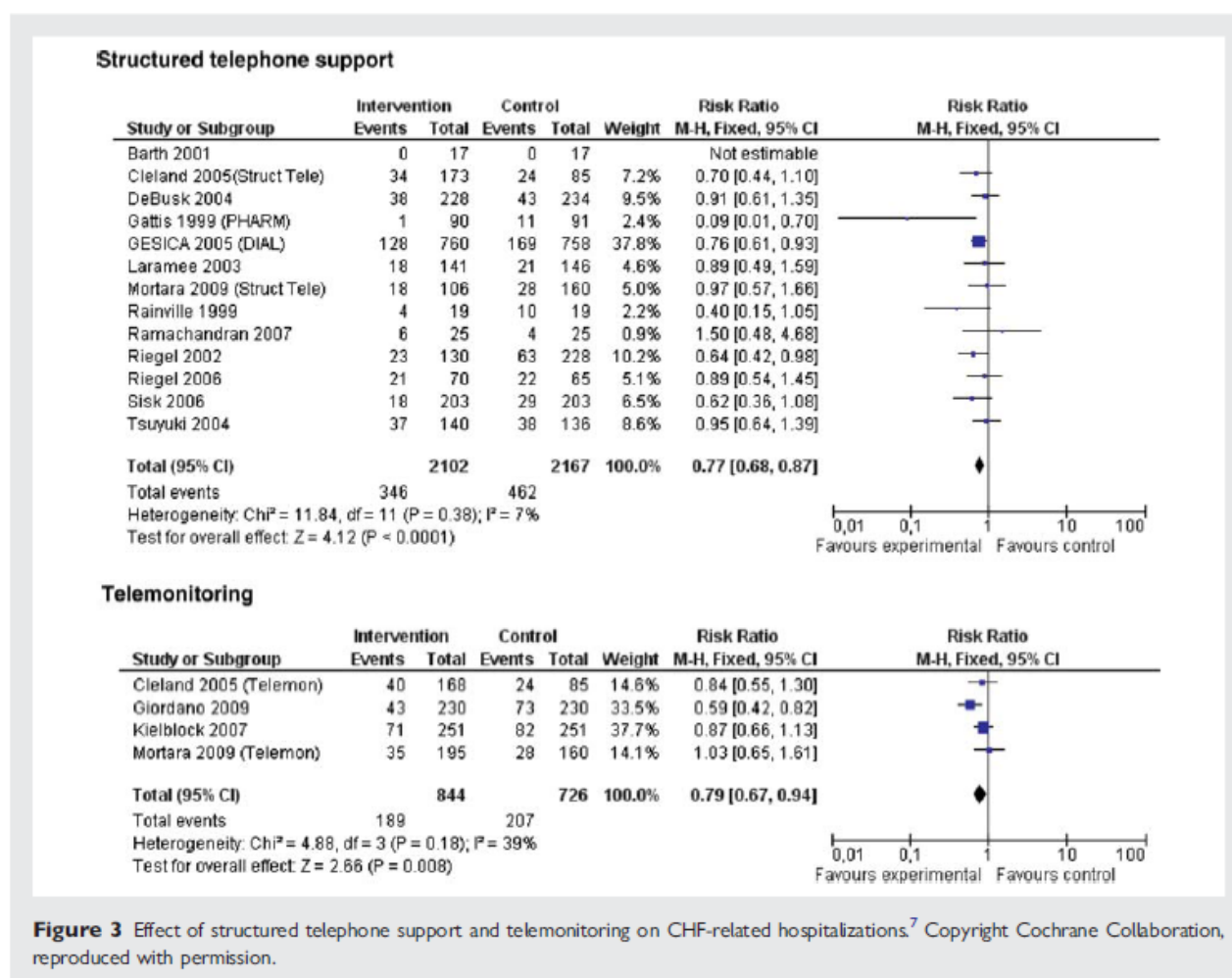
## All-cause mortality

Fifteen studies of STS<sup>11,13,15–18,21,22,25,26,28–30,32,33</sup> and 11 studies of TM<sup>11,13,34,35,38–42,44,45</sup> measured the effect on the risk of all-cause mortality (Figure 2). Telemonitoring was effective in reducing the risk of all-cause mortality in patients with CHF, with a 34% reduction in the risk of mortality observed [RR 0.66 95% confidence interval (CI) 0.54–0.81,  $P < 0.0001$ ,  $I^2 = 0\%$ ]. A similar non-significant trend was noted for STS [RR 0.88 (95% CI 0.76–1.01),  $P = 0.08$ ,  $I^2 = 0\%$ ].

Addition of studies published as abstracts<sup>14,23,36,43,47</sup> had no substantial impact on the results [STS: RR 0.85, (95% CI 0.75–0.97), I2 = 0%, P = 0.02; TM: RR 0.68, (95% CI 0.57–0.82), I2 = 0%, P < 0.0001] nor did exclusion of studies lasting 6 months or less<sup>15,21,25,28,29,32,41,44,45</sup> [STS: RR 0.87, (95% CI 0.74–1.02), I2 = 0%, P = 0.08; TM: RR 0.69, (95% CI 0.55–0.86), P = 0.0009, I2 = 0%].

### Chronic heart failure-related hospitalization

Thirteen studies of STS<sup>11,13,15,16,21,22,25–30,32</sup> and four studies of TM<sup>11,13,40,42</sup> examined the effect of these interventions on the risk of CHF-related hospitalization (Figure 3). Structured telephone support reduced the proportion of patients hospitalized due to CHF by 23% [RR 0.77, (95% CI 0.68–0.87), P < 0.0001, I2 = 7%] and TM reduced this by 21% [RR 0.79, (95% CI 0.67–0.94), P = 0.008, I2 = 39%].

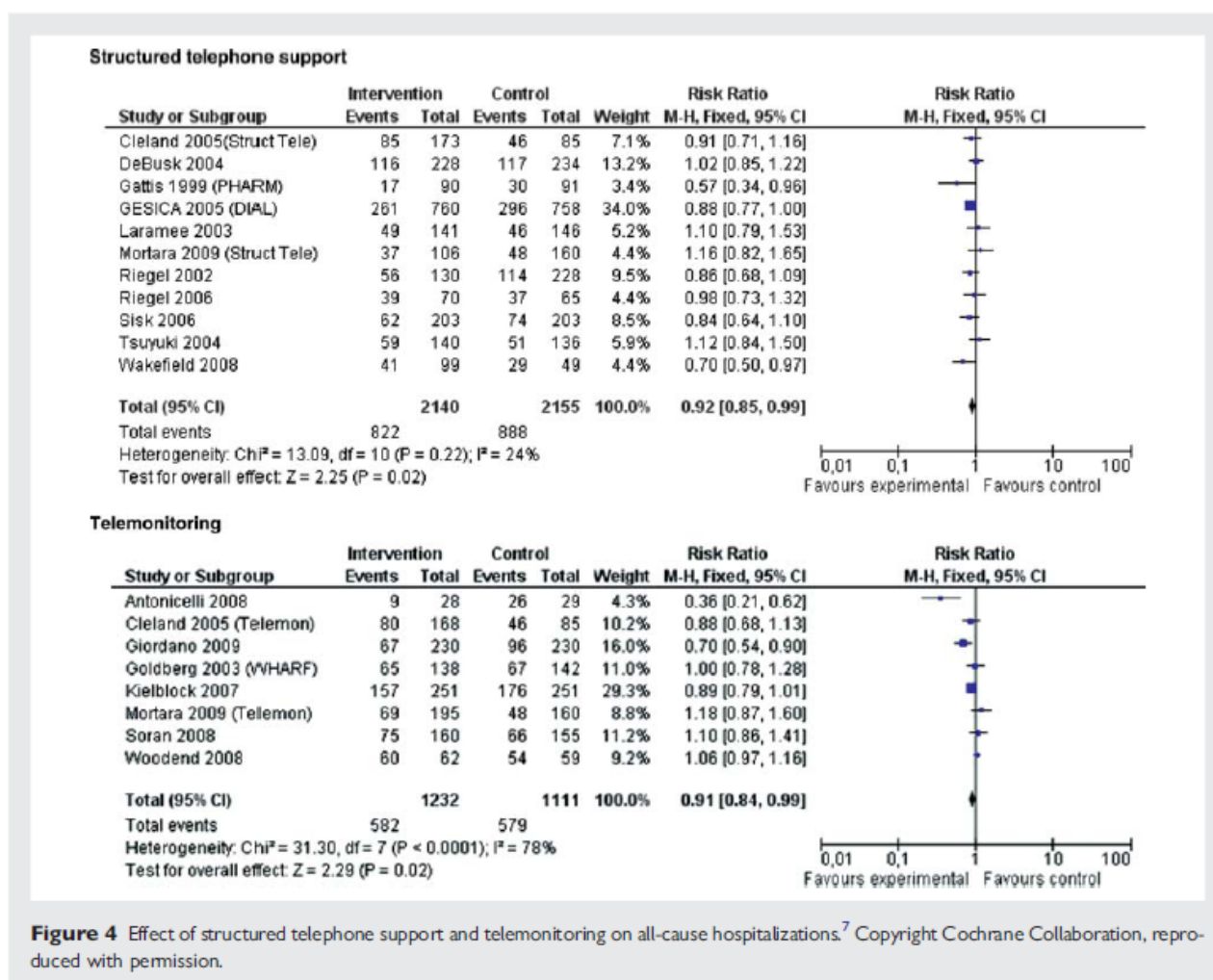


**Figure 3** Effect of structured telephone support and telemonitoring on CHF-related hospitalizations.<sup>7</sup> Copyright Cochrane Collaboration, reproduced with permission.

Addition of one STS study published as an abstract<sup>23</sup> did not alter the result of the meta-analysis other than to reduce heterogeneity (I2 = 0%). Addition of two TM studies published as abstracts<sup>43,47</sup> to the meta-analysis marginally improved the effect [RR 0.76, (95% CI 0.64–0.89), P = 0.0006; I2 = 34%]. Excluding studies with a follow-up period of 6 months or less<sup>15,21,25,27–29,32</sup> did not change the results of the meta-analyses [STS: RR 0.76, (95% CI 0.65–0.89), P = 0.0005; I2 = 0%]. All TM studies reporting CHF-related hospitalizations had a follow-up period > 6 months.

## All-cause hospitalization

Eleven studies of STS<sup>11,13,16,21,22,25,28–30,32,33</sup> and eight studies of TM<sup>11,13,34,40–42,44,45</sup> examined the effect of these interventions on the proportion of participants with at least one hospitalization for any cause (Figure 4). The effect of STS and TM on the risk of a hospitalization was similar [STS: RR 0.92, (95% CI 0.85–0.99),  $P = 0.02$ ,  $I^2 = 24\%$ ; TM: RR 0.91, (95% CI 0.84–0.99),  $P = 0.02$ ,  $I^2 = 78\%$ ].



**Figure 4** Effect of structured telephone support and telemonitoring on all-cause hospitalizations.<sup>7</sup> Copyright Cochrane Collaboration, reproduced with permission.

No substantial change was observed in the results of the meta-analyses when studies published as abstracts were added<sup>23,43,47</sup> [STS: RR 0.90 (95% 0.84–0.97),  $P = 0.003$ ,  $I^2 = 32\%$ ; TM: RR 0.94, (95% CI 0.87–1.01),  $P = 0.09$ ,  $I^2 = 73\%$ ]. Excluding studies with a follow-up period of 6 months or less,<sup>21,25,28,29,32,41,44</sup> did not substantially change the outcome [STS: RR 0.91, (95% CI 0.83–0.99),  $P = 0.03$ ;  $I^2 = 22\%$ ; TM: RR 0.87, (95% 0.80–0.95),  $P = 0.002$ ,  $I^2 = 85\%$ ].

## Length of stay

Only one STS study<sup>32</sup> reported a statistically significant reduction in the length of stay for patients in the intervention group compared with those receiving usual care. One study reported a substantial difference in the number of hospital days per patient.<sup>43</sup>

## Health-related quality of life

Sixteen studies reported quality of life.<sup>14,15,17,19,22,27,29,30,33–35,37,39,41,44,45</sup> These were either a direct comparison between the intervention and control groups at study conclusion, or between baseline and study conclusion within the study arm. A range of psychometric tools were used [Chronic Heart Failure Symptomatology Questionnaire; Minnesota Living with Heart Failure Questionnaire (MLWHFQ); Kansas City Cardiomyopathy Questionnaire (KCCM); Short-Form-12 Item; Short-Form-36 Item (SF-36); Health Distress Score].

Six studies of STS<sup>14,15,22,27,30,33</sup> reported improvements in quality of life, with significant improvements in physical (P = 0.03)<sup>14</sup> and overall measures (MLWHFQ and KCCM). Three TM studies,<sup>34,37,45,46</sup> reported improvements in quality of life (MLWHFQ P = 0.001 and SF-36 mental (P = 0.001), and physical component scores (P = 0.003);<sup>37</sup> MLWHFQ P = 0.025,<sup>46</sup> and SF-36 P < 0.05;<sup>45</sup> SF-36 health perception P = 0.04634).

## Cost

Twelve studies (nine STS<sup>15,18,20,25,27–29,31–33</sup> and three TM<sup>35,40,42</sup>) provided details on cost of the intervention or cost reductions associated with the intervention or cost effectiveness. The cost of the interventions varied according to the type of intervention, in particular the technologies used and the intensity at which it was delivered. Of the 11 studies which reported the effect of the intervention on the cost of care,<sup>18,20,25,27–29,32,33,35,40,42</sup> all but three,<sup>18,20,29,35</sup> reported reductions in cost (either cost per admission or overall reduction in healthcare costs), with those reporting per cent reductions ranging between 14%<sup>25</sup> and 86%.<sup>33</sup>

## Other outcomes

Few studies reported adherence to the intervention (compliance). Among those that did,<sup>13,24,38,39,41,44</sup> adherence was measured at 65.8% for STS,<sup>24</sup> and 75% to 98.5% for TM.<sup>13,38,39,41,44</sup> The adaptation to the technology was high, with two studies, reporting that 96–97% of patients (often aged >70 years) were able to learn and use the STS or TM systems.<sup>12,24</sup> Acceptance (satisfaction) of patients receiving healthcare via STS or TM was rated between 76%<sup>24</sup> and 100%.<sup>12,24,35,42,45</sup> Improvements in other outcomes from these trials included: New York Heart Association (NYHA) functional class that improved in three<sup>14,18,27</sup> studies. Chronic heart failure knowledge and self-care improved in both studies reporting this outcome;<sup>17,35</sup> 6 min walk test improved in one study,<sup>27</sup> of the two<sup>18</sup> that reported this outcome; improvements in evidence-based pharmacotherapy were seen in six<sup>18,21,22,25,27,42</sup> of the seven studies<sup>16</sup> that reported this outcome and the only study to report brain natriuretic peptide, reported an improvement in this measure.<sup>37</sup>

## Discussion

This systematic review and meta-analysis suggests that both TM and STS have a broad range of benefits for patients with heart failure: including a substantial reduction in all-cause mortality for TM, a substantial reduction in the risk of CHF hospitalization for both TM and STS and a modest reduction in the risk of all-cause hospitalization. These interventions improved quality of life, reduced costs, and were acceptable to patients. Improvements in prescribing, patient knowledge and self-care, and functional class were observed. The precise mechanisms by which these interventions produce these effects are unclear but probably reflect a combination of improved implementation of and adherence to guideline therapies, early identification of complications or disease progression, and a positive impact on patient psychology.<sup>48</sup> Patients in these trials reported a sense of reassurance and security, feeling that they have a lifeline to expert care.<sup>23,27</sup>

Two substantial studies<sup>49,50</sup> have been reported since this review was completed and will be incorporated in the next revision which is currently underway. The Tele-HF study<sup>49</sup> which included 1653 patients, was a study of a voice interactive system (STS) applied to patients recently discharged from hospital after an episode of worsening heart failure. Adherence with the system was very poor, suggesting that patients did not engage with the service, perhaps because of the nature of the technology. No benefits were observed on death or hospitalization. This is consistent with the results of our systematic review,<sup>7,51</sup> at least with respect to mortality. The TIM-HF study,<sup>50,52,53</sup> including 710 patients, was a TM study of patients with exceptionally well-managed chronic stable heart failure monitored by a remote expert group. Trends to fewer deaths and hospitalizations with TM were not significant; suggesting that home TM might not be an effective intervention in stable patients when other systems have ensured a high quality of care. However, TM might be a more efficient and less expensive option when the quality of care is not of a similar standard to that provided in TIM-HF. Also, it is unclear as to whether home TM is most successfully deployed as an adjunct to personalized care from a local specialist clinic or as a remote a regional or national service.

We excluded from this analysis other methods of follow-up and management that have also been reported to improve outcomes, such as nurse-led or specialist heart failure clinic or home visits.<sup>2</sup>

It is possible that intensified self-management and remote management are the key factors driving clinical benefit with these interventions. If so, the main issues revolve around an organization and cost effectiveness. The most expensive aspect of healthcare in high-income countries is staff to run services and deliver care. Delivering care by increasing direct one-to-one interactions is likely to be an expensive long-term strategy. Development of TM systems that support the patient directly in making decisions about issues such as diuretic dose, diet, and life-style and when to seek professional advice have the potential to offer expert care to most patients with CHF. Implementation of TM will require a change in the approach of healthcare systems to the delivery of care with redeployment of existing staff rather than an expansion of the healthcare work force required by other strategies. Indeed, it is quite likely that TM has not worked optimally in clinical trials since the studies were generally done in parallel to rather than integrated with existing services. Restructuring healthcare around TM could be more effective and cost efficient.

An additional and increasingly apparent dimension to TM is that it is a direct investment in the patient rather than in healthcare services. The patient is less likely to be a passive recipient of services from health professionals, and becomes more actively involved in their care. Patients provide information on symptoms and vital signs and receive feedback and education, which they can review at their leisure as often as they wish and together with their carers and family. More advanced systems will ensure that the patients know when and how medication should be adjusted and when they can do this themselves and when they need professional support. Because the patients know what care they should receive, health professionals may be more likely to deliver it or explain why the patients should deviate from the plan. Telemonitoring will create more expert patients. Undoubtedly, this will create headaches for health professionals, leading to resistance to change. The medical profession should offer the best service to patients even if this means moving out of their professional comfort zone.

Compared with other recent systematic reviews of remote monitoring in CHF,<sup>54,55</sup> our review<sup>7</sup> is unique in using robust Cochrane methodology.<sup>8,9</sup> We have synthesized and quantified the benefits of STS and TM, while limiting the influence of confounders such as home-visits by specialized healthcare staff or frequent visits to a specialized CHF clinic on the efficacy of these interventions in managing patients with CHF.

Previous reviews on this topic have included a mixture of research methods (RCTs and cohort studies) and studies of both invasive and non-invasive remote monitoring, many of which have involved home visits.<sup>54,55</sup>

These findings have important clinical implications. The findings of this review are highly relevant to the future planning and implementation of CHF disease-management globally. This analysis provides strong evidence that these technologies reduce mortality and hospitalizations as well as improving measures such as quality of life. There may be benefits of using these technologies to manage patients with CHF that relate to human or financial resources, but perhaps the biggest advantage can be gained from utilizing these technologies to reach patients with CHF who are without access to home or clinic-based CHF-management programmes.<sup>3,4</sup> Such benefits may not be restricted to high-income countries. Indeed, China and India<sup>56</sup> both have programmes for delivering care remotely.

The average age of patients in these included trials ranged from 45 to 78 years, with the majority of patients aged >68 years. It is clear that many older people are able to use and benefit from STS and TM. In fact TM devices are usually designed specifically with older people in mind.

Our synthesis of the evidence of STS and TM is only as good as the included studies. We were limited by the format of published results, especially for those where we were unsuccessful in obtaining further study details. In addition, the heterogeneity is large for some of the meta-analyses of the primary outcomes. This heterogeneity is not only within methodology but also the types and intensity of applied technologies.

There was evidence of publication bias. It is likely that many small studies are never published, either because the investigator does not offer their results for publication or because editors reject under-powered and negative studies. There is a dearth of evidence about how long patients should be supported by TM or STS. It is possible that the greatest benefit in terms of education and medication patterns is accrued within a few weeks and that long-term monitoring is redundant. However, the weight monitoring in heart failure trial showed that a 6-month TM intervention was associated with a reduction in mortality but that withdrawal led to rapid loss of this initial benefit, suggesting that long-term TM might be superior to short-term TM.<sup>57</sup>

In conclusion, STS and TM improve outcomes for patients with CHF, although only TM appears to have a substantial impact on reducing mortality. This may reflect the impact of improved access to specialist care, which could be delivered by more conventional means but at additional cost. The effects appear substantial and might be an underestimate of the true impact when properly integrated into care pathways. Given the wealth of evidence and the impact on hospitalization that is likely to mitigate costs, all patients with CHF should have access to enhanced surveillance.

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