Title Page

Title: Effective technologies for non-invasive remote monitoring in heart failure

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Abstract

Background

Trials of new technologies to remotely monitor for signs and symptoms of worsening heart failure are continually emerging. The extent to which technological differences impact the effectiveness of non-invasive remote monitoring for heart failure management is unknown.

Objective

To examine the effect of specific technology used for non-invasive remote monitoring of people with heart failure on all-cause mortality and heart failure-related hospitalisations.

Methods

A sub-analysis of a large systematic review and meta-analysis was conducted. Studies were stratified according to the specific type of technology used and separate meta-analyses were performed. Four different types of non-invasive remote monitoring technologies were identified including structured telephone calls, videophone, interactive voice response devices and telemonitoring.

Results

Only structured telephone calls and telemonitoring were effective in reducing the risk of all-cause mortality (RR 0.87; 95% CI=0.75-1.01; p=0.06 and 0.62; 95% CI=0.50-0.77; p<0.0001) and heart failure-related hospitalisations (RR 0.77; 95% CI=0.68-0.87; p<0.001) and 0.75; 95% CI=0.63-0.91; p=0.003). More research data is required for videophone and interactive voice response technologies.

Conclusions

This sub-analysis identified that only two of the four specific technologies used for non-invasive remote monitoring in heart failure improved outcomes. When results of

studies that involved these disparate technologies were combined in previous meta-analyses, significant improvements in outcomes were identified. As such, this study has highlighted implications for future meta-analyses of randomised controlled trials focused on evaluating the effectiveness of remote monitoring in heart failure.

Keywords: *Heart failure, remote monitoring, systematic review, meta-analysis*

Introduction

In this era of rapidly advancing and wider community access to information technology, trials of new technologies to remotely monitor for signs and symptoms of worsening heart failure are continually emerging. Moreover, many health services around the world have already started to implement varying forms of these technologies into practice. This is most likely due to the fact that high quality meta-analyses of randomized controlled trials have indicated that remotely monitoring people with heart failure reduces their relative risk of death and hospitalisations in comparison with usual care.[1-4] However, debate regarding appropriate methods to compare remote monitoring studies in heart failure has emerged since the publication of results from two randomized controlled trials that directly contrasted with earlier meta-analyses.[5, 6]

In this regard, it is important to note that many specific technological differences exist. For example, technologies vary from a structured telephone call (normal telephone, conducted in person, supported by computer data gathering) to interactive voice response systems (a computer voice guides the patient to press phone keys in response to questions, similar to telephone banking). The extent to which these technological differences impact the effectiveness of post-discharge heart failure management have been unknown. The aim of this study was to examine the effect of specific technologies on outcomes in heart failure management.

Methods

We conducted a sub-analysis of our previously published systematic review and meta-analysis using Cochrane methodology.[3, 7, 8] First, the 25 randomized controlled

trials included in our systematic review were further scrutinized in order to group the studies according to the specific type of non-invasive remote monitoring technology that was used. Then, separate meta-analyses of all-cause mortality and heart failure-related hospitalizations were performed for each group of studies. This sub-analysis was not published in the Cochrane Review.[8]

Information sources and search strategy

The full report of the information sources and search strategy are published elsewhere. In brief, though, as per the protocol,[7] all known relevant search engines and electronic databases were utilized for the period to November 2008. In addition, bibliographies of relevant studies and systematic reviews were hand-searched. Abstracts from major cardiology conferences were also hand-searched for the years 2006, 2007 and 2008. Keywords included heart failure, cardiac failure, telehealth, telephone, telemonitoring and disease management. Language restrictions were not applied.

Study selection

Randomized controlled trials of non-invasive remote monitoring for heart failure compared to usual care were eligible to be included in this sub-analysis if they were published in full in a peer-reviewed journal.[7] Studies which were published as abstracts were excluded because in the main review, it was identified that addition of the studies published as abstracts had no substantial impact on results of the meta-analyses.[3]

Data extraction

Two reviewers independently reviewed the results of each search according to the inclusion and exclusion criteria with a standardised data extraction tool and also

applied standard scales to judge study quality and risk of bias. A third reviewer adjudicated.

Data analysis

Meta-analyses on the primary outcomes of 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^2 statistic.[7] All analyses were performed using Review Manager (RevMan) Version 5.0 (Copenhagen: The Nordic Cochrane Centre, Cochrane Collaboration, 2008).[7] In technology applications where there were only a small number of studies, results were not subjected to meta-analysis and instead individual results have been presented and discussed narratively.

Results

Technologies identified

Four different modes of non-invasive remote monitoring technologies were identified among the 25 randomised controlled trials included in our systematic review *Table 1*. A summary of the studies included in our review is reported in detail elsewhere.[8] The specific technologies identified include: 1) structured telephone calls; 2) videophone; 3) interactive voice response, which involved the manual input of data using a telephone keypad in response to questions from a computerized interactive voice response system; and 4) telemonitoring, which involved 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. Table 2 presents a summary of the results of meta-analyses, or results of single randomised controlled trials where

meta-analysis could not be conducted, according to the type of technology used.

Structured telephone call

Meta-analysis of 15 studies that compared structured telephone calls for post-discharge heart failure management with usual care identified reductions in all-cause mortality (RR 0.87; 95% CI=0.75-1.01; *p*=0.06) *Figure 1*. Similarly, the relative risk of heart failure-related hospitalisations was reduced in meta-analysis of 13 studies that involved structured telephone calls (RR 0.77; 95% CI=0.68-0.87; *p*<0.0001) *Figure 2*.

Videophone

Only one study (*n*=148 participants) examined the effectiveness of videophone follow-up on heart failure outcomes.[23] No differences were found for all-cause mortality and in this study (RR 1.28; 95% CI=0.66-2.52). Hospitalisations were not reported.

Interactive Voice Response

The effectiveness of interactive voice response devices was examined in two studies included in our review.[17, 33] No significant reductions in the relative risk of all-cause mortality, all-cause hospitalisations or heart failure-related hospitalisations were observed in either of these studies (Table 2).

Telemonitoring

Significant reduction in the relative risk of all-cause mortality (RR 0.62; 95% CI=0.5-0.77; *p*<0.0001) was identified in meta-analyses of nine studies *Figure 3*. Fewer studies reported on heart-failure related hospitalisations. However, the relative risk of heart failure-related hospitalisations (RR 0.75; 95% CI=0.63-0.91; *p*=0.003) was also reduced compared with usual care in meta-analysis of three studies *Figure 4*.

Interactive Voice Response and telemonitoring

One arm of the study reported by Mortara et al.[17] included a group of patients who used both interactive voice response and telemonitoring technologies. No significant differences were identified for all-cause mortality, all-cause hospitalizations or heart failure-related hospitalisations between the intervention and control groups in this study. [17]

Risk of bias

The heterogeneity within the structured telephone call and telemonitoring studies that were subjected to meta-analysis was low for all-cause mortality (I^2 = 0%). Meta-analyses of all-cause and heart failure-related hospitalizations for structured telephone call studies was low (I^2 = 13% and 7% respectively). In contrast, for telemonitoring studies, heterogeneity for all-cause hospitalizations was substantial (I^2 = 81%) and for heart failure-related hospitalizations, heterogeneity was moderate ($I^2$42%) (I^2 statistic Low = 0-40%; Moderate = 30-60%; Substantial = 50-90%, Considerable 75-100%).[34]

Discussion

This sub-analysis of our Cochrane Collaboration systematic review has identified that only two of the four specific technologies used for non-invasive remote monitoring in heart failure showed statistically significant improvements on the primary outcomes. These results are in contrast to our previous systematic review and those published by other groups, where these disparate technologies have been combined to show significant improvements in outcomes.[2, 3] As such, the results from this sub-analysis have considerable implications for future research and provide methodological insights to consider in the conduct of future meta-analyses of

randomised controlled trials focused on evaluating the effectiveness of remote monitoring in heart failure.

Interestingly, one of the technologies that significantly improved outcomes in this sub-analysis was the telephone call between a patient and health professional following a structured format. The other effective technology was telemonitoring. The most notable difference between these two effective technologies is that, in the studies that involved a structured telephone call, education, self–care and symptom monitoring were an essential part of the process conducted. In contrast, the studies that involved telemonitoring only involved transmission of physiological data and maintained dependence on the providers. The unique contribution of incorporating the provision of education for self-care and self-monitoring empowerment and autonomy has not specifically been determined. However, results from our sub-analysis suggest the additional benefit may be limited, as both strategies produced significant reductions in mortality and hospitalisations in our meta-analyses. As such, further investigation is required, as there are cost and health service implications associated with the allocation of a case manager to conduct follow up calls to patients with heart failure. For example, it has been reported that it is typical for a case manager to provide follow-up calls for fifty patients in comparison to the two to three hundred-patient capacity of an telemonitoring strategy.[35] On the other hand, more complex information technology infrastructure is required to facilitate telemonitoring as opposed to a simple telephone call, which might limit the extent to which telemonitoring can be made available for heart failure patients to access. However, only 50% of the trials that involved structured telephone calls were conducted after 2005 in comparison to 80% that involved telemonitoring. This temporal trend, which indicates a recent preference for evaluating the potentially

more cost-effective technology of telemonitoring for remote monitoring in heart failure, may indicate that information technology infrastructure issues are not a significant barrier to implementation.

We have also considered the results of our sub-analysis in regard to the mechanisms by which providing follow up for heart failure patients with either a structured telephone call or with telemonitoring might produce their protective effects. In this regard, recent evidence suggests that remote monitoring, in which change in weight is the only variable recorded, is not sensitive enough to detect worsening heart failure. Zhang and colleagues found only 20% of episodes of worsening heart failure were preceded by an increase in weight.[36] It has been proposed that fluid redistribution as opposed to fluid accumulation is an important contributory mechanism in exacerbation of heart failure.[37, 38] Three studies of telemonitoring included in our sub-analysis monitored weight in isolation, whereas others included blood pressure, electrocardiography and oxygen saturations measurement. As such, consideration should be given to measuring more than weight in telemonitoring interventions. Moreover, while the provision of education during remote follow-up would theoretically lead to improved self-care in patients with heart failure, a recent review that focused specifically on this issue noted that results from trials are equivocal.[39] For these reasons, we suggest that future trials should directly compare structured telephone call and telemonitoring strategies to provide further insight into which particular technology is the most effective in terms of clinical and cost-effectiveness.

In contrast to structured telephone calls and telemonitoring, we have identified in this sub-analysis that more research data would be required to provide a robust evaluation of the effectiveness of two other specific technologies; videophone and

interactive voice response systems. That being said, the need to conduct further investigations of videophone technology is not abundantly clear from the evidence at hand, because the use of structured telephone calls seems to be a highly effective remote monitoring strategy. Videophone technology is associated with more costs than telephone follow-up, due to the cost of equipment.[23] As such, if investigations of videophone technology are conducted in the future, it is suggested that the research design should incorporate a group of patients receiving structured telephone call follow-up for comparison.

Interactive voice response technology was investigated in only two studies included in our review.[17, 33] The trials enrolled 594 patients in total and there were no significant reductions in mortality or hospitalisations identified in either of the studies. These findings are consistent with a more recent and larger randomised controlled trial of interactive voice response technology, which was published after our systematic review. The Tele-HF trial, which randomised 1,653 patients, found that there were no significant differences between the primary outcome of hospitalisation or death within six months.[5] Of note, though, when we grouped the two interactive voice response studies under the broader 'telemonitoring' group in our Cochrane review, reductions in mortality and hospitalisations remained statistically significant. Therefore, based on the disparate results of our sub-analysis, it does not seem that grouping interactive voice response systems with telemonitoring technologies is an appropriate strategy for comparison of clinical studies of remote monitoring for heart failure. For this reason, in the update of our Cochrane Review, capturing the latest randomized controlled trial evidence, subgroup analysis of specific technologies will provide further insight into the effectiveness of interactive voice response technology in improving post-discharge heart failure follow-up care. Once these findings of the

updated review are published, if it is confirmed that remote monitoring using an interactive voice response device is not associated with reductions in mortality or hospitalisations, serious consideration should be given as to the appropriateness of further investigations of this particular technology.

It should also be noted that, to provide more standardized comparisons between trials of remote monitoring for heart failure, Anker and colleagues recently proposed a classification scheme in their review of contemporary issues related to remote telemedical management of heart failure.[35] Their proposed scheme comprised four generations. The main discriminating factors between generations are the methods by which the information that is collected is used by the health care practitioner and whether or not data from invasive devices have been incorporated into clinical decision-making. Whilst we share Anker and colleagues view that it is important to establish robust methods of comparing the results of similar studies in order to determine which specific approach is the most effective, as we have identified in this sub-analysis, there are substantial differences in outcomes between just the non-invasive technologies, therefore it does not seem appropriate to apply this specific classification scheme as the sole basis to make comparisons.[35]

Limitations

It is important to note that the degree of heterogeneity in this sub-analysis was similar to that reported in our overall Cochrane review. This is likely due to the fact that only one study that involved videophone technology was separated out from the broader structured telephone support category and only two studies that involved interactive voice response technology were separated out from the broader telemonitoring category. An important limitation of this analysis is the exclusion of

more recent randomized controlled trials of non-invasive remote monitoring in heart failure. In order to avoid introducing bias into our methodology, we have limited this analysis to the studies currently included in our Cochrane review. The latest randomized controlled trial evidence will be included in the update of our Cochrane Review.

Conclusion

This sub-analysis has identified that while four unique technologies for the non-invasive remote monitoring of heart failure have been evaluated in randomised controlled trials, only structured telephone calls and telemonitoring, in which physiological data is automatically transmitted, reduced the relative risk of all-cause mortality and hospitalizations when results were combined in the meta-analyses. More research data is required to evaluate the effectiveness of videophone and interactive voice response technologies.

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Author disclosure statement

No competing financial interests exist.

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Table 1 Study characteristics categorized by type of technology

Study	Intervention	Follow-up
Structured Telephone Call vs. Usual Care		
Barth (2001)[9]	Education and monitoring.	3 months
Cleland et al. (2005)[10] TEN-HMS Study	Education and monitoring.	240 days; 15 months
DeBusk et al. (2004)[11]	CHF lifestyle education and medication management.	12 months
DeWalt et al. (2006)[12]	Education and monitoring.	12 months
Galbreath et al. (2004)[13]	Education and monitoring.	18 months
Gattis et al. (1999)[14] PHARM Study	Pharmacist-led medication review and education.	6 months
GESICA Investigators (2005)[15] DIAL Trial	Education and monitoring.	16 months (mean)
Laramee et al. (2003)[16]	Education and monitoring.	3 months
Mortara et al. (2009)[17] HHH Study	Education and monitoring.	11·6 months (mean)
Rainville (1999)[18]	Pharmacist-led medication review, education, medication management.	12 months
Ramachandran et al. (2007)	Education and drug dose modification	6 months
Riegel et al. (2002)[19]	Education and counseling.	6 months
Riegel et al. (2006)[20]	Education, monitoring and	6 months

	guidance.	
Sisk et al. (2006)[21]	Patient assessment and education.	12 months
Tsuyuki et al. (2004)[22]	Education and monitoring.	6 months
Wakefield et al. (2008)[23]	Education and monitoring.	12 months
Videophone vs. Usual Care		
Wakefield et al. (2008)[23]	Education and monitoring.	12 months
Interactive Voice Response vs. Usual Care		
Capomolla et al. (2004)[24]	Weight, systolic BP, HR.	12 months
Mortara et al. (2009)[17] HHH Study	Weight, HR, BP and symptoms (Telemonitoring data was collected but not used)	11·6 months (mean)
Interactive Voice Response plus Telemonitoring vs. Usual Care		
Mortara et al. (2009)[17] HHH Study	Weight, HR, BP and symptoms plus ECG, respiration rate and physical activity	11·6 months (mean)
Telemonitoring vs. Usual Care		
Antonicelli et al. (2008)[25]	BP, HR, weight and 24h urine output, ECG.	12 months
Balk et al. (2008)[26]	MOTIVA system.	288 days (mean)
Cleland et al. (2005)[10] TEN-HMS Study	Weight, BP, ECG.	240 days; 15 months
de Lusignan et al.	Pulse, BP, weight.	12 months

(2001)[27]		
Giordano et al. (2008)[28]	One-lead ECG.	12 months
Goldberg et al. (2003)[29] WHARF Trial	Weight.	6 months (mean)
Kielblock et al. (2007)[30]	Weight.	12 months
Mortara et al. (2009)[17] HHH Study	Weight, BP and symptoms.	11·6 months (mean)
Soran et al. (2008)[31]	Weight.	6 months
Woodend et al. (2003)[32]	Weight, ECG, BP.	3 and 12 months

Table 2 Outcomes according to type of technology used

Technology	All-cause mortality	Heart failure-related hospitalizations
Structured telephone call vs usual Care	Meta-analysis of 15 studies: RR 0.87 (95% CI=0.75-1.01)	Meta-analysis of 13 studies: RR 0.77 (95% CI=0.68-0.87)
Video-phone vs usual care	Wakefield et al.[23] RR 1.28 (95% CI=0.66-2.52)	Not reported
Interactive voice response vs usual care	Capomolla et al.[33] RR 0.7 (95% CI= 0.24-2.11) Mortara et al.[17] RR 1.32 (95% CI=0.51-3.44)	Mortara et al.[17] RR 1.03 (95% CI=0.60 -1.78)
Telemonitoring and Interactive voice response vs usual care	Mortara et al.[17] RR 1.41 (95% CI=0.56-3.53)	Mortara et al.[17] RR 1.02 (95% CI=0.60 – 1.74)
Telemonitoring vs usual care	Meta-analysis of 9 studies: RR 0.62 (95% CI=0.50-0.77)	Meta-analysis of 3 studies: RR 0.75 (95% CI=0.63-0.91)

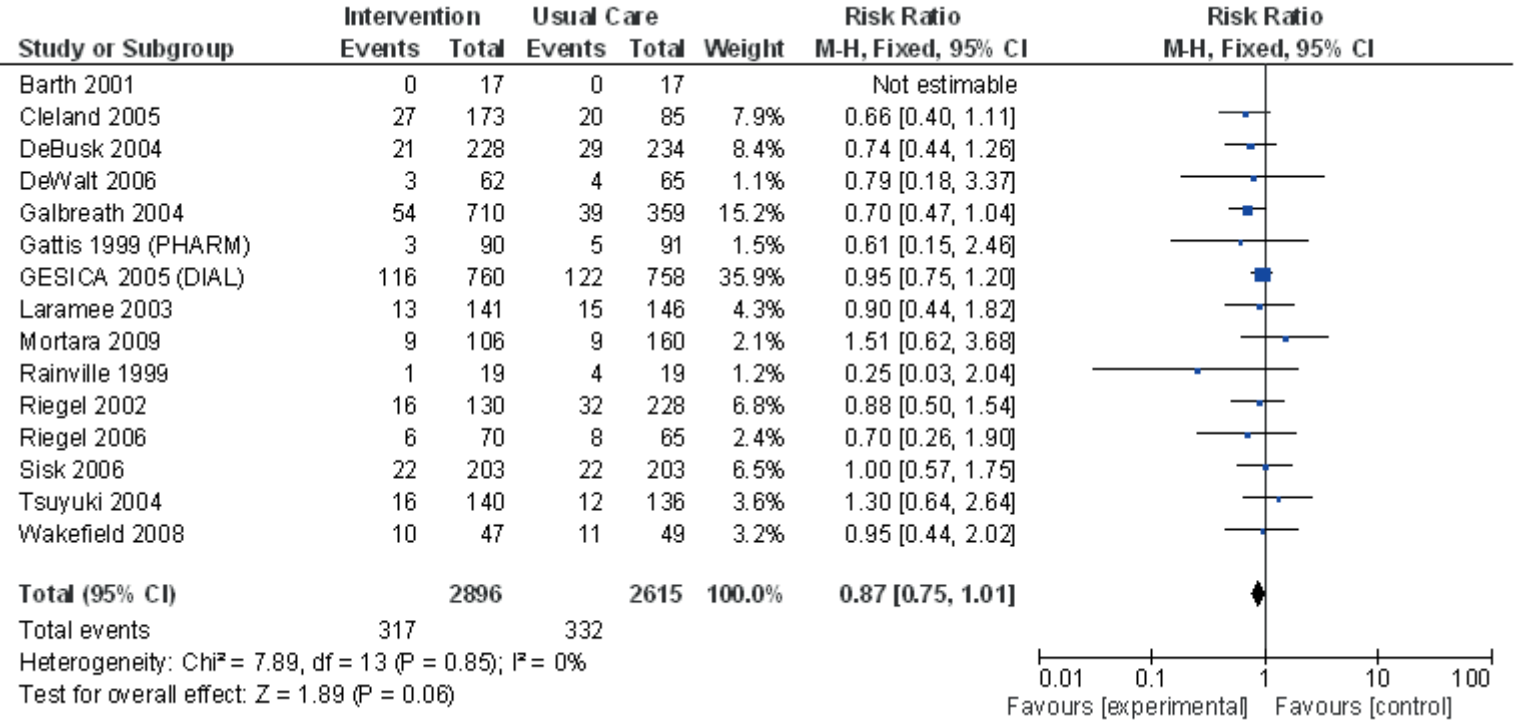

Figure 1 Effect of structured telephone calls on all-cause mortality

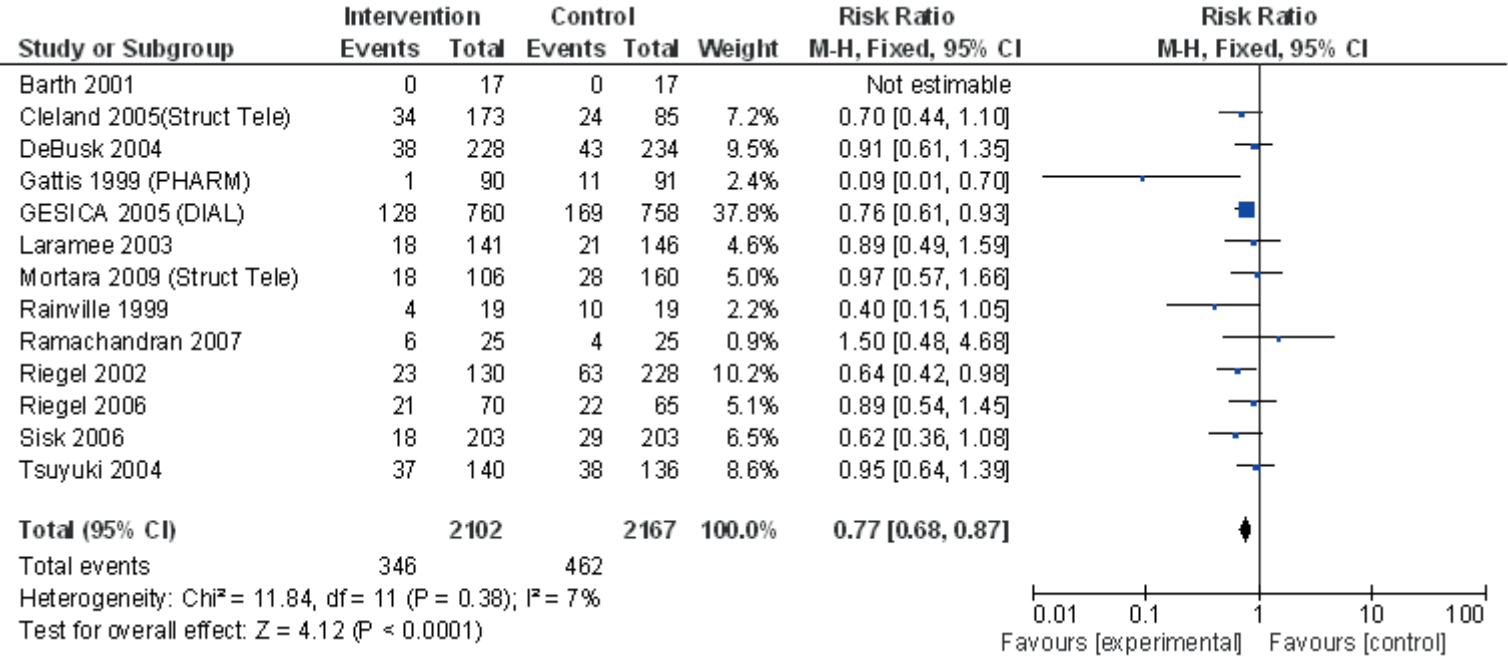

Figure 2 Effect of structured telephone calls on heart-failure related hospitalisations

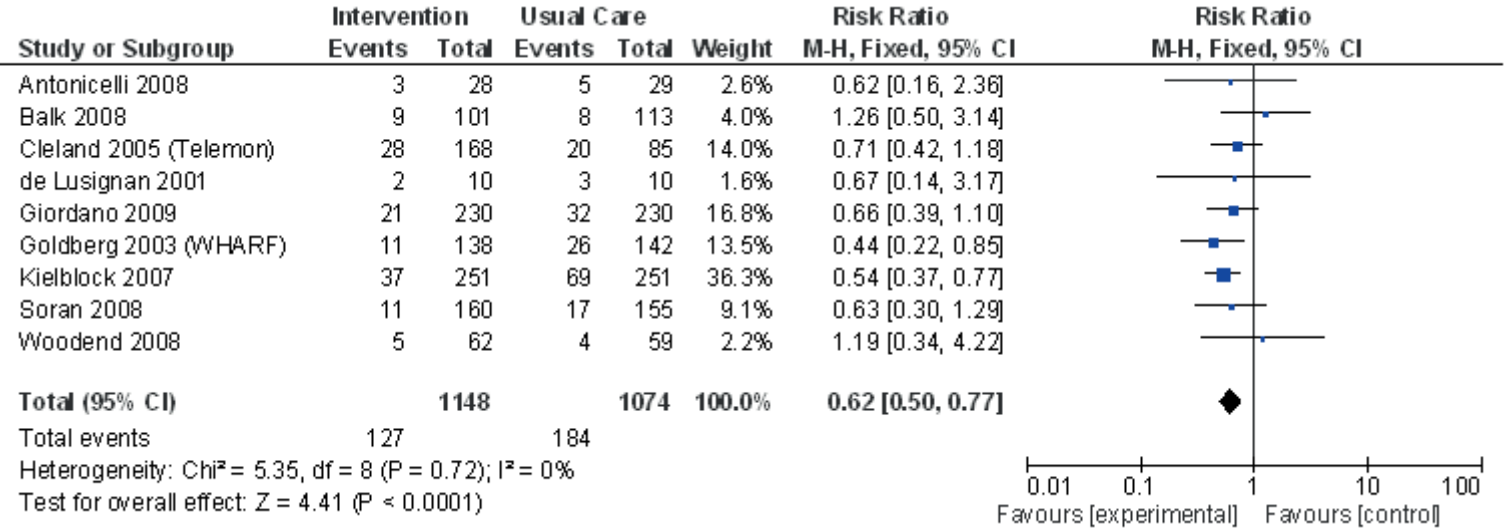

Figure 3 Effect of telemonitoring on all-cause mortality

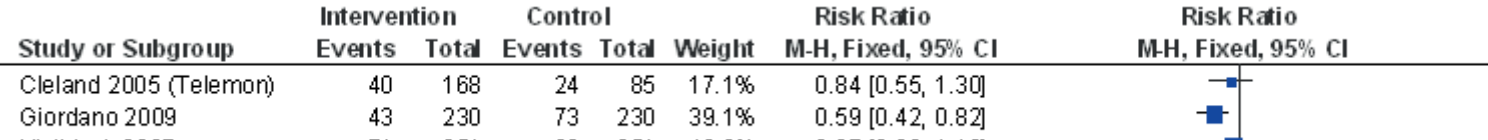

Figure 4 Effect of telemonitoring on heart failure-related hospitalisations