Is age a factor in the success or failure of remote monitoring in heart failure? Telemonitoring and structured telephone support in elderly heart failure patients

Authors:

Dr Sally C Inglis

Senior Research Fellow

Faculty of Health

University of Technology, Sydney

PO Box 123

Broadway NSW 2077

+61 2 9514 4819

sally.inglis@uts.edu.au

Dr Aaron Conway

Research Fellow

Institute of Health & Biomedical Innovation

Queensland University Technology

Kelvin Grove Campus,

Kelvin Grove, Queensland 4059.

Email: aaron.conway@qut.edu.au

Professor John GF. Cleland

Academic Unit of Cardiology

Castle Hill Hospital

East Yorkshire, UK

Tel: +44 1482 461776 Fax: +44 1482 461779

Email: j.g.cleland@hull.ac.uk

Prof Robyn A Clark

Prof Robyn Clark

School of Nursing & Midwifery

Flinders University

GPO Box 2100 Adelaide 5001
Phone: +61 8 8201 3468 | F: +61 8 8276 1602
Email: robyn.clark@flinders.edu.au

Corresponding author and address for reprints

Professor Robyn Clark
Prof Robyn Clark
School of Nursing & Midwifery
Flinders University
GPO Box 2100 Adelaide 5001
Phone: +61 8 8201 3468 | F: +61 8 8276 1602

ABSTRACT

Background

There are few data regarding the effectiveness of remote monitoring for older people with heart failure. We conducted a *post-hoc* sub-analysis of a previously published large Cochrane systematic review and meta-analysis of relevant randomized controlled trials to determine whether structured telephone support and telemonitoring were effective in this population.

Methods

A *post hoc* sub-analysis of a systematic review and meta-analysis that applied the Cochrane methodology was conducted. Meta-analyses of all-cause mortality, all-cause hospitalizations and heart failure-related hospitalizations were performed for studies where the mean or median age of participants was 70 or more years.

Results

The mean or median age of participants was 70 or more years in eight of the 16 (*n*=2,659/5,613; 47%) structured telephone support studies and four of the 11 (*n*=894/2,710; 33%) telemonitoring studies. Structured telephone support (RR 0.80; 95% CI=0.63-1.00) and telemonitoring (RR 0.56; 95% CI=0.41-0.76) interventions reduced mortality. Structured telephone support interventions reduced heart failure-related hospitalizations (RR 0.81; 95% CI=0.67-0.99).

Conclusion

Despite a systematic bias towards recruitment of individuals younger than the epidemiological average into the randomized controlled trials, older people with heart failure did benefit from structured telephone support and telemonitoring.

These *post-hoc* sub-analysis results were similar to overall effects observed in the main meta-analysis. While further research is required to confirm these observational findings, the evidence at hand indicates that discrimination by age alone may be not be appropriate when inviting participation in a remote monitoring service for heart failure.

Keywords: *Heart failure, remote monitoring, systematic review, ageing, elderly, geriatric*

INTRODUCTION

Meta-analyses of randomized controlled trials and cohort studies have found that remote monitoring of heart failure reduced mortality and hospitalizations compared with usual care.[1-3] It has been suggested that frequent monitoring may work in a 'health maintenance' mode by improving titration of and compliance with therapy or in an early 'crisis-detection' mode, by spotting early evidence of fluid accumulation, enabling timely intervention.[4]

The balance of available evidence suggests that remote monitoring interventions prolong survival and reduce hospitalizations and health care costs. This has encouraged many healthcare providers to consider implementing remote monitoring.[4, 5] In this regard, there is a great need to investigate which particular technologies are most effective and whether remote monitoring interventions are effective in particular subsets of the heart failure population: including those who, for example, have mild cognitive impairment,[6] are from culturally or linguistically diverse backgrounds and, given broad trends in the natural history of heart failure, older individuals.[7] Our study focused on the issue of whether or not remote monitoring interventions are effective, specifically in elderly heart failure patients.

Determining whether remote monitoring interventions are effective in this particular subset of people with heart failure is important because the condition predominantly affects older people, who also have higher morbidity and mortality rates.[8-10] However, few studies have examined the effectiveness of remote monitoring in elderly patients with heart failure.[11] We sought to address this gap in the evidence-base with a *post-hoc* sub-analysis of a large Cochrane systematic

review, which focused specifically on structured telephone support and telemonitoring interventions.

METHODS

A *post hoc* sub-analysis of a previously published systematic review and meta-analysis of randomized controlled trials that applied the Cochrane methodology was performed.[1, 12] Meta-analyses of all-cause mortality, all-cause hospitalizations and heart failure-related hospitalizations were applied to those studies where the mean or median age of participants was 70 years or more. The age of 70 was used as the cut-off for the older age-group because it has been previously used to classify elderly patients. [8, 13, 14] This sub-analysis was not published in the Cochrane Review.

Information sources and search strategy

The full report of the information sources and search strategy are published elsewhere.[1] In brief, though, as per the Cochrane Collaboration protocol,[12] all known relevant search engines and electronic databases were utilized. 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. Language restrictions were not applied. Our definition of structured telephone support and telemonitoring and the specific eligibility criteria of included studies are presented in **Table 1**.

Study selection

Randomized controlled trials of structured telephone support or telemonitoring compared to usual care were eligible to be included in this sub-analysis if they were published in full in a peer-reviewed journal.[12] Studies which were published as

abstracts were excluded because in the main review, addition of these studies had no substantial impact on the results.[1]

Data extraction

Two reviewers 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. A third reviewer adjudicated in cases of doubt.

Data and analysis

Meta-analyses of all-cause mortality, heart failure-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.[12] All analyses were performed using Review Manager (RevMan) Version 5.0 (Copenhagen: The Nordic Cochrane Centre, Cochrane Collaboration, 2008).[12]

RESULTS

Study characteristics

Full details of study selection results are available.[1] Twenty-five studies were published as full peer-reviewed publications (16 on structured telephone support, n=5,613 and 11 on telemonitoring, n=2,710). Two studies[15, 16] had two separate intervention arms (structured telephone support vs. telemonitoring vs. usual care) and each was considered as a separate comparison with usual care (and are included in the aforementioned counts). The mean or median age was ≥70 years for the study participants in eight of the 16 (*n*=2,659/5,613; 47%) structured telephone support

studies and four of the 11 (*n*=894/2,710; 33%) telemonitoring studies **(Table 2)**. Statistical heterogeneity within the studies was low (I^2=0%) for all comparisons with the exception of all-cause hospitalizations for telemonitoring (I^2 = 85%) (I^2 statistic Low = 0-40%; Moderate = 30-60%; Substantial = 50-90%, Considerable 75-100%)[12].

All-cause mortality

Telemonitoring statistically significantly (p<0.05) reduced the risk of all-cause mortality for the group of studies where the mean/median age of participants was over 70 years (0.56, 95% CI=0.41-0.76) **(Figure 1)**. Structured telephone support was also effective (0.80, 95% CI=0.63-1.00) but was not statistically significant **(Figure 2)**.

Heart failure-related hospitalizations

Compared with usual care, structured telephone support reduced the risk for hospitalizations due to heart failure in a meta-analysis of studies with a mean participant age over 70 (0.81; 95% CI=0.67-0.99) **(Figure 3)**. As there was only one telemonitoring study with a mean age over 70, meta-analysis could not be performed.

All-cause hospitalizations

The results from the meta-analysis of all-cause hospitalizations did not achieve statistical significance for either structured telephone support (1.00, 95%=0.90-1.12) or telemonitoring (0.89, 95% CI=0.80-1.00) (**Figures 4 & 5)**.

DISCUSSION

This analysis suggests that, compared to usual care, remotely monitoring older patients with heart failure using structured telephone support or telemonitoring

reduces mortality rates. Structured telephone support also reduces the risk of heart failure-related hospitalizations but there was insufficient evidence to conduct a meta-analysis of the effect of telemonitoring. Reassuringly, these post-hoc sub-analysis results were similar to overall effects observed in the main, previously published meta-analysis; albeit with the exception of all-cause hospitalizations **(Table 3)**.

In the primary meta-analysis reported in the published Cochrane Review,[1] a modest yet statistically significant reduction in all-cause hospitalization was observed. The protective effect of remote monitoring on all-cause hospitalizations was not sustained when only studies that enrolled a majority of older people were examined. Such findings might reasonably be expected though. Remote monitoring in heart failure is thought to be effective because it facilitates early detection of clinical deterioration, which can subsequently prompt a reactive change in care or improvement in treatment adherence.[4] Typically, only selected physiological variables and symptoms that are indicative of heart failure decompensation, such as weight, oxygen saturation, blood pressure and peripheral oedema, are measured. Some of the signs and symptoms that are indicative of heart failure deterioration may also indicate clinical deterioration for conditions like Chronic Obstructive Pulmonary Disease and Chronic Kidney Disease. However, it should not be expected that monitoring these variables would consistently prompt early intervention and prevent hospitalization for the vast number of other co-morbid conditions in elderly people with heart failure that could potentially require in-patient care.

Two conclusions can be drawn from the findings of this *post-hoc* sub-analysis. First,

consistent with a general mismatch between clinical trial and real world heart failure populations; we found a relative paucity of study cohorts that included typically older individuals with heart failure. Only half (50%) the studies in our Cochrane review that investigated structured telephone support, comprising 47% of the total number of participants, recruited samples with a mean age over 70 years. Also, a minority (*n*=4; 33%) of the telemonitoring studies included in our review had a mean age over 70 years. Moreover, only one of these studies reported on the effectiveness of this type of intervention on heart failure related hospitalizations. These findings suggest a systematic bias in recruiting older individuals into such trials; despite the appropriateness of recruiting them.

The lack of recruitment of elderly patients into trials evaluating the effectiveness of interventions for heart failure is an alarming finding, given the fact that heart failure becomes more prevalent as age is increased.[17] This is a significant issue for all clinical trials in heart failure, and experts have called for at least 30% of future clinical trial participants to be aged over 75 years of age.[8] As such, we recommend that future studies examining remote monitoring in heart failure should aim to meet this enrolment goal. It should be noted that while two large trials of telemonitoring in heart failure failed to identify a reduction in the composite outcome of mortality or hospitalisation, these were published after our Cochrane review was conducted and the median and mean age of participants in these studies was 61 years and 66.9 years respectively.[18, 19] For these reasons, data from these trials could not be included in the *post-hoc* sub-analysis focusing on the effect of remote monitoring interventions in elderly heart failure patients. Therefore, the update of our Cochrane

review, which is currently underway, will continue to examine this important issue.[1]

It is may be thought that the frailty of the elderly population, in particular the degenerative musculoskeletal and sensory (auditory/visual) changes as well as increased number and severity of comorbidities, both biomedical and psychosocial, could impair functional ability to the extent that it would impede participation in remote monitoring programs. An individual patient meta-analysis would be needed to provide further insight as to whether a higher burden of comorbidities in elderly participants impacts on the clinical benefits of remote monitoring in heart failure. As such, the second conclusion drawn from the results of this sub-analysis is that the current accumulated evidence supports the use of structured telephone support and telemonitoring in elderly heart failure patients and goes some way towards dispelling a popularly held belief among some clinicians that elderly patients will not benefit from telehealth interventions.[20] Previous studies focused on patient adherence as opposed to the outcomes associated with remote monitoring in heart failure generally support our findings. Results from these studies have consistently identified that elderly patients are able to effectively, and indeed do regularly, use the remote monitoring technology. For example, a study of telemonitoring in heart failure found that only 3% of a sample of patients with mean age of over 70 were unable to learn how to use the technology competently.[21] High rates of adherence to remote monitoring for heart failure was also found in a more recent study with an even older sample of patients; all participants were aged over 65 years and the mean age was 78 years.[22]

It is important to note that, as this was a between-study as opposed to a within-

study *post-hoc* sub-group analysis, findings should be considered as observational in nature.[23] Therefore, our results require confirmation in within-study sub-analyses or future randomized controlled trials designed specifically to determine the effectiveness of remote monitoring in elderly heart failure patients. Also, we have presented the findings of our review which was published in the Cochrane Database of Systematic Reviews in 2010. Therefore, a limitation of this analysis is the absence of more recent randomized controlled trials of non-invasive remote monitoring in heart failure.

In summary, our findings indicate that older people with heart failure benefit from structured telephone support and telemonitoring. Age alone does not appear a valid reason for refusing such interventions.

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Table 1 Inclusion and exclusion criteria

Inclusion criteria
Study type: Randomized controlled trials
Publication: Only full, peer-reviewed publications were included.
Participants: Adult patients with a confirmed diagnosis of heart failure who were discharged from an acute care setting to home (excluding nursing or convalescent homes). Participants could also be recruited if they were being managed for heart failure in the community setting
Intervention: Remote heart failure monitoring (via structured telephone support or telemonitoring) occurring on a regular schedule (daily, weekly, or monthly). The remote monitoring had to be initiated by a healthcare professional (for example, medical, nursing, social work, pharmacist) and must have been delivered as the only heart failure disease management intervention, without home-visits or intensified clinic follow-up. In particular, study could not include any home visits by a specialized heart failure healthcare professional or study personnel for any purposes such as education or clinical assessment and such visits were only permitted for setting up study equipment.
Comparison: Usual heart failure care, which could involve standard post-discharge care, but not any intensive attendance at cardiology clinics or clinic-based heart failure disease management program or home-visits.
Outcomes: Primary outcomes were all-cause mortality, CHF-related or all-cause hospitalizations
Exclusion criteria
Remote monitoring of conditions other than heart failure
Studies with intensified clinic follow-up or any home visits which were conducted with the purpose of delivering education or performing clinical assessment.

Table 2 Characteristics of included studies by mean/median age of sample

Study	Intervention	Number of patients	Mean/ Median age (years)
Structured Telephone Support vs. Usual Care Age ≥ 70			
Barth (2001)[24]	Education and monitoring.	34	75
DeBusk et al. (2004)[25]	CHF lifestyle education and medication management.	462	72
Galbreath et al. (2004)[26]	Education and monitoring.	1,069	71
Laramee et al. (2003)[27]	Education and monitoring.	287	71
Rainville (1999)[28]	Pharmacist-led medication review, education, medication management.	38	70
Riegel et al. (2002)[29]	Education and counseling.	358	74
Riegel et al. (2006)[30]	Education, monitoring and guidance.	135	72
Tsuyuki et al. (2004)[31]	Education and monitoring.	276	72
Telemonitoring vs. Usual Care Age ≥ 70			
Antonicelli et al. (2008)[32]	BP, HR, weight and 24h urine output, ECG.	57	78
de Lusignan et al. (2001)[33]	Pulse, BP, weight.	20	75
Kielblock et al. (2007)[34]	Weight.	502	74
Soran et al. (2008)[35]	Weight.	315	76

Table 3. Comparison with primary meta-analysis results

	Elderly (age ≥70)	Primary meta-analysis
ALL-CAUSE MORTALITY RR [95% CI]		
Structured telephone support	0.80 [0.63, 1.00]	0.88 [0.76, 1.01]
Telemonitoring	0.56 [0.41, 0.76]	0.66 [0.54, 0.81]
ALL-CAUSE HOSPITALIZATION RR [95% CI]		
Structured telephone support	1.00 [0.90, 1.12]	0.92 [0.85, 0.99]
Telemonitoring	0.89 [0.80, 1.00]	0.91 [0.84, 0.99]
HEART FAILURE-RELATED HOSPITALIZATION RR [95% CI]		
Structured telephone support	0.81 [0.67, 0.99]	0.77 [0.68, 0.87]
Telemonitoring	Only 1 study	0.79 [0.67, 0.94]

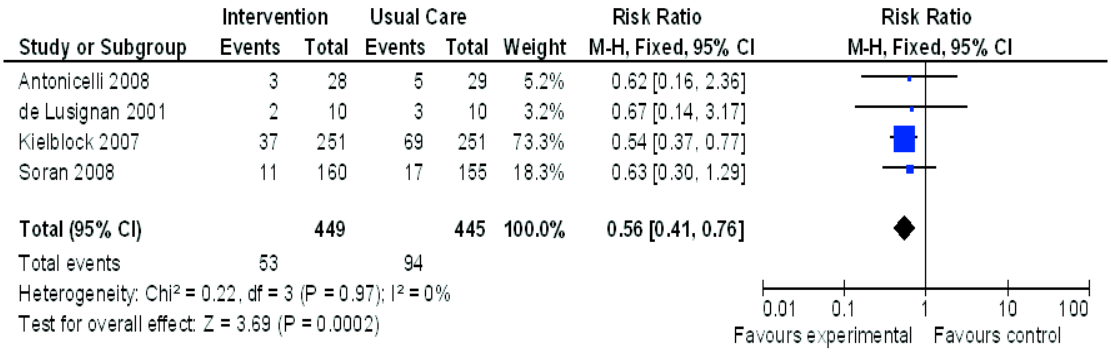

Figure 1. Effect of telemonitoring on all-cause mortality

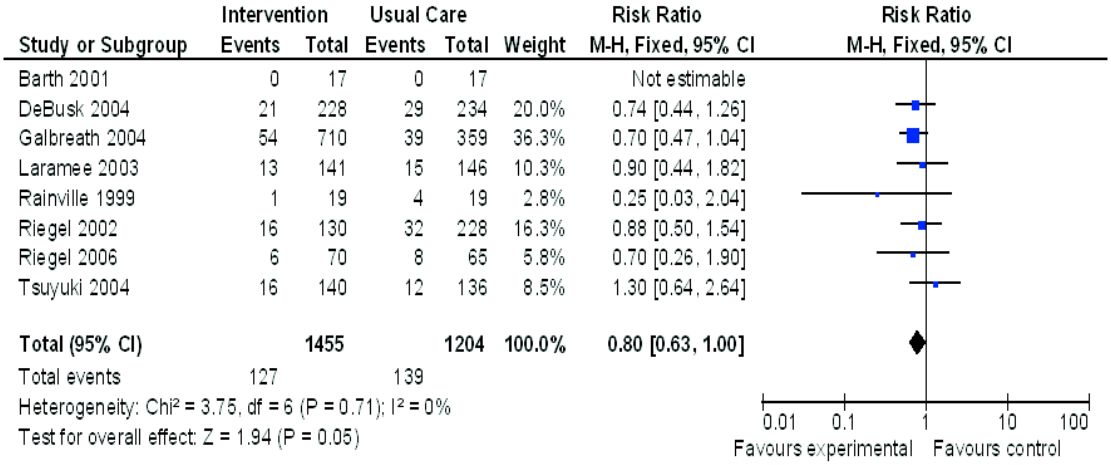

Figure 2. Effect of structured telephone support on all-cause mortality

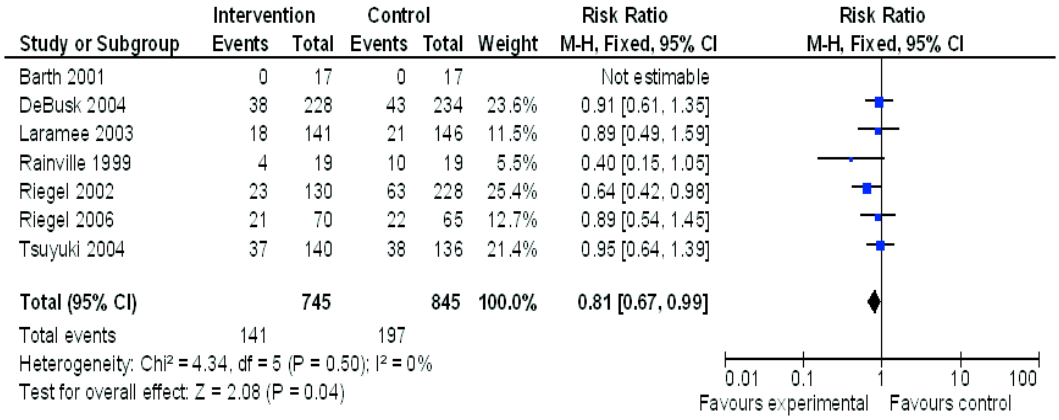

Figure 3. Effect of structured telephone support on heart failure-related hospitalizations

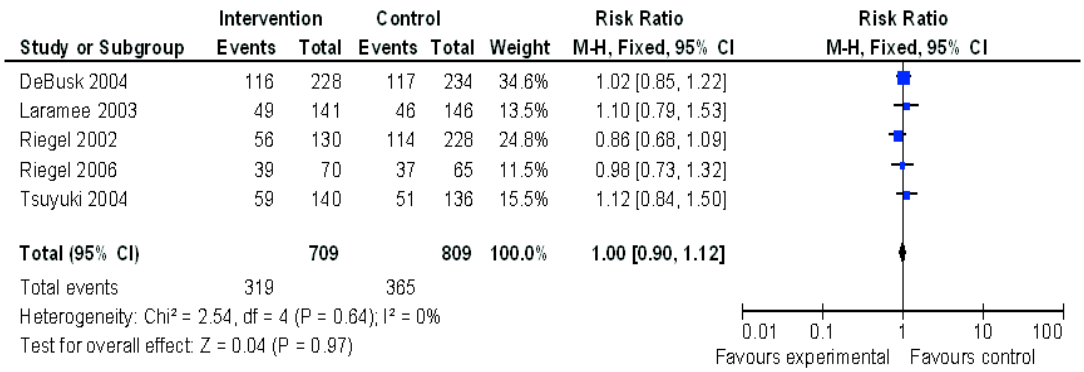

Figure 4. Effect of structured telephone support on all-cause hospitalizations

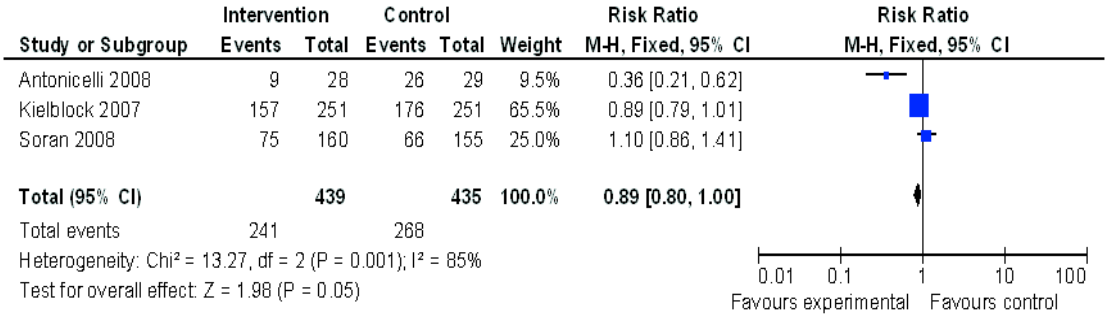

Figure 5. Effect of telemonitoring on all-cause hospitalizations