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Structured telephone support or telemonitoring programs for patients with chronic heart failure (Protocol)

Inglis SC, Clark RA, Cleland JGF, McAlister F, Stewart S



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[Intervention Protocol]

Structured telephone support or telemonitoring programs for patients with chronic heart failure

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The objective of this study is to update the review previously completed by [Clark 2007b](#) and assess systematically the effects of telemonitoring and/or structured telephone support programmes on:

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

The cost of the intervention and acceptability of the intervention to patients will also be examined.

BACKGROUND

Description of the condition

Chronic heart failure (CHF) is a complex, debilitating syndrome which is the consequence of structural abnormality or 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 physical effort. CHF often results from damage to the myocardium for which the aetiology differs according to the population studied. In high income nations CHF is often the end-product of underlying coronary heart disease. In low to medium income nations the syndrome is often the result of long-standing hypertension, cardiomyopathy or rheumatic heart disease (Sliwa 2005). This trend is changing, with the incidence and prevalence of cardiovascular disease increasing in low to medium income nations (Yusuf 2001). CHF exerts a significant burden on healthcare systems, with the majority of its economic burden attributable to repeated and lengthy admissions to hospital (Stewart 2002). As the prevalence of CHF increases with the ageing of populations internationally, this situation will deteriorate unless new management strategies are developed (Cleland 2000).

Description of the intervention

The effectiveness of multidisciplinary non-pharmacological approaches to manage patients with CHF has been proven by meta-analyses, such as that conducted by Taylor 2005 and Cleland 2000 and specialist CHF disease management programmes are now recommended in best practice guidelines (Hunt 2005; Krum 2006; Swedburg 2005).

To date, trials of specialist, multidisciplinary CHF management programmes have tested multifaceted approaches (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). Nevertheless, it is clear that within most populations access to these programmes is limited as a result of barriers related to funding or geography (Clark 2007a; Jaarsma 2006). To meet the needs of CHF populations who are distal to traditional home or clinic-based CHF disease management programmes, alternative models of care have been proposed and tested (Clark 2007a). These alternative models typically involve information communication technology (ICT) and may include telemonitoring (transfer of physiological data via digital cable e.g. electrocardiograph (ECG), blood pressure (BP), weight, pulse oximetry (SPO2) respiratory rate and medicine administration) or structured computer-assisted education and monitoring delivered via standard telephone or videoconferencing (Clark 2007b).

These remote monitoring programmes may allow patients who can not or do not wish to be visited at home, or those that are unable to attend a clinic or do not have local access to traditional

CHF management programmes, to receive the best practice for non-pharmacological management of CHF.

It should be noted that in the context of this review “remote monitoring” will be defined as monitoring CHF patients outside of a CHF specialist centre of care and not remote in the geographical sense, although these patients are often one in the same group. In all studies of structured telephone support, having access to a touch-tone telephone was an essential inclusion criteria. In the case of telemonitoring the ICT equipment and monitoring devices are provided by the project. Patients from socio-economically disadvantaged groups would have been excluded if they did not have access to a basic telephone in their place of residence.

Why it is important to do this review

In this era of rapidly advancing technology and wider community access and adaptation to ICT, new trials of remote monitoring interventions are continually being commissioned and published. Previous systematic reviews and meta-analyses (Clark 2007b; Louis 2003; McAlister 2004) have examined the benefits of telemonitoring and/or structured telephone support within CHF disease management programmes on mortality and hospitalisation, however to date only a few trials have been included in these reviews.

By far the largest systematic review and meta-analysis to date of those which have examined these programmes (Clark 2007b; Louis 2003; McAlister 2004) is that by Clark 2007b. Clark reported benefits on the rate of admission to hospital for CHF and on all-cause mortality in 14 trials. The reviews of Louis 2003 and McAlister 2004 were published before a significant number of trials had been published to demonstrate effect.

Previous findings by Clark 2007b suggest that remote strategies such as telemonitoring and/or structured telephone support might have an important role as a part of a strategy for the delivery of effective healthcare for patients with CHF. They may also provide a means for keeping patients under close supervision, which could reduce the rate of admission, length of stay and subsequent cost to the healthcare system.

At the time of Clark's review (Clark 2007b) only 14 trials of remote monitoring were available and suitable for inclusion. The authors of this review are aware of several large trials of remote monitoring (in particular those of Mortara 2004 and Scalvini 2004) for which final results will soon be published. Considering the interest of healthcare providers to provide healthcare via this mode to patients with CHF it is pertinent to perform the most up-to-date evaluation of these interventions.

OBJECTIVES

The objective of this study is to update the review previously completed by [Clark 2007b](#) and assess systematically the effects of telemonitoring and/or structured telephone support programmes on:

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

The cost of the intervention and acceptability of the intervention to patients will also be examined.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials or controlled trials (that is studies in which a contemporaneous comparison group is identified but in which random allocation to intervention or comparison group was not performed) comparing CHF management delivered via structured telephone support and/or telemonitoring with usual post-discharge care in patients with CHF living within the community. Studies will be included in the analyses regardless of whether they are single-blind, double-blind or not blinded.

Types of participants

Adult (aged 18+ years) of either sex, any age or ethnic group with definitive diagnosis of CHF discharged from an acute care setting (including emergency departments and one-day-stay procedures) to home (including a relative's home but excluding nursing homes or convalescence homes). Studies dealing generally with cardiac disorders but not specifically denoting CHF will be excluded.

Types of interventions

Structured telephone support and/or telemonitoring interventions need to be structured as opposed to offering telephone follow-up on an "as needed" basis. They must be initiated by a healthcare professional (medical, nursing, social work, pharmacist) and delivered to patients with CHF living in the community as the only aftercare intervention, without home visits or more than usual clinic follow-up. They must be performed at least once within the first 28 days following discharge from hospital, they must be targeted towards the patient, and intended to address the patients concerns and problems not those of caregivers.

Usual care will consist of standard post-discharge care without regular attendance at a clinic-based CHF disease management programme or any visits at home by a specialised CHF healthcare professional.

Types of outcome measures

Primary outcomes

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

Secondary outcomes

- All-cause hospitalisation rate (calculated as the proportion of patients readmitted to hospital at least once during the period of follow-up).
- Chronic heart failure-related hospitalisation rate (calculated as the proportion of patients readmitted to hospital at least once during the period of follow-up due to chronic heart failure).
- Length of stay (total number of days in hospital accumulated by each study group)
- Health-related quality of life (difference between mean total score on validated measures such as Minnesota Living with Heart Failure Questionnaire between baseline and at study conclusion for the intervention and control groups).
- Cost of the intervention, costs savings (reported cost of the intervention; reported difference in the cost of medical care during the course of the study between the intervention and control groups).
- Acceptability of the intervention to patients (difference between acceptability/satisfaction scores on a Likert scale at study conclusion between the intervention and control groups).

Search methods for identification of studies

Electronic searches

The following databases will be searched, from 7 May 2006 forwards to update the search performed for from the previous review ([Clark 2007b](#)): Cochrane Central Register of Controlled Trials (CENTRAL) on *The Cochrane Library*; MEDLINE; EMBASE; CINAHL; AMED; Science Citation Index Expanded; DARE; National Research Register. No date limits will be applied to the searches of the following databases; IEEE Xplore; OAIster; Google Scholar; Informit; Vivisimo; Australian Digital Theses Program and Proquest Digital Dissertations. Language restrictions will not apply. Details of the strategies for searching these electronic databases are in [Appendix 1](#).

Searching other resources

Bibliographies of identified studies and published systematic reviews relevant to this topic area will be hand searched. National and international experts in the field will be contacted to identify published and/or unpublished trials.

Data collection and analysis

Selection of studies

Two investigators will independently review the results of each search according to exclusion and inclusion criteria. Studies will be excluded if there are additional home or clinic visits (more than usual care) offered to patients in the intervention or control groups. A third reviewer will adjudicate in the instance of indecision by the first two reviewers.

Data extraction and management

Two reviewers will abstract the data from the included studies in a blinded manner and all extracted data will be checked by a third reviewer.

Assessment of risk of bias in included studies

In consideration of Cochrane methodology ([Higgins 2006](#)) study quality will be assessed independently by two reviewers.

The study quality characteristics will be rated as (1) unclear or not stated; (2) inadequate; (3) adequate with examples from the text to support this classification.

Adequacy and inadequacy of each of the study quality parameters will be defined as follows.

Inclusion criteria of the included participants

The definition and confirmation of diagnosis of CHF.

- Adequate - LVEF < 40%, a diagnosis of CHF (systolic or preserved) recorded
- Inadequate - LVEF > 40% or ventricular dysfunction not classified

Generation of the randomisation sequence

- Adequate - random permuted blocks, random computer generated, sealed assignment, sequentially numbered sealed opaque envelopes.
- Inadequate - case record numbers, date of birth or days of the week.

Allocation concealment

- Adequate - allocation to each group performed adequately and group assignment revealed after provision of consent.
- Inadequate - group assignment revealed prior to subject consent, non-opaque sealed envelopes, case record numbers, date of birth or day of the week.

Baseline comparability of the groups

- Adequate - the baseline characteristics of each study group (in particular age, NYHA Class and/or LVEF) is clearly outlined and any differences identified are accounted for.
- Inadequate - baseline characteristics (in particular age, NYHA Class and/or LVEF) of each study group are not outlined.

Blinding

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

- Adequate - independent outcome assessors and data analysts who are blinded to which group the patient belongs to.
- Inadequate - outcomes assessed and data analysed by those involved in the intervention, or those who are aware of group membership.

Completeness of follow up

- Adequate - proportion and characteristics of those participants lost to follow up clearly reported for each group and outcome. A clear outline is provided as to how losses of participants were handled.
- Inadequate - proportion and characteristics of those completing and not completing the study according to group and outcome not reported. No statement regarding how losses to follow up were accounted for in the study analysis.

Statistical power

- Adequate - a power calculation was performed and reported. The study was adequately powered to detect differences in outcomes.
- Inadequate - a power calculation was not performed. A power calculation was performed and reported but the study was not adequately powered to detect differences in outcomes. A power calculation was performed but not reported, the study states it was adequately powered to detect differences in outcomes.

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

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

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

Measures of treatment effect

Risk ratios and 95% confidence intervals will be calculated for all-cause mortality, all-cause and CHF-related hospitalisation rates. All analyses will be performed according to intention-to-treat principles, that is, all patients and their outcomes will be analysed in the groups to which they were allocated, regardless of whether they received the treatment.

Should there be sufficient reporting of continuous outcomes such as quality of life measured by Minnesota Living with Heart Failure Questionnaire these will be pooled and analysed accordingly. If there is infrequent or inconsistent reporting of these outcomes these will be tabulated and described.

Assessment of heterogeneity

Statistical heterogeneity in each outcome of interest will be examined using Cochran's Q test and I² statistic.

Data synthesis

Owing to expected differences in patient populations, programme characteristics, and length of follow-up, a Der Simonian and Laird random effects model will be used to perform the meta-analysis.

Sensitivity analysis

A sensitivity analysis will be performed according to severity of CHF (i.e. NYHA Class I and II versus III and IV) of included participants. Another sensitivity analysis will examine the inclusion criteria of the studies, comparing those which reported an adequate classification of CHF diagnosis (i.e. left ventricular ejection fraction (LVEF)) relative to those which only stated "patients with CHF".

ACKNOWLEDGEMENTS

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Finlay McAlister receives salary support from the Alberta Heritage Foundation for Medical Research Population Health Scholar Program, the Canadian Institutes of Health Research New Investigator Program, and the University of Alberta/Merck Frost/Aventis Chair in Patient Health Management.

Our team wishes to make special acknowledgement to the contribution of the University of South Australia's Health Sciences Librarian, Ms Margaret Goedhart. Margaret's knowledge and skill in navigating current bibliographies and electronic sources of knowledge was essential to ensuring quality and rigor of the search strategies.

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- * Indicates the major publication for the study

APPENDICES

Appendix I. Search strategies

MEDLINE (Ovid Web version)

- 1 exp Heart Failure/
- 2 heart failure.tw
- 3 cardiac failure.tw
- 4 or/1-3
- 5 exp Telemedicine/
- 6 exp Telecommunications/
- 7 Case Management/
- 8 exp Comprehensive Health Care/
- 9 disease management/
- 10 telemed\$.tw

11 telecare\$.tw.
 12 telecardiol\$.tw.
 13 telemonitor\$.tw.
 14 teleconsult\$.tw.
 15 teleconferenc\$.tw.
 16 telecommunicat\$.tw.
 17 telephon\$.tw.
 18 telehealth\$.tw.
 19 telemetry.tw.
 20 (remote\$ adj3 consult\$).tw.
 21 tele-med\$.tw.
 22 tele-consult\$.tw.
 23 tele-conferenc\$.tw.
 24 tele-health\$.tw.
 25 Home Care Services/
 26 Home Care Services, Hospital-Based/
 27 disease management.tw.
 28 Nurse Clinicians/
 29 Nurse Practitioners/
 30 nurse led.tw.
 31 Monitoring, Ambulatory/
 32 telehome.tw.
 33 tele-home.tw.
 34 phone\$.tw.
 35 Clinical Protocols/
 36 Patient Care Planning/
 37 or/5-36
 38 37 and 4
 39 randomized controlled trial.pt.
 40 controlled clinical trial.pt.
 41 Randomized controlled trials/
 42 random allocation/
 43 double blind method/
 44 single-blind method/
 45 or/39-44
 46 exp animal/ not humans/
 47 45 not 46
 48 clinical trial.pt.
 49 exp Clinical Trials as Topic/
 50 (clin\$ adj25 trial\$).ti,ab.
 51 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj (blind\$ or mask\$)).ti,ab.
 52 placebos/
 53 placebo\$.ti,ab.
 54 random\$.ti,ab.
 55 research design/
 56 or/48-55
 57 56 not 46
 58 57 not 47
 59 comparative study.pt.
 60 exp evaluation studies/
 61 follow up studies/
 62 prospective studies/
 63 (control\$ or prospectiv\$ or volunteer\$).ti,ab.

- 64 or/59-63
- 65 64 not 46
- 66 65 not (47 or 58)
- 67 47 or 58 or 66
- 68 38 and 67
- 69 [limit by date]

CINHAL (Ovid Web version)

1. (congestive adj heart adj failure).mp. [mp=title, subject heading word, abstract, instrumentation]
2. (heart adj failure).mp. [mp=title, subject heading word, abstract, instrumentation]
3. (cardiac adj failure).mp. [mp=title, subject heading word, abstract, instrumentation]
4. 1 or 2 or 3
5. (patient adj care adj management).mp. [mp=title, subject heading word, abstract, instrumentation]
6. (patient adj care adj management).mp. [mp=title, subject heading word, abstract, instrumentation]
7. (home adj care adj services).mp. [mp=title, subject heading word, abstract, instrumentation]
8. (patient adj care).mp. [mp=title, subject heading word, abstract, instrumentation]
9. (manag\$ adj care).mp. [mp=title, subject heading word, abstract, instrumentation]
10. (home adj intervention).mp. [mp=title, subject heading word, abstract, instrumentation]
11. (home adj care).mp. [mp=title, subject heading word, abstract, instrumentation]
12. (secondary adj prevent#).mp. [mp=title, subject heading word, abstract, instrumentation]
13. homecare.mp. [mp=title, subject heading word, abstract, instrumentation]
14. rehabilitat#.mp. [mp=title, subject heading word, abstract, instrumentation]
15. nurs?.mp. [mp=title, subject heading word, abstract, instrumentation]
16. multidisciplin?.mp. [mp=title, subject heading word, abstract, instrumentation]
17. discharge near plan?.mp. [mp=title, subject heading word, abstract, instrumentation]
18. 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
19. 4 and 18
20. exp telephone/
21. exp telecommunication/
22. exp phone/
23. tele, communication?.mp. [mp=title, subject heading word, abstract, instrumentation]
24. tele? communication.mp. [mp=title, subject heading word, abstract, instrumentation]
25. telemedicine.mp. [mp=title, subject heading word, abstract, instrumentation]
26. phone.mp. [mp=title, subject heading word, abstract, instrumentation]
27. phonecall\$.mp. [mp=title, subject heading word, abstract, instrumentation]
28. telephon?.mp. [mp=title, subject heading word, abstract, instrumentation]
29. phon?.mp. [mp=title, subject heading word, abstract, instrumentation]
30. call? back.mp. [mp=title, subject heading word, abstract, instrumentation]
31. electronic communication.mp. [mp=title, subject heading word, abstract, instrumentation]
32. tele?health.mp. [mp=title, subject heading word, abstract, instrumentation]
33. exp telenursing/
34. exp telehealth/
35. tele?nurs?.mp. [mp=title, subject heading word, abstract, instrumentation]
36. 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35
37. 19 and 36
38. Experimental Studies/
39. exp Clinical trials/
40. ((control\$ or clinic\$ or prospectiv\$) adj5 (trial\$ or study or studies)).tw.
41. ((allocat\$ or assign\$ or divid\$) adj5 (condition\$ or experiment\$ or treatment\$ or control\$ or group\$)).tw.
42. ((sing\$ or doubl\$) adj (blind\$ or mask\$)).tw.
43. cross?over\$.tw.
44. placebo\$.tw.

- 45. exp Clinical research/
- 46. Comparative studies/
- 47. exp Evaluation research/
- 48. exp "control (research)"/
- 49. Random assignment/
- 50. exp Prospective studies/
- 51. exp Evaluation research/
- 52. random\$.tw.
- 53. RCT.tw.
- 54. (compar\$ adj5 (trial\$ or study\$ or studies)).tw.
- 55. or/35-51

EMBASE (Ovid)

- 1 exp Heart Failure/
- 2 heart failure.tw.
- 3 cardiac failure.tw.
- 4 or/1-3
- 5 exp Telemedicine/
- 6 exp Telecommunications/
- 7 Case Management/
- 8 disease management/
- 9 telemed\$.tw.
- 10 telecare\$.tw.
- 11 telecardiol\$.tw.
- 12 telemonitor\$.tw.
- 13 teleconsult\$.tw.
- 14 teleconferenc\$.tw.
- 15 telecommunicat\$.tw.
- 16 telephon\$.tw.
- 17 telehealth\$.tw.
- 18 telemetry.tw.
- 19 (remote\$ adj3 consult\$).tw.
- 20 tele-med\$.tw.
- 21 tele-consult\$.tw.
- 22 tele-conferenc\$.tw.
- 23 tele-health\$.tw.
- 24 Home Care/
- 25 Home Monitoring/
- 26 disease management.tw.
- 27 Nurse Practitioners/
- 28 nurse led.tw.
- 29 Ambulatory Monitoring/
- 30 telehome.tw.
- 31 tele-home.tw.
- 32 phone\$.tw.
- 33 Patient Care Planning/
- 34 or/5-33
- 35 34 and 4
- 36 controlled clinical trial/
- 37 random\$.tw.
- 38 randomized controlled trial/
- 39 follow-up.tw.

40 double blind procedure/
41 placebo\$.tw.
42 placebo/
43 factorial\$.ti,ab.
44 (crossover\$ or cross-over\$).ti,ab.
45 (double\$ adj blind\$).ti,ab.
46 (singl\$ adj blind\$).ti,ab.
47 assign\$.ti,ab.
48 allocat\$.ti,ab.
49 volunteer\$.ti,ab.
50 Crossover Procedure/
51 Single Blind Procedure/
52 or/36-51
53 35 and 52
54 [limit by date]

CENTRAL on The Cochrane Library

#1 MeSH descriptor Heart Failure, Congestive explode all trees
#2 heart next failure
#3 cardiac next failure
#4 (#1 or #2 or #3)
#5 MeSH descriptor telemedicine explode all trees
#6 MeSH descriptor telecommunications explode all trees
#7 MeSH descriptor case management this term only
#8 MeSH descriptor comprehensive health care explode all trees
#9 MeSH descriptor disease management this term only
#10 MeSH descriptor home care services this term only
#11 MeSH descriptor Home Care Services, Hospital-Based this term only
#12 MeSH descriptor Nurse Clinicians this term only
#13 MeSH descriptor nurse practitioners this term only
#14 MeSH descriptor monitoring, ambulatory this term only
#15 MeSH descriptor clinical protocols this term only
#16 MeSH descriptor patient care planning this term only
#17 tele*
#18 (remote near/3 consult*)
#19 disease next management
#20 nurse next led
#21 phone*
#22 (manage* near/3 program*)
#23 (nurse* near/3 manage*)
#24 case next management
#25 (home near/3 service*)
#26 nurse next practitioner*
#27 nurse next clinician*
#28 care next plan*
#29 (#5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13)
#30 (#14 or #15 or #16 or #17 or #18 or #19 or #20 or #21)
#31 (#22 or #23 or #24 or #25 or #26 or #27 or #28)
#32 (#29 or #30 or #31)
#33 (#4 and #32)

HISTORY

Protocol first published: Issue 3, 2008

CONTRIBUTIONS OF AUTHORS

Sally C Inglis

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

Robyn A Clark

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

Finlay McAlister

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

John GF Cleland

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

Simon Stewart

Responsible for revising the review critically for important intellectual content and final approval of the version to be published. Performed previous work that was the foundation of this study.

DECLARATIONS OF INTEREST

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