Telephone Support to Rural and Remote Patients with Heart Failure: The Chronic Heart Failure Assessment by Telephone (CHAT) study

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SUMMARY
Background: Heart failure (HF) remains a condition with high morbidity and mortality. We tested a telephone support strategy to reduce major events in rural and remote Australians with HF, who have limited healthcare access. Telephone support comprised an interactive telecommunication software tool (TeleWatch) with follow-up by trained cardiac nurses. Methods: Patients with a general practice (GP) diagnosis of HF were randomized to usual care (UC) or UC and telephone support intervention (UC+I) using a cluster design involving 143 GPs throughout Australia. Patients were followed up for 12 months. The primary endpoint was the Packer clinical composite score. Secondary endpoints included hospitalization for any cause, death or hospitalization, as well as HF hospitalization. Results: Four hundred and five patients were randomized to CHAT. Patients were well matched at baseline for key demographic variables. The primary endpoint of the Packer score was not different between the two groups ($P = 0.98$), although more patients improved with UC+I. There were fewer patients hospitalized for any cause (74 vs. 114, adjusted HR 0.67 [95% CI 0.50–0.89], $P = 0.006$) and who died or were hospitalized (89 vs. 124, adjusted HR 0.70 [95% CI 0.53–0.92], $P = 0.011$), in the UC+I vs. UC group. HF hospitalizations were reduced with UC+I (23 vs. 35, adjusted HR 0.81 [95% CI 0.44–1.38]), although this was not significant ($P = 0.43$). There were 16 deaths in the UC group and 17 in the UC+I group ($P = 0.43$). Conclusions: Although no difference was observed in the primary endpoint of CHAT (Packer composite score), UC+I significantly reduced the number of HF patients hospitalized among a rural and remote cohort. These data suggest that telephone support may be an efficacious approach to improve clinical outcomes in rural and remote HF patients.

Background
Chronic heart failure (CHF) is a major public health problem. This condition is associated with reduced survival, frequent hospitalization, poor quality of life, and high healthcare costs [1]. Disparities exist between rural and remote areas in comparison with major metropolitan locations with regard to prevalence of the disease and its management. We have previously shown a higher prevalence of chronic heart failure in such remote areas as well as reduced utilization of diagnostic techniques such as echocardiography, less prescription of life-saving therapies, and fewer referrals to specialists in the field [2]. Many of these issues relate to distances involved in accessing adequate care of such patients. Furthermore, multidisciplinary and community-based care which has been shown to provide substantial benefit to patients with heart failure [3–5] is unavailable in these areas. Such models of care are not ideally suited to that of rural and remote patients because of issues of access, with these services being located primarily in inner metropolitan areas.

Thus, new strategies are required to help optimize the care of the rural and remote patients. Telephone support of such patients may help overcome some of these problems of access. A recent
meta-analysis showed that structured telephone support reduced heart failure-related hospitalizations [6]. However, studies included in this meta-analysis did not focus on patients in rural and remote areas. Thus, the question of its efficacy for rural and remote patients remains unanswered.

The aim of this study was therefore to determine whether an automated telephone support system would improve quality of life and reduce death and hospital admissions for rural and remote heart failure patients.

**Methods**

The study was approved in 2003 by the Monash University Human Research Ethics committee (no. 2003/306). All patients provided written informed consent. Recruitment began in 2003 with first patient randomized in 2004.

**Patient Population**

Patients were enrolled based on their general practitioners’ location in rural and remote areas of Australia. We later also included general practitioners in outer metropolitan areas whose patients had limited or no access to heart failure management programs run by major metropolitan hospital centers.

The patients were required to have New York Heart Association (NYHA) class II–IV heart failure, left ventricular ejection fraction <40% on echocardiogram, or echocardiographic features of diastolic dysfunction with impaired ventricular relaxation reported with no other diagnostic explanation for CHF-type symptoms such as chronic obstructive airways disease and bronchial asthma. Patients had to have a recent primary hospital discharge diagnosis of heart failure within the previous 5 years. They also had to have touchtone telephone access and the ability to operate this system [7].

**Study Design**

The study involved cluster randomization at the level of the general practitioner (1:1, usual care, usual care plus intervention, stratified by rural, remote and outer metropolitan area [RRMA] classification). This was to minimize contamination across the two interventions to which patients were randomized. Usual care (UC) involved standard general practice management of heart failure. Study personnel provided general practitioners with the National Heart Foundation of Australia/Cardiac Society of Australia and New Zealand Heart Failure Management Guidelines (2001) [8], a quick reference guide of this information including hospital and general practitioner visits, and an individualized patient diary to record all clinical information including hospital and general practitioner visits.

General practitioners randomized to this group also received a copy of the National Heart Foundation of Australia/Cardiac Society of Australia and New Zealand Heart Failure Management Guidelines (2001) [8], a quick reference guide of this information for their desktop, heart failure-specific educational material, and regular study newsletters.

All patients regardless of treatment allocation were followed up by an independent reviewer, blinded to treatment allocation, and asked to complete a telephone survey at baseline and at 6 and 12 months. The survey included questions relating to quality of life (Minnesota Living with Heart Failure questionnaire), NYHA class, global health assessment [8], EQ-5D EuroQOL, and questions regarding utilization of health services.

**Study Endpoints**

The primary endpoint of the study was the Packer clinical composite score [9] at 12 months comprising the following elements:

1. Death.
2. Hospital admission for heart failure.
3. Withdrawal from study due to worsening heart failure.
4. Seven-point global health assessment questionnaire with regard to overall well-being in comparison with baseline.

This telemedicine system was required to be dialed into by the patient on an at least a monthly basis at which time questions were asked with regard to heart failure clinical status, medical management of their condition, and social questions relevant to their heart failure status. Specific questions are summarized in Table 1. Alerts were set up within the TeleWatch system, alerting the CHAT nurse via the Patient Watch Screen to follow up patients who reported prespecified signs or symptoms warranting intervention.

In addition to monthly phone calls, patients were able at any time to dial to this automated system and receive advice about management of their heart failure symptoms or be directed to either general practitioner follow-up or presentation to the emergency department of their local hospital, based on automated responses generated by patient interaction. Furthermore, patients could at any time elect to speak to a heart failure specialist nurse who was available throughout the study program. If the patient was unable to access their general practitioner, the heart failure nurses could implement a study-specific diuretic algorithm if needed. The patients were advised to see their general practitioner or to attend the emergency department as soon as possible. Diuretics were the only medications that were titrated by the heart failure specialist nurses.

The heart failure specialist nurses consisted of four core staff with between 5 and 25 years of cardiac nursing experience. Each of the nurses received training in the TeleWatch™ system in addition to biannual heart failure seminars.

Patients in the UC + 1 were also provided with an action plan that outlined how to detect clinical deterioration and when and how to access emergency medical care. They also received a patient information resource about heart failure, regular newsletters, and an individualized patient diary to record all clinical information including hospital and general practitioner visits.

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Patients were considered as improved, worse, or unchanged depending on these responses as per the original Packer scoring system [9].

Secondary endpoints comprised all-cause death and all-cause hospitalization as well as heart failure-related death and heart failure-specific hospitalization. All hospitalization data were adjudicated by three cardiologists (blinded to randomization allocation) to determine whether the hospitalizations were related to heart failure. Utilization of life-saving therapies comprising use and dose of an ACE inhibitor was recorded in the UC + I group at 12 months. A substudy of patients had N-terminal-proBNP plasma levels measured at baseline and at 6 and 12 months.

Sample Size

Sample size was based on the Packer composite scale as the primary outcome. It was assumed that at the end of 12 months, follow-up of the UC patients would comprise 25% improved, 50% unchanged, and 25% worsened. A shift of approximately 10% in the UC + I group (to a distribution of 36%, 48%, 16%) corresponding to an odds ratio of 1.65 in a proportional odds model was desired to be detected with 80% power. With patients individually randomized, this would have required 222 patients per arm. With an average of three patients per practice in a cluster-randomized design, an esti-
mated intrapractice correlation was 0.10, and applying the design effect for interval-scaled measures, the approximate sample size inflation factor was 20%, leading to a total sample size of 534 patients from 178 practices. Due to slower-than-expected recruitment, sample size calculation was revisited after approximately 400 patients had been recruited. Calculations indicated that a shift of approximately 11% (to 37%, 47%, 16% in the UC + I arm) corresponding to an odds ratio of 1.78 was able to be detected with 80% power using this sample size. Because this represented only a very minor difference from the original target of a 10% shift, the trial was terminated at that point in recruitment.

**Statistical Analysis**

Intention-to-treat analyses were performed for all endpoints. All analyses were adjusted for clustering at practice level using a robust variance estimator. The 3-point scale of the Packer composite score was analyzed with a proportional odds model that assesses the odds of a better outcome in UC + I patients compared with UC. Assessment of proportionality of odds was performed using Wald tests [10]. Time-to-event endpoints were displayed with Kaplan–Meier curves and hazard ratios estimated using Cox proportional hazards regression, first unadjusted then adjusted for covariates as above. All analyses were performed using Stata version 10 (Stata Corp, College Station, TX, USA).

**Results**

**Characteristics of General Practitioners**

One hundred and forty-three rural, remote, and outer metropoli-
tan general practitioners from 127 individual general practitioner clusters were recruited to the CHAT study (Figure 1). Several general practitioners failed to recruit patients (n = 170). However,

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**Figure 1** Flowchart of patient enrollment.
there were no significant differences in characteristics of general practitioners between those who recruited patients and those who did not. Barriers to patient recruitment were outside the scope of this study.

In the UC group, 23 of 74 general practitioners were sole general practitioners in their practice compared with 22 of 69 general practitioners in the UC + I. The number of general practitioners in the practice ranged from 1 to 12 general practitioners in both the UC and UC + I groups.

General practitioners participated from all Australian states and territories (Figure 2). The distribution of general practitioners between rural, remote, and outer metropolitan areas was not significantly different between groups (Figure 3).

### Patient Characteristics

Patients were well matched at baseline for disease severity, comorbidities, hemodynamic parameters, and concomitant medications (Table 2).

**Table 2** Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>Usual care (n = 217)</th>
<th>Usual care + Intervention (n = 188)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>73 ± 11</td>
<td>73 ± 10</td>
</tr>
<tr>
<td>Gender (% female)</td>
<td>36</td>
<td>38</td>
</tr>
<tr>
<td>NYHA class (II/III/IV)</td>
<td>60/37/5</td>
<td>58/34/9</td>
</tr>
<tr>
<td>Systolic heart failure</td>
<td>122 ± 19</td>
<td>124 ± 19</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>71 ± 11</td>
<td>71 ± 11</td>
</tr>
<tr>
<td>Heart rate (bpm)</td>
<td>72 ± 12</td>
<td>73 ± 12</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>63 ± 28</td>
<td>59 ± 22</td>
</tr>
<tr>
<td>Baseline NT-proBNP</td>
<td>1053 (370–2341)</td>
<td>1105.5 (367.75–2572.5)</td>
</tr>
<tr>
<td>Medications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACE inhibitor (%)</td>
<td>61</td>
<td>54</td>
</tr>
<tr>
<td>ARB (%)</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Both (%)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HF specific (%)</td>
<td>66</td>
<td>56</td>
</tr>
<tr>
<td>Non-HF specific (%)</td>
<td>13</td>
<td>19</td>
</tr>
<tr>
<td>Aldosterone antagonist</td>
<td>28</td>
<td>24</td>
</tr>
<tr>
<td>Diuretic (%)</td>
<td>76</td>
<td>84</td>
</tr>
</tbody>
</table>

NYHA, New York Heart Association; ICD, internal cardiodefibrillator; eGFR, estimated glomerular filtration rate; NT-proBNP, N-terminal pro-brain natriuretic peptide; bpm, beats per minute; IQR, interquartile range.

### Resource Utilization

Patients in the UC group visited their general practitioner more frequently compared with those in UC + I (12.55 GP visits/patient [UC] vs. 5.85 GP visits/patient [UC + I]). Overall, more than 65% of patients adhered to the TeleWatch™ protocol (65.8%, 95% confidence interval 0.54–0.75, P < 0.001) [11] and made an average of 24 unscheduled calls/patient to the TeleWatch™ system.

### Primary Endpoint

Results related to the Packer clinical composite score are shown in Figure 4. There was no difference in the percentage of patients who were worse, unchanged, or better between the UC and UC + I (proportional odds ratio = 1.01, P = 0.98). Adjustment for age, gender, practice region (RRMA), and baseline NYHA class resulted in minimal difference to this result (OR = 1.02, P = 0.91).

In terms of the components of the Packer score, there were 16 deaths in UC compared with 17 in UC + I; 35 of 204 heart failure-related hospitalizations in UC compared with 23 of 161 patients in UC + I; 8 patients withdrew in UC due to worsening heart failure

![Figure 2](image-url) Clusters of participating general practitioners throughout Australia.

![Figure 3](image-url) Distribution of general practitioner clusters.
compared with 10 patients in UC + I; and 29 of 102 patients had an improvement in the global health questionnaire at 12 months in UC compared with 32 of 90 patients in UC + I.

**All-Cause Death and All-Cause Hospitalization**

One hundred and twenty-four of 209 UC and 86 of 170 UC + I patients reached the endpoint of all-cause death or all-cause hospitalization. This resulted in an unadjusted hazard ratio of 0.75 (range 0.57–0.99, \( P = 0.045 \)) and an adjusted hazard ratio of 0.70 (range 0.53–0.92, \( P = 0.011 \)). Kaplan–Meier plot of the timing of events in the UC and UC + I group is shown in Figure 5. There was no significant difference in all-cause death or all-cause hospitalization according to general practitioner location in rural, remote, or outer metropolitan areas.

**All-Cause Hospitalization**

One hundred and fourteen of 204 UC and 74 of 161 UC + I patients were hospitalized during the 12-month follow-up period of the trial. This resulted in an unadjusted hazard ratio of 0.71 (range 0.53–0.95, \( P = 0.021 \)) and an adjusted hazard ratio of 0.67 (range 0.50–0.89, \( P = 0.006 \)). The Kaplan–Meier plot of these events is shown in Figure 6.

**Heart Failure Hospitalization**

Thirty-five of 204 and 23 of 161 patients were hospitalized for heart failure. This resulted in an unadjusted hazard ratio of 0.81 (0.44–1.38, \( P = 0.43 \)) and an adjusted hazard ratio of 0.78 (0.45–1.33, \( P = 0.36 \)).

**All-Cause Death**

Sixteen of 209 patients in the UC group and 17 of the 170 patients in UC + I group died during the study. This resulted in an unadjusted hazard ratio of 1.3 (range 0.65–2.77, \( P = 0.43 \)) and an adjusted hazard ratio of 1.36 (0.63–2.93, \( P = 0.439 \)).

**Prescribing of ACE Inhibitor Therapy**

In the UC and UC + I groups, 61% and 54% of patients were prescribed ACE inhibitors at baseline, respectively. Of the patients receiving ACE inhibitors at baseline, there was no significant difference between randomized groups in the percentage of patients prescribed maximal dose (8% of patients in UC compared with 7% of patients in UC + I). Fifty-five percent of UC + I patients were receiving these medications postrandomization, of which 15% were prescribed maximum dose.

**Change in Plasma NT-proBNP**

Plasma NT-proBNP values (median and IQR) at baseline were 1053 (370–2341) and 1105.5 (367.75–2572.5) for UC (\( n = 203 \)) and UC + I (\( n = 176 \)) groups, respectively. At 12 months, the NT-proBNP levels were 960 (374–2007) and 1083 (408.5–2182.5) for UC (\( n = 123 \)) and UC + I (\( n = 117 \)) groups, respectively.

**Discussion**

This study found that an automated telephone support system provided to rural, remote, and outer metropolitan heart failure patients resulted in no change in the Packer clinical composite score in comparison with usual care, the primary endpoint. It did, however, lead to a significant reduction in the risk of the composite of all-cause death or hospitalization, as well as all-cause death.
hospitalization alone. Furthermore, there was a nonsignificant (approximately 20%) reduction in risk of heart failure hospitalization, but no difference in all-cause mortality. There was also a reduction in the utilization of general practitioners, with the control group visiting their general practitioner more than twice as often as the intervention group. This may be due to compliance (in 65%) with the automated telephone support system in the intervention group, reducing the need for participants in the intervention group to visit their general practitioner.

Based on the favorable effects of the telephone-based intervention, primarily on hospitalizations, this may represent a novel approach to healthcare delivery targeting rural and remote patients with chronic disease, particularly those without access to multidisciplinary community-based care.

Two recent studies found results similar to these, particularly in the nonsignificant effect on all-cause mortality and heart failure-related hospitalizations. A recent study of 710 stable chronic heart failure patients investigated the efficacy of a physician-led telemedical management system [12]. Patients randomized to the telemedical management group used electronic devices for monitoring of the ECG, blood pressure, and weight. All patients were followed up for 2 years. The investigators found no significant difference in all-cause mortality, cardiovascular death, or heart failure-related hospitalizations between the usual care and telemedical management groups [12]. They did not report all-cause hospitalizations. In another controlled trial, the Tele-HF study [13] tested a structured telephone support system similar to that used in our study. They randomized 1653 patients who had been recently hospitalized with heart failure to undergo telemonitoring or usual care [13]. Their telemonitoring system was a telephone-based interactive voice system that collected information about symptoms and weight. All patients were followed up for 6 months. The study found no significant difference in all-cause mortality or hospitalization, or heart failure-related hospitalizations between the groups [13]. The major difference in this study was the length of follow-up as all patients in our study were followed up for 12 months, which may account for our finding of a significant reduction in all-cause death or hospitalization. Both of these studies have been published since previous meta-analyses of the efficacy of telemonitoring in heart failure patients.

In summary, we have found that an automated telephone support approach to the management of rural and remote patients with heart failure who have reduced access to management programs impacts primarily and significantly on hospitalization. This has attendant benefits to the individual patient and the healthcare system. These findings support further evaluation to determine the cost-effectiveness of such an intervention as well as its potential for implementation across other chronic disease states.

Limitations

This study has several limitations. Firstly, it is unclear why a corresponding reduction in mortality was not also observed with the usual care plus intervention group compared with those receiving usual care alone. It may be that the intervention had insufficient power to impact on survival but could on hospitalization or that the study was under-powered to reliably address effects on this endpoint. In addition, the initial aim of the study was to determine the effect of an automated telephone support system in exclusively rural and remote patients. However, due to an insufficient number of general practitioners in these areas, general practitioners in inner metropolitan areas were subsequently recruited. It is also of interest that background use of ACE inhibitors was not increased in the intervention group. Therefore, the improved outcomes in this group did not relate to utilization of this life-saving class of agent. Data on beta-blocker use following randomization were not collected in this study, as the automated telephone support system was not set up to collect such information.

The automated telephone support system provides insight into the potential benefits of multidisciplinary care in patients with heart failure. In particular, the ability to closely interact with a healthcare professional with appropriate expertise may provide significant security to the patient, reduce anxiety, and improve quality of life [11].

Based on the beneficial impact on hospitalization in the present study of patients with chronic heart failure, automated telephone support may be considered for other chronic disease states where ongoing management is required and multidisciplinary approaches cannot be accessed by patients living in rural and remote regions. Such disease states may include chronic arthritis, chronic obstructive pulmonary disease, diabetes mellitus, and osteoporosis.

In summary, we have found that an automated telephone support approach to the management of rural and remote patients with heart failure who have reduced access to management programs impacts primarily and significantly on hospitalization. This has attendant benefits to the individual patient and the healthcare system. These findings support further evaluation to determine the cost-effectiveness of such an intervention as well as its potential for implementation across other chronic disease states.

Author Contributions

HK, AF, JY, PD, EK, DH, HE, SS, LP, and AT involved in concept and design of the study. HK and AD involved in drafting the article. JY, RC, AD, JC, BC, and LH involved in data collection. AF involved in data analysis and interpretation. All authors involved in critical revision and approval of the article.

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Conflict of Interest

The authors declare no conflict of interest.
References


