Home-Based Disease Management Program to Improve Psychological Status in Patients With Heart Failure in Japan

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**Background:** A disease management program can reduce mortality and rehospitalization of patients with heart failure (HF), but little is known about whether it can improve psychological status. The purpose of this study was to determine the effects of home-based disease management on the psychological status of patients with HF.

**Methods and Results:** We randomly assigned patients hospitalized for HF to undergo either home-based disease management (n=79) or usual care (n=82). The mean age of the study patients was 76 years, 30% were female, and 93% were in NYHA class I or II. Home-based disease management was delivered by nurses via home visit and telephone follow-up to monitor symptoms and body weight and to educate patients. The primary endpoint was psychological status, including depression and anxiety assessed by the Hospital Anxiety and Depression Scale during follow-up of 1 year. Secondary endpoints included quality of life, all-cause death and hospitalization for HF. The intervention group had significantly lower depression (P=0.043) and anxiety (P=0.029) scores than the usual-care group. There were no significant differences in all-cause death [hazard ratio (HR) 1.02, 95% confidence interval (CI) 0.37–2.61, P=0.967]. However, hospitalization for HF was significantly lower in the intervention group than in the usual-care group (HR 0.52, 95% CI 0.27–0.96, P=0.037).

**Conclusions:** Home-based disease management improved psychological status and also reduced rehospitalization for HF in patients with HF. (Circ J 2013; 77: 926–933)

**Key Words:** Disease management; Heart failure; Prognosis; Psychological status; Quality of life

Psychological distress, including depression and anxiety, are common in patients with heart failure (HF), with a prevalence reaching approximately 30–40%.[1,4] In addition, quality of life (QOL) is low in HF patients when compared with the general population.[5] Physical and psychosocial functioning are severely impaired in HF, even when compared with other chronic illness such as arthritis and ischemic heart disease.[6] HF patients with depression or anxiety exhibit lower physical function, more severe HF symptoms, decremented daily activities, impaired health-related QOL, and poor outcomes, including mortality and morbidity.[7,9] Therefore, despite considerable advances in evidence-based medical therapy, psychological problems and low QOL remain critical issues in HF.[10–12] Even though improvement in survival is definitely important,[13,14] many HF patients need to have better QOL rather than longer length of life.[15]

Over the past 25 years, a number of disease management programs have been developed and tested for whether they could improve clinical outcomes in HF patients.[16–18] These programs include HF clinics, home-based intervention, and telemonitoring. Key components of all these interventions are education and counseling, symptom monitoring, accessibility to healthcare providers when there are problems, optimization of medication, and social support service after discharge. A meta-analysis of these trials demonstrated that they could decrease hospitalization for worsening HF, prolong the time to the first major event, decrease medical costs, and improve QOL.[19] However, there have been few studies regarding the
effects of disease management programs on the psychological status of HF patients.

We conducted a multicenter, randomized, controlled trial, the Japanese Heart Failure Outpatients Disease Management and Cardiac Evaluation (J-HOMECARE), to test the hypothesis that a home-based disease management program could improve the psychosocial status and QOL, as well as clinical outcomes including mortality and HF hospitalization, in Japanese patients with chronic HF.

### Methods

**Study Design and Patients**

The design of this trial has been published. The study was registered for Clinicaltrials.gov (NCT01284400).

Patients were enrolled from December 2007 to March 2010 at 3 cardiology hospitals in Hokkaido, Japan. Hospitals were selected on the basis of their organizational capability and enthusiasm for participating in the study. Exclusion criteria of patients were end-stage HF defined as requiring mechanical support or continuous intravenous inotropic agents, serious life-threatening illness with a life-expectancy of less than 6 months, stroke within the past 3 months, cognitive dysfunction, and substance abuse or psychotic disorder. After informed consent had been obtained from eligible patients, they are randomized on a 1:1 basis to either usual care or a home-based disease management intervention. Patients were treated with standard medications in accordance with guidelines for the treatment of chronic HF in Japan.

**Usual Care and Home-Based Disease Management Intervention**

All enrolled patients received comprehensive discharge education by cardiologist, nurse, dietitian, and pharmacist using a booklet that provided information on pathophysiology, medical treatment, diet, physical activity, lifestyle modification, self-measurement of body weight, self-monitoring of worsening HF, and emergency contact methods. Follow-up assessments were performed 2, 6, and 12 months after discharge.

A home-based disease management program consisted of home visit by nurses to provide symptom monitoring, education, and counseling, and telephone follow-up by nurses in addition to routine follow-up by cardiologists. A home visit was made within 14 days after discharge from hospital. Nurses visited each patient’s home to assess how the patient was coping in the home environment, HF status, general health status, adherence to medication, lifestyle modification, daily activity, and social support needs. Home visits were made once every 2 weeks until 2 months after discharge. At the conclusion of home visiting, nurses then conducted monthly telephone fol-
| Characteristic | Home-based intervention (n=79) | Usual care (n=82) | P value |
|---------------|-------------------------------|-----------------|---------|
| Age (years, mean ± SD) | 76.9±10.9 | 75.8±12.1 | 0.548 |
| Female (%) | 37 (46.8) | 33 (40.2) | 0.399 |
| BMI (kg/m², mean ± SD) | 22.0±4.3 | 22.0±3.6 | 0.945 |
| Living alone (%) | 11 (13.9) | 16 (19.5) | 0.343 |
| Etiology of HF (%) | | | |
| Ischemic | 22 (27.8) | 22 (26.8) | 0.885 |
| Hypertensive | 28 (35.4) | 21 (25.6) | 0.175 |
| Valvular | 21 (26.6) | 25 (30.5) | 0.583 |
| Cardiomyopathic | 20 (25.3) | 24 (29.3) | 0.574 |
| Unknown | 4 (5.1) | 3 (3.7) | 0.662 |
| Other | 15 (19.0) | 11 (13.4) | 0.337 |
| Medical history (%) | | | |
| Prior admission for HF | 22 (27.8) | 21 (25.6) | 0.748 |
| Hypertension | 41 (51.9) | 41 (50.0) | 0.810 |
| Diabetes mellitus | 20 (25.3) | 18 (22.0) | 0.615 |
| Dyslipidemia | 21 (26.6) | 16 (19.5) | 0.286 |
| Hyperuricemia | 35 (44.3) | 35 (42.7) | 0.836 |
| Myocardial infarction | 17 (21.5) | 15 (18.3) | 0.608 |
| Stroke | 14 (17.7) | 12 (14.6) | 0.595 |
| COPD | 8 (10.1) | 4 (4.9) | 0.205 |
| Atrial fibrillation | 34 (43.0) | 51 (62.2) | 0.030 |
| PCI or CABG | 12 (15.2) | 10 (12.2) | 0.580 |
| Clinical status | | | |
| NYHA (%) | | | |
| I | 8 (10.1) | 14 (17.1) | 0.403 |
| II | 67 (84.8) | 63 (76.8) | |
| III | 4 (5.1) | 5 (6.1) | |
| SBP (mmHg, mean ± SD) | 117.6±17.1 | 116.9±13.6 | 0.789 |
| DBP (mmHg, mean ± SD) | 66.6±15.5 | 65.7±10.3 | 0.694 |
| Heart rate (beats/min, mean ± SD) | 67.9±8.6 | 66.1±8.5 | 0.177 |
| Serum creatinine (mg/dl, mean ± SD) | 1.2±0.4 | 1.6±0.3 | 0.260 |
| Hemoglobin (g/dl, mean ± SD) | 12.4±2.3 | 12.7±2.1 | 0.398 |
| Serum sodium (mEq/L, mean ± SD) | 139.3±3.8 | 139.5±6.2 | 0.772 |
| Serum albumin (g/dl, mean ± SD) | 3.9±0.4 | 4.0±0.5 | 0.283 |
| Plasma BNP (pg/ml, mean ± SD) | 344.9±366.9 | 291.6±367.1 | 0.410 |
| LVEF (%), mean ± SD | 47.4±16.8 | 47.4±15.7 | 0.986 |
| LVEF <40% | 28 (35.4) | 30 (36.6) | 0.880 |
| Medication (%) | | | |
| ACE inhibitor or ARB | 58 (73.4) | 65 (79.3) | 0.382 |
| β-blocker | 37 (46.8) | 37 (45.1) | 0.827 |
| Diuretic | 74 (93.7) | 79 (96.3) | 0.436 |
| Aldosterone antagonist | 40 (50.6) | 37 (45.1) | 0.484 |
| Digitalis | 17 (21.5) | 24 (29.3) | 0.259 |
| Calcium-channel blocker | 8 (10.1) | 5 (6.1) | 0.348 |
| Antiarrhythmic drug | 19 (24.1) | 26 (31.7) | 0.279 |
| Aspirin | 32 (40.5) | 30 (36.6) | 0.609 |
| Warfarin | 24 (30.4) | 29 (35.4) | 0.501 |
| Statin | 12 (15.2) | 18 (22.0) | 0.271 |
| Insulin | 2 (2.5) | 5 (6.1) | 0.267 |
| Antidepressant | 1 (1.3) | 1 (1.2) | 0.979 |
| Anxiolytic | 5 (6.3) | 4 (4.9) | 0.689 |
| Device therapy | | | |
| Pacemaker (%) | 11 (13.9) | 12 (14.6) | 0.898 |
| ICD (%) | 1 (1.3) | 2 (2.4) | 0.582 |

ACE, angiotensin-converting enzyme; ARB, angiotensin-receptor blocker; BMI, body mass index; BNP, brain natriuretic peptide; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; SBP, systolic blood pressure; DBP, diastolic blood pressure; HF, heart failure; ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention.
low-up until 6 months after discharge. Nurses monitored HF symptoms, patient’s general health status, and requirement for other health and social support. Nurses consulted a multidisciplinary team during the intervention period to optimize the advice given to each patient. This multidisciplinary team consisted of a cardiologist, dietitian, pharmacist, and social worker. Other healthcare professionals were consulted as required.

Patients in the usual-care group received usual care and follow-up. After hospital discharge, patients assigned to the usual-care group continued to receive routine management by the cardiologist. No extra follow-up by a HF nurse or multidisciplinary team was provided.

Endpoints
The primary endpoint was the patient’s psychological status, including depression and anxiety assessed by using the Hospital Anxiety and Depression Scale at baseline, 2, 6 and 12 months of follow-up. The secondary endpoint included QOL, all-cause death, and hospitalization for HF. QOL was assessed by Short Form-8 at baseline and 2, 6, and 12 months of follow-up. All-cause death and hospitalization were analyzed as the time to the first event. Hospitalization for HF was defined as an unplanned overnight stay in a hospital because of progression in HF symptoms or directly related to HF.

Data Collection
Baseline data were collected from medical records by the investigators at each hospital. Information on depression, anxiety and QOL at baseline, 2, 6, and 12 months were collected directly or by phone interview by investigators. Prognostic data were reported based on medical records or follow-up by telephone.

Statistical Analysis
Patients’ baseline characteristics were summarized according to treatment group. Baseline characteristics between the 2 groups were compared by Welch’s t-test for continuous variables and chi-square test for discrete variables. The analysis of primary and secondary endpoints was prespecified to be performed in the per-protocol population, which included all patients who received usual care or home-based intervention (Figure 1). To evaluate the difference between groups, the psychological status and QOL from baseline to 2, 6, and 12 months after discharge were compared using 2-way analysis of variance (ANOVA) with repeated measure. We used a paired t-test to compare the scores between baseline and each time point, where α level was adjusted by the Bonferroni method.

To assess prognosis, we summarized the endpoints on the basis of treatment group and tested the primary hypothesis using a chi-square test of independence. Event rates of all-cause death and hospitalization for HF over time were summarized using Kaplan-Meier survival curves, and we also estimated the corresponding hazard ratio (HR) and 95% confidence interval (CI), using a Cox proportional-hazards model. All statistical analyses were performed with IBM SPSS Statistics version 20 (Chicago, IL, USA).
**Results**

**Patients**
A total of 384 potential participants were screened (Figure 1) and of these, 212 were ineligible and 4 declined to participate. The remaining 168 patients were enrolled: 84 were randomly assigned to undergo home-based intervention and 84 to receive usual care. A total of 95.8% of the study patients completed the follow-up of 1 year with no between-group difference in the rate of completion (94.1% vs. 97.6%, *P*=0.247).

The baseline characteristics were similar between groups (Table). The mean age was 76.3 years and 43.5% of the patients were female. The principal causes of HF were ischemic (27.3%), hypertensive (30.4%), and cardiomyopathic (27.3%). Hypertension and atrial fibrillation were the most common comorbidities; however, the home-based intervention group was less likely to have atrial fibrillation than the usual-care group (45.0% vs. 62.2%, *P*=0.030). In total, 80.1% of the patients were classified as NYHA class II. The mean left ventricular ejection fraction (LVEF) was 47.4% and the prevalence of reduced LVEF was 36.0%. Regarding medications, 76.4% of patients had received angiotensin-converting-enzyme inhibitor or angiotensin-receptor blocker, and 46.0% had received β-blocker. Antidepressant or anxiolytic drugs were used in 6 patients from the home-based intervention group and 5 patients from the usual-care group, which did not differ between groups.

**Depression and Anxiety**
Depression and anxiety scores were comparable between groups at baseline. The home-based intervention significantly improved both depression and anxiety compared with usual care (depression: *P*=0.043; anxiety: *P*=0.029, by repeated measure ANOVA) (Figure 2). Regarding score differences within the intervention group, the anxiety score at 6 months after discharge was significantly decreased compared with the baseline score (*P*=0.001), whereas it did not significantly change in the usual-care group. The depression score did not change significantly at each time point from baseline in either group. However, both depression and anxiety scores significantly increased from 6 to 12 months in the intervention group (depression: *P*=0.006; anxiety: *P*=0.003).

**QOL**
Physical and mental health QOL scores were comparable between groups at baseline. In the comparison between groups, physical health QOL changes did not differ (*P*=0.359) (Figure 3A). The physical health QOL score significantly increased from baseline to all follow-up time points in the intervention group (*P*≤0.001 at 2-months vs. baseline, *P*≤0.001 at 6 months, *P*≤0.001 at 12-months). It significantly increased only at 2 months (*P*≤0.001) and did not change at 6 (*P*≤0.041) or 12 months (*P*≤0.037) in the usual-care group.

The home-based intervention significantly improved mental health QOL compared with usual-care when analyzed by repeated measure ANOVA (*P*=0.046) (Figure 3B). The mental health QOL score significantly increased from baseline to 2, 6, and 12 months in the intervention group (*P*≤0.001 at 2 months vs. baseline, *P*≤0.001 at 6 months, *P*≤0.003 at 12-months), but was unchanged in the usual-care group.
Interaction between nurses and patients could help establish a firm “therapeutic alliance”, resulting in improved psychiatric status and QOL of the patient. Such an educative intervention could also contribute to improvements in self-care and self-efficacy of HF patients.

The present study demonstrated that depression and anxiety scores increased after 6 months (ie, after completion of the intervention), which suggests that the intervention needs to be continued for a longer time after discharge. Further investigations are needed to determine whether the duration of intervention may influence its effect on the psychological status of HF patients.

The home-based intervention in the present study effectively reduced the rate of hospitalization for worsening HF (Figure 4B), a finding that was consistent with previous studies. A meta-analysis showed that home-based disease management was effective in reducing the risk of rehospitalization because of HF or other cardiovascular disease (relative risk (RR)=0.61, 95% CI 0.46–0.79) and of rehospitalization for all types of reasons (RR=0.75, 95% CI 0.66–0.85). In contrast, our home-based disease management intervention did not reduce the number of all-cause deaths in the present study (Figure 4A). A meta-analysis by Roccaforte et al reported that disease management programs could reduce mortality by a pooled odds ratio of 0.80 (95% CI 0.69–0.93). The reasons for this discrepancy are not clear. However, a possible explanation might be the low annual mortality rate in the present study (10%) compared with recent clinical trials of disease management from Europe (27% in 18 months) and Australia (20%). Based on the findings that previous trials, especially small-scale trials, also failed to demonstrate efficacy of this type of intervention on mortality rates, further

**All-Cause Death and Hospitalization for HF**

In both the home-based intervention group and usual-care group, there were 8 cases of all-cause death (10% in each group) (Figure 4A). The risk of all-cause death in the intervention group was comparable to that in the usual-care group (HR=1.02, 95% CI 0.37–2.61, P=0.967). Hospitalization because of HF was required by 16 patients (20%) in the intervention group and 28 patients (34%) in the usual-care group (Figure 4B). Hospitalization for HF was significantly lower in the intervention group than in the usual-care group (HR=0.52, 95% CI 0.27–0.96, P=0.037).

**Discussion**

In the present study, a home-based disease management intervention improved depression and anxiety, as well as mental health QOL, in HF patients. It also significantly reduced the rate of hospitalization for HF. These results verify the efficacy on psychological status and QOL of home-based disease management by nurses via home visit and telephone follow-up. Therefore, such intervention can be effective also in Japan, where the medical care system is distinct from those in the United States and Europe.

There are several possible factors that might explain the effectiveness of this disease management program on psychological status and QOL (Figures 2,3). The intervention included provision of knowledge about HF to patients, symptom monitoring, and assessment of treatment adherence by nurses via home visit and telephone follow-up. Nurses could reduce the mental stress of patients living with their disease and their anxiety about the exacerbation of HF by providing knowledge and management strategies. In addition, the face-to-face interaction between nurses and patients could help establish a firm “therapeutic alliance”, resulting in improved psychiatric status and QOL of the patient. Such an educative intervention could also contribute to improvements in self-care and self-efficacy of HF patients.

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investigation on larger scale is needed.

**Study Limitations**

First, we did not analyze medical care costs as an outcome. Recently, telemonitoring and teledicine have been proposed as cost-effective programs of disease management in HF. Therefore, it will be important to evaluate the medical care costs required for our home-based disease management program. Second, the present study was conducted in 3 hospitals specializing in cardiovascular treatment, which might limit the application of the present findings in general. Further studies need to be conducted in a larger number of hospitals to ensure the generalizability of the present results. We also could not determine whether the effects of the intervention differed among hospitals or among the methods of conducting the program. Therefore, this point needs to be assessed by a multi-institutional collaborative trial. Finally, improved adherence to medical treatment in the intervention group might affect the endpoints. However, the present study did not evaluate adherence to medical treatment. Adherence to medical treatment, as well as self-care behavior, needs to be assessed in future studies.

In conclusion, home-based disease management by nurses via home visit and telephone follow-up was effective in improving the quality of life: A cross-sectional study comparing common chronic elderly patients over 80 years hospitalized with heart failure: A report from the Japanese Cardiac Registry of Heart Failure in Cardiology (JCARE-CARD). Circ J 2011; 75: 2403–2410.

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Appendix

Steering Committee
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Endpoint Adjudication Committee
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Assistant: Mayumi Koasa, Hokkaido University.

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