Effectiveness of a multidisciplinary disease management program on outcomes in patients with heart failure in China: A randomized controlled single center study

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ABSTRACT

Background: Multidisciplinary disease management programs (MDMP) for patients with heart failure (HF) have been delivered, but evidence of their effectiveness in China is limited.
Objective: To determine if a MDMP improves quality of life (QoL), physical performance, depressive symptoms, self-care behaviors and mortality or rehospitalization in patients with HF in China.
Methods: This is a randomized controlled single center trial in which patients with HF received either MDMP with discharge education, physical training, follow-up visits and telephone calls for 180 days (n = 31) or standard care (SC, n = 31).
Results: Compared with SC, QoL, depressive symptoms, and self-care behaviors were significantly improved by MDMP from baseline to 180 days (37% vs 66%, 20% vs 61%, and 8% vs 33%, respectively, all p < 0.001). There were no differences in physical performance and mortality or rehospitalization during follow-up.
Conclusions: A HF MDMP can improve QoL, depressive symptoms and self-care behaviors in China.

Introduction

Heart failure (HF) is the final pathway for several heart diseases. Patients with HF often experience episodes of exacerbation, leading to decline of functional status, and multiple hospital readmissions.[1]

Quality of life (QoL) is very important for patients with HF. First, patients often value QoL more than longer survival.[2] Second,

improvement in QoL results in lower rates of hospitalization and morality[3,4] Third, compared with healthy populations and those with other chronic diseases, QoL in patients with HF is reduced.[5,6] In Chinese patients with HF, QoL is poorer.[7] Thus, QoL in Chinese patients with HF needs to be addressed. Several disease management programs (DMP) have been provided to improve QoL and other outcomes,[8–10] and some showed significant improvement in the outcomes.[8,9]

Physical performance has been found to be impaired in many patients with HF.[11] and has been associated with poor QOL.[12] and high hospitalization and mortality rates.[13] Diminished physical performance also predicts poor QoL in Chinese patients with HF.[14]

Depressive symptoms are common in patients with HF.[15] and have been connected to worsening of HF symptoms, poor QoL, and high rates of hospitalization and mortality,[6,16] They are also associated with HF symptoms such as dyspnea.[17] and predict mortality and hospitalization.[18] in Chinese patients with HF.

Self-care is defined as an active cognitive process undertaken by patients to maintain health status or manage diseases.[19] HF is a chronic disease requiring self-care. Nevertheless, self-care

behaviors were inadequate in HF patients,[20–23] and inadequate self-care behaviors were associated with worsening of HF symptoms, poor QoL and high rates of hospitalization.[24,25] Chinese patients' self-care behaviors were also poor and diminished over time.[26,27]

Rehospitalization and mortality rates are high among patients with HF in China as well as in other countries.[28–31] Therefore, they should be addressed in this population.

All the above outcomes are of great importance for patients with HF and should be improved in China. When we deal with overall health (QOL), physical issues (functional status), psychological issues (depressive symptoms), behaviors (self-care), and mortality or hospitalization rate at the same time, we need multidisciplinary approaches.

Previous studies of MDMPs in other countries revealed improvement in some of the five outcomes,[10,32–35] although not all outcomes were targeted nor the intervention effective. Even though in several studies, MDMPs did not improve QOL,[10,35,36] possibly because of lack of disease management education and self-management in China, a MDMP may show better outcomes in China than in other countries where more education is routinely provided.

As described above, the status of the five outcomes was poor in patients with HF. MDMPs have not been provided to Chinese patients with HF to improve the five outcomes simultaneously. Therefore, this study was designed to assess the effectiveness of a MDMP on QoL, physical performance, depressive symptoms, self-care behaviors and mortality or rehospitalization among patients with HF in China.

Methods

Study design and participants

This was a randomized controlled trial conducted at a hospital in Changsha, China. This trial was performed according to the ethical standards in the 1964 Declaration of Helsinki and received approval of an institutional review board. Sample size calculation was based on detecting statistically significant difference in the primary outcome (QoL), assuming that the average score for the Minnesota Living with Heart Failure Questionnaire (MLHFQ) was 40 and the standard deviation was 20 based on previous studies in China.[37,38] The effect-size of the MDMP varied from a reduction in MLHFQ score of 12 to 25.[37,39,40] As such, we projected that our intervention would decrease the MLHFQ score by 15. With 80% power and a 5% significance level, 28 patients were required in each study group. Considering an attrition rate estimated at 10% during follow-up, 31 patients were enrolled for each group. Patients who were admitted from December 2013 to June 2015 at the Department of Cardiology or Geriatrics were screened (N = 1624) and a total of 62 with chronic HF were enrolled. A HF diagnosis was made on the basis of Boston criteria.[41] After informed consent was signed at discharge, patients were randomized to the MDMP or standard care (SC) group. A computer-generated randomization list was created by a statistician for patient randomization. Inclusion criteria were HF diagnosis with NYHA class II to IV and >18 years old. Exclusion criteria were: 1) cognitive impairment (people with scores <24 on the Mini-mental State Examination Questionnaire; 2) inconvenience of home visit; 3) inaccessible by telephone; 4) concurrent inclusion in another study; 5) diagnosis of chronic obstructive pulmonary disease; 6) diagnosis of other diseases whose life expectancy is less than 1 year; and 7) diagnosis of other conditions that restricted the patient's activity.

Outcome measures

The MLHFQ is a 21-item questionnaire with response scales of 0–5. It has been extensively acknowledged as a specific tool to determine QoL in patients with HF. The maximum total score is 105, with lower scores indicating better QoL. Ho and colleagues have shown that content validity index (CVI) and Cronbach's alpha coefficient of the Chinese version of MLHFQ are 0.98 and 0.95, respectively, indicating good validity and reliability.[42] The Short Physical Performance Battery (SPPB) is a group of objective measures broadly adopted to evaluate physical performance in HF and is highly predictive of subsequent disability. It is more feasible and safer than the 6-min walk test.[43,44] The summary scores range from 0 to 12, with higher scores indicating better physical performance. SPPB was conducted as previously implemented in China.[45] The Patient Health Questionnaire (PHQ-9) is an inventory for screening depressive disorders, which is characterized by its high specificity and sensitivity.[46] PHQ-9 score of ≥10 is commonly considered as diagnostic of depressive disorders.[46,47] The sensitivity, specificity and internal consistency of the Chinese version of PHQ-9 have been shown to be 0.86, 0.94, and 0.8, respectively.[48] The European Heart Failure Self-care Behavior Scale (EHFScBS) is used to measure self-care behaviors in patients with HF. The maximum total score is 60 points, with lower scores indicating better self-care behavior. The CVI and Cronbach's alpha coefficient of the Chinese version of EHFScBS are 0.89 and 0.82, respectively.[49] Mortality and rehospitalization rates were also recorded during follow-up.

Data collection protocol

Baseline demographic and clinical data were collected from medical records. All participants were asked to complete the MLHFQ, SPPB, PHQ-9 and EHFScBS at baseline, 90 days and 180 days under the guidance of trained nurses.

Protocols for SC and MDMP group

Medications recommended by the 2013 American College of Cardiology Foundation/American Heart Association Guideline for the Management of Heart Failure[50] were prescribed for all the patients in this study at optimal dosage if there was no contradiction.

SC group

Patients assigned to the SC group received standard care that included a telephone call within 2 weeks after discharge by a nurse and two follow-up visits for adjustment of medications by a cardiologist at our out-patient clinic at 90 days and 180 days after discharge. Contacts with the cardiologists and nurses on our HF team were discouraged.

MDMP group

Patients in the MDMP group were followed by the HF team consisting of 3 cardiologists, 1 coach nurse, 10 nurses, 1 dietitian and 1 psychiatrist, and received a multidisciplinary intensive intervention in addition to standard care. This intervention included enhanced discharge education, physical exercise training, and follow-up contacts.

We initiated individualized education with a cardiologist at discharge. The education included an introduction of the definition, signs and symptoms of HF, the importance of body weight control and input/output monitoring, what to do when they feel