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ORIGINAL ARTICLE

Effectiveness of an educational self-management program for outpatients with chronic heart failure

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Abstract

Aim: The occurrence rate of chronic heart failure (CHF) in Japan is estimated to be 50 000 per one million persons. It is important for the Japanese medical financial system to institute a program of disease management in order to prevent the deterioration of persons with CHF. However, there are still few studies on the disease management of CHF in Japan. Therefore, the purpose of this study was to provide an educational self-management program to Japanese outpatients with CHF in order to improve their clinical outcomes.

Methods: A randomized, controlled trial with 102 outpatients with CHF was conducted. There were 50 participants in the intervention group and 52 participants in the control group. The control group received medical treatment and standard care. In addition to this, the intervention group also received an educational program for 6 months. The program consisted of six nurse-directed sessions that were provided to each outpatient once per month in a clinical setting for a total of 6 months. A follow-up session was conducted each month for 6 months. The data collection was carried out at the start of the program and at 3, 6, 9, and 12 months.

Results: Significant differences could be observed in the primary and secondary outcomes and in the process indicators between the two groups after the program began. In other words, all the indicators improved for the intervention group, compared to the control group. Therefore, this program was considered to be effective.

Conclusion: Further long-term care is necessary for outpatients with CHF in order to prevent their deterioration and to maintain their health status, even though this 6 month program did provide them with proper knowledge regarding self-care for CHF and affected their therapy results.

Key words: chronic heart failure, disease management, educational program, self-management.

INTRODUCTION

With advancements in medicine and an increasing proportion of lifestyle diseases, the percentage of patients with chronic diseases who must personally manage themselves has increased and, at the same time, the onset and deterioration of many chronic diseases greatly alter patients' personal lifestyle and daily living (Matsuda & Sakamaki, 2004). Therefore, it is very important for patients to manage their daily life, including their lifestyle. Although health professionals widely recognize the importance of self-management and patient education in order to promote self-management, a support system to promote such patient education and disease management has yet to be developed in Japan, as compared with other advanced countries, because of restrictions in the Japanese health system and insurance support system (Matsuda & Sakamaki, 2004).

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The causes of chronic heart failure (CHF) vary, so treatment is pathognomonic. Although the treatment is determined by the underlying etiology, evidence-based clinical guidelines give a uniform procedure, regardless of the causative factor. This consists of improving the patients' risk factors, such as reducing heart strain, drugs to strengthen heart function, control of fluid and sodium intake, exercise, smoking, and weight control. Respiratory management and ventricular assistance are applicable in relation to severe patients (Association Study Group, 2005).

Heart failure is a major cause of hospital admission for patients who are ≥65 years old in the USA and Europe and the rate of rehospitalization is high. As a result, many intervention studies regarding disease management programs have been carried out and considerable achievement has been made in preventing readmission (Cline, Israelsson, Willenheimer, Broms, & Erhardt, 1998; Ekman *et al*., 1998; Jaarsma *et al*., 1999; Naylor *et al*., 1999; Rich *et al*., 1993; 1995; Schneider, Hornberger, Booker, Davis, & Kralicek, 1993; Serxner, Miyjaji, & Jeffords, 1998; Stewart, Marley, & Horowitz, 1999; Stewart, Pearson, & Horowitz, 1998; Stewart, Vandenbroek, Pearson, & Horowitz, 1999; Strömberg *et al*., 2003). In contrast, there are hardly any studies regarding disease management programs in Japan, except for those on the rehabilitation of patients with CHF (Goto *et al*., 2005; Izawa, Morio, Watanabe, Osada, & Omiya, 2006; Maruko & Ikeda, 2006). These studies, however, did not focus on a global approach or disease management. Furthermore, medical education regarding health care is lacking in Japan and only medical therapy is carried out by doctors (Moriyama *et al*., 2006; Otsu & Moriyama, 2008).

Therefore, we developed a CHF disease management program, based on effective programs from previous studies that have been carried out in other countries, a Japanese evidence-based clinical guideline, and a survey of the actual self-management conditions of patients with CHF (Otsu & Moriyama, 2008). The results of the survey showed, in particular, that the patients with CHF had inadequate knowledge of, and poor adherence to, a low-sodium diet. The patients who lacked such knowledge regarding a correct low-sodium diet developed more serious conditions. Consequently, we developed a CHF disease management program by which outpatients with CHF could acquire self-management skills. This program can contribute to the reduction of healthcare costs and the development of medical treatment by reducing the deterioration of patients with CHF and their readmission and by improving their quality of life (QOL).

METHOD

Development of the educational program

Consideration of a disease management program

An educational program and clinical indicators were developed by using the evidence-based clinical guidelines of the Heart Failure Society of America (HFSA, 2006), a Japanese evidence-based clinical guideline on CHF (revised version) (Association Study Group, 2005), and the results of a baseline examination by Otsu & Moriyama (2008).

The relationship between the framework and the clinical indicators in this program is shown in Figure 1. The left-side boxes with white downward arrows indicate the educational program and its process of skills acquirement by the intervention group participants. The right-side boxes with slightly slanting black arrows mean the type of assistance by the support people in this program: one nurse, one doctor, and/or the family. Furthermore, the thick, black downward arrows reflect improvements in the outcomes as a result of the implementation of this framework.

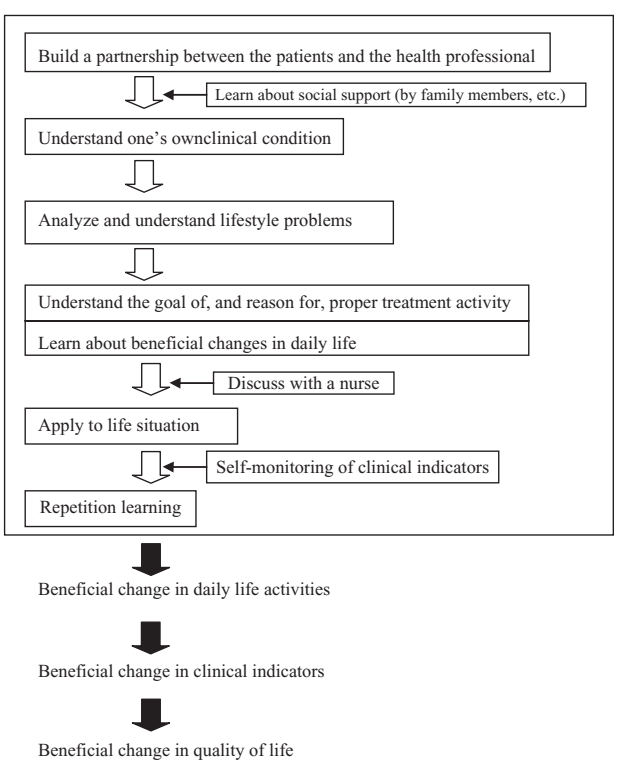

Figure 1 Framework of the educational program and indicative outcomes of the study.

Therefore, it is hypothesized that, after receiving appropriate education, as shown in Figure 1, outpatients with CHF will choose and carry out appropriate self-management activities and, as a result, will improve their clinical indicators and QOL.

Program description

The implementation period was set at 6 months, as the minimum time that is required to acquire self-care skills is >6 months (Prochaska, Norcross, & DiClemente, 1994). The program was carried out with a licensed nurse as the researcher, who followed the research protocol that we developed, and the same researcher also conducted the interviews. A 30 min session with an outpatient after a clinical examination was carried out each month. The six sessions consisted of the following: an introduction on "How to adjust to CHF" and "How to quit smoking" (if applicable), "A letter to the family", "A reduced sodium and fluid diet and how to stop drinking (alcohol)", "Self-management", "Medicine administration-monitoring", "Activities and exercises", and "How to control one's emotions". In particular, the outpatients with CHF who did not practise a restricted sodium diet were more likely to suffer from brain natriuretic peptide (BNP), a deteriorative indicator of CHF (Otsu & Moriyama, 2008), so this program aimed to provide them with appropriate knowledge about the low-sodium diet. The participants initially were required to record the contents of their meals over 4 days and then a researcher provided individual feedback regarding a correct low-sodium diet, based on a textbook by Makino (1998). In the first session, the researcher prepared a letter, describing ways to assist patients and skills such as self-care, self-monitoring, and self-management. This was given to the families. The researcher provided individual education to the intervention group members by using the textbook by Makino in the first half of the program and then discussing how to apply the knowledge in the second half of the program. In the first session, the correct amounts of sodium and fluid intake and activities or exercises, based on a doctor's directions for each patient, were provided. These amounts were set as the target values. At each session, the participants' level of compliance and performance at home was verified.

Regarding self-monitoring, a calendar was used to check the daily medicine and weight-monitoring of each patient in order to verify correct medicine administration, to monitor for signs of advancing deterioration in CHF symptoms, and to promote self-management. Furthermore, the heart function level of the participants in this study was slight-to-moderate, as determined by a doctor. Strict fluid intake restriction was not required at this time and was excluded from goal-setting, even though knowledge on this subject was provided. The researcher and each participant confirmed and reviewed the inspection data and compliance together at each visit and feedback for the participant and the primary doctor was provided.

This educational program was based on the adult learning method of learning through one's own experience and was based on the theory of cognitive behavior (Hori, 1996; Lindeman, 1989). Therefore, the researcher used the motivation interview method, which provides operant reinforcement through praise.

Qualification of the project team member and quality control of the program

The team consisted of a cardiovascular specialist, a nurse with >10 years of cardiovascular nursing experience in a cardiovascular unit, and a researcher with a nursing license. The doctor listed all of the outpatients with CHF that he had diagnosed and he was in charge of providing general care and reviewing the treatment results for all the participants. The nurse handled the data collection and general care and the researcher carried out the educational program and data assessment. Information was actively shared and the plan was closely followed. The researcher learned behavior-modification techniques and how to carry out a motivating interview and all the team members reviewed the implementation method and procedures, using the guidebook that was developed by the researcher.

Design and timeframe of the study

A randomized controlled trial was used and the enrollment of the participants occurred from August 20 to September 30 2007. The research was carried out from August 20 2007 to October 31 2008.

Eligibility criteria

The purpose of this program was to strengthen self-care activity, prevent disease deterioration, and improve QOL. The participants consisted of outpatients with CHF, regardless of age, sex, primary disease or complication, description of treatment, resident status, or family composition, whose heart function level was at Grades I–III, according to the New York Heart Association's (NYHA's) heart function levels (Criteria Committee, New York Heart Association, 1964), and who had the physical, mental, and cognitive competence to fully participate in this program. Hence, the exclusion criteria

in this program were: (i) dementia; (ii) mental illness; (iii) critical illness and end-stage disease; and (iv) those who were under long-term care (i.e. levels 4–5 by Japanese certification; Ministry of Health, Labor and Welfare, 2009). The sample size was estimated to be 100 participants because the α, β, and standard effect sizes for the two-way ANOVA were 0.05, 0.20, and 0.70, respectively.

Study procedures

After receiving written and oral consent from the participants, they were randomly divided into an intervention group and a control group by using a computer program. For the intervention group, a mental and social assessment interview was carried out. Subsequently, an interview and data collection were carried out each month for 6 months. The interview was conducted in a private room. The control group received standard treatment and care at a medical facility. Both groups were given follow-up reviews at 6 months and additional data was collected for 6 months after the intervention period.

The evaluation was carried out at the time of enrollment (baseline) and at 3, 6 (completion of the intervention), 9, and 12 months (6 months after the intervention). At the last session, the degree of satisfaction of the intervention group also was determined.

Evaluation index

Program completion rate and evaluation of the program by the participants

The probability of program completion and an evaluation of the program were carried out. The latter evaluation was based on a one-to-five point scale: 1 represented "Very bad" and 5 represented "Very good".

Primary outcomes

The primary outcomes were identified as: death due to CHF, hospital admission due to CHF, BNP data, the NYHA's heart function level, blood pressure (including systolic blood pressure, diastolic blood pressure, and pulse pressure), weight, and a deterioration in the symptoms related to CHF, such as arrhythmia, paroxysmal dyspnea, distention of the jugular vein, moist rale, ankle edema, coughing at night, and shortness of breath. The doctor measured the clinical indicators and recorded the results during the examinations and the intervention group members monitored any symptoms of deterioration related to CHF by themselves at home.

Secondary outcomes

The secondary outcomes were identified by using the MacNew Heart Disease Health-related Quality of Life (QOL) Instrument, as developed by Höfer, Lim, Guyatt, and Oldridge (2004), in order to measure the QOL of patients with heart disease, including patients with coronary artery and/or heart failure. This original scale consists of 27 items and we developed a Japanese version that consists of 19 items. The reliability, validity, and value were confirmed by Otsu, Moriyama, and Nakaya (2010). The subscale includes emotional, physical, and social conditions with a seven-grade scale. The scores were calculated from each condition or as a cumulative score, with a higher score representing a better condition. The researcher interviewed the participants, using the MacNew Heart Disease Health-related QOL Instrument, and assessed their condition from the results.

Process indicators

The process indicators were identified as compliance with a sodium-restricted diet, compliance with medicine administration, compliance with activities or exercise, quitting smoking and drinking, and the self-monitoring of weight and a deterioration in the symptoms of CHF. The self-monitoring of the deterioration in the symptoms of CHF included the monitoring of paroxysmal dyspnea, ankle edema, coughing at night, and shortness of breath. The level of compliance with sodium restriction, medicine, activities or exercise, and weight were described on a four-point scale (0–3), with a higher score representing greater compliance. Other indicators were evaluated as "Good" or "Poor". The researcher assessed compliance on the basis of the participants' self-reports.

Regarding the data-collection period of effect measurements, the process indicators were taken every month; the clinical and secondary outcomes were taken every 3 months.

Data analysis

Chi-squared tests and *t*-tests or Mann–Whitney *U*-tests were carried out after verifying normality at the time of enrollment (baseline) in order to analyze the basic attributes and physiological data. Regarding the compliance data in the process indicators, a four-level score was given for each compliance performance: 3.0 was given to the participants who were always in compliance, 2.0 was given to the participants who were partially in compliance, 1.0 was given to those who were slightly in compliance, and 0 was given to the patients who were not in compliance at all. After that, the

average compliance performance score was calculated for each group. A repeated comparative two-way ANOVA was carried out on the physiological data, such as the blood pressure, weight, BNP, NYHA's heart function level, process indicators (such as sodium restriction, medicine, activities, and weight-monitoring), and QOL score at 3, 6, 9, and 12 months between the intervention and control groups. Additionally, multiple comparisons were carried out if interaction effects were not confirmed but the main effect was confirmed within groups. The degree of satisfaction of the program was determined on a percentage basis. SPSS ver.15.0 (SPSS, New York, USA) was used for the analysis and a rate of <5% was considered to be significant.

Regarding the symptoms related to CHF and self-monitoring, the participants were divided into an "existence" group if they had any symptoms and into a "non-existence" group if they did not have any symptoms at all, according to the self-reported data. Regarding compliance with quitting smoking and/or drinking and the self-monitoring of a deterioration in symptoms, the participants also were divided into "existence" and "non-existence" groups. The former had very or mostly good compliance behavior and the latter had fairly or quite bad compliance behavior, according to the self-reported data. On this basis, the χ^2-test was carried out.

Ethical considerations

Approval from the ethics committee of the university of the researcher was obtained and all the necessary procedures for this research were carried out at the target facilities. The purpose and description of the study, method and type of data collection, method of publication of the research results, voluntary participation, refusal to participate (which did not result in any disadvantage), and protection of privacy were all explained. The participants' consent was obtained in writing. The data was managed by using serial numbers without personal names. Additionally, we explained that the control group members could participate in this program after the study period was over if they so desired.

RESULTS

Probability of program completion and evaluation of the program

One-hundred-and-four outpatients with CHF were enrolled in this study and were divided into two groups of 52 each. Immediately after this, two patients from the intervention group no longer could participate due to hospital admission. Thus, at the start there were 50 patients in the intervention group and 52 patients in the control group. The flow of participants in this study is shown in Figure 2. Moreover, one patient in the intervention group asked to withdraw after 1 month. Therefore, 49 patients in the intervention group completed the program, with a program completion probability of 98.0%. In contrast, the probability rate of the control group was 90.3%. The number of participants from the control group at the conclusion of the study was 47 due to one hospital admission for a deterioration in CHF symptoms after 2 months, one withdrawal after 3 months, one fatality due to gastric cancer after 4 months, one hospital admission due to pneumonia after 4 months, and one fatality due to an unknown cause after 5 months.

The educational self-management program was rated as either "good" or "very good" by 78.4% of the intervention group. In contrast, a small 6.1% of the group felt that the tasks were "a little difficult".

Baseline comparison between the groups

The variables of the participants are shown in Table 1. There was no significant difference between the two groups at baseline.

Examination of the effects of the program

Primary outcomes

There was no fatality due to CHF in either group. No one was hospitalized due to a deterioration in CHF symptoms during the program. However, there was one hospital admission for 30 days from the intervention group due to a deterioration in CHF symptoms after 6 months (after the end of the program) and one for 90 days from the control group after 3 months.

The interaction effects were not shown between the two groups regarding BNP as a result of the repeated two-way ANOVA, but the main effect was confirmed within the intervention group. Therefore, in addition, multiple comparisons were carried out and, as a result, there were significant differences regarding BNP in the intervention group at 3 months ($P = 0.032$) and at 6 months ($P = 0.002$) (Table 2).

There was no significant difference in the NYHA's heart function levels, but there was a 13.6% improvement in the intervention group after 12 months (Table 3). Regarding the systolic blood pressure, the interaction effects were not shown between the two groups as a result of the repeated two-way ANOVA, but the main effect was confirmed within the interven-

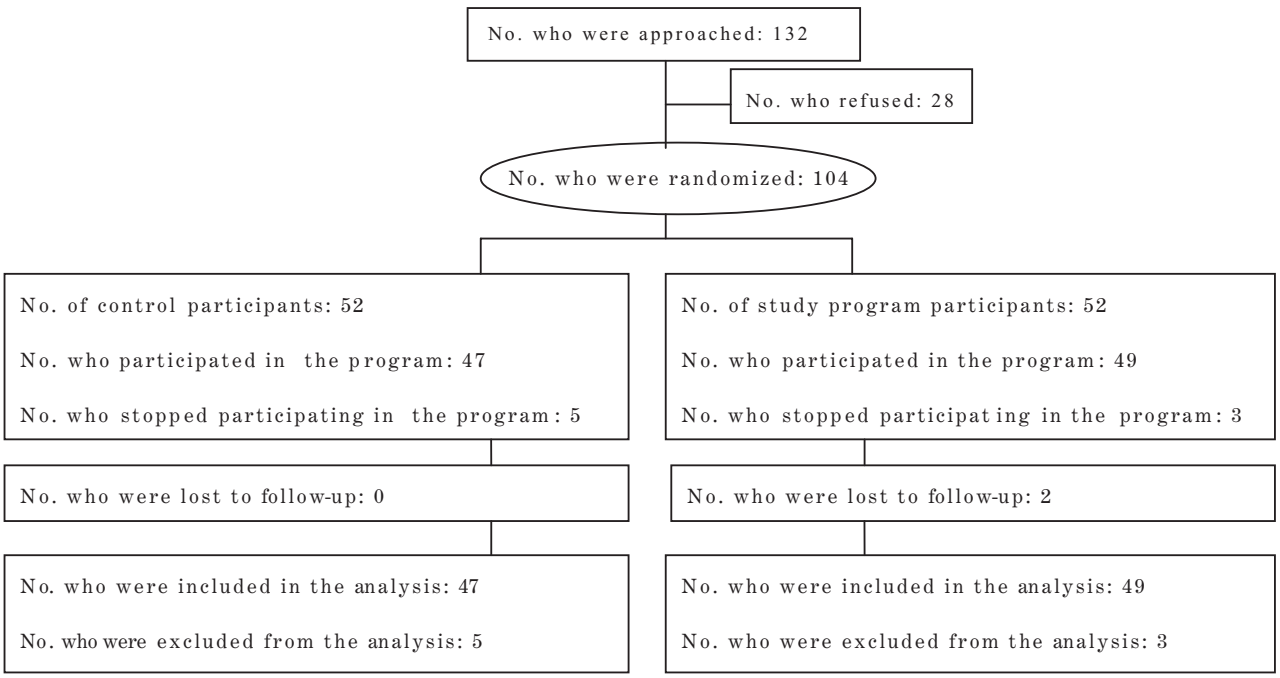

Figure 2 Participant flow in the study.

tion group. Therefore, in addition, multiple comparisons were carried out and, as a result, the systolic blood pressure in the intervention group improved significantly between 3 and 12 months ($P = 0.040$), 6 and 12 months ($P = 0.045$), and 9 and 12 months ($P = 0.025$). In contrast, there was no significant difference between the two groups regarding the diastolic blood pressure and pulse pressure (Table 2). Regarding the participants' weight, the intervention group significantly improved from the time of enrollment (baseline) and at 3, 9, and 12 months, at a rate of 5% (Table 2).

The related deterioration in the symptoms of CHF is shown in Table 4. The participants were divided into an "existence" group if they had any deterioration of symptoms and a "non-existence" group if they did not have any such symptoms at all, according to the self-reported data. On this basis, the χ^2-test was carried out. The control group showed significantly higher levels of shortness of breath at 3 months ($P = 0.038$), 9 months ($P = 0.011$), and 12 months ($P = 0.041$). There was no significant difference between the two groups regarding the other symptoms, such as arrhythmia, paroxysmal dyspnea, moist rale, ankle edema, and coughing at night.

Secondary outcomes

The results of the MacNew Heart Disease Health-related QOL Instrument are shown in Table 5. The total, emotional, physical, and social scores in the intervention group were significantly better at 6, 9, and 12 months, at a rate of 1%, as compared to the control group.

Process indicators

The participants were divided into an "existence" group and a "non-existence" group. The former had very or mostly good compliance behavior and the latter had fairly or quite bad compliance behavior, according to the self-reported data. On this basis, the χ^2-test was carried out. The level of compliance with medicine administration and activities or exercise was significantly high in the intervention group. However, there was no significant difference between the two groups regarding compliance with quitting smoking and drinking (Table 6). The implementation rate of self-monitoring regarding a deterioration in the symptoms of CHF in the intervention group significantly improved, as compared to the control group, at 6 and 12 months.

Table 1 Baseline comparison between the groups

Participant variable	Intervention group ($n = 49$) N (%) or mean ± SD	Control group ($n = 47$) N (%) or mean ± SD	*P*-value
Basic attributes			
Sex (male/female)	31 (63.3)/18 (36.7)	30 (63.8)/17 (36.2)	1.000
Age (years)	71.6 ± 9.3	74.6 ± 8.1	0.198
Living alone	7 (14.3)	6 (12.8)	1.000
Worker	13 (26.5)	6 (12.8)	0.125
Underlying disease			
Hypertension	40 (81.6)	36 (76.6)	0.620
Ischemic heart disease	16 (32.7)	22 (46.8)	0.211
Valvular disease	24 (49.0)	23 (48.9)	1.000
Cardiomyopathy	5 (10.2)	1 (2.1)	0.204
Blood pressure			
Systolic blood pressure	128.2 ± 11.9	131.2 ± 7.0	0.565
Diastolic blood pressure	71.3 ± 5.5	71.5 ± 4.7	0.881
Pulse pressure	57.7 ± 10.0	58.6 ± 9.4	0.656
Body weight	62.1. ± 11.4	62.7 ± 10.7	0.780
Clinical condition			
New York Heart Association's heart function Grade II	39 (79.6)	38 (80.9)	1.000
Brain natriuretic peptide	153.2 ± 149.1	163.6 ± 198.5	0.769
Arrhythmia	12 (24.5)	11 (23.4)	1.000
Paroxysmal dyspnea	0 (0.0)	0 (0.0)	–
Distention of the jugular vein	0 (0.0)	0 (0.0)	–
Moist rale	0 (0.0)	0 (0.0)	–
Ankle edema	3 (6.1)	0 (0.0)	0.242
Coughing at night	0 (0.0)	0 (0.0)	–
Shortness of breath	5 (10.2)	6 (12.8)	0.757
Curative drug			
Angiotensin-converting enzyme inhibitor	5 (10.2)	2 (4.3)	0.436
β-blocker	23 (46.9)	17 (36.2)	0.308
Digitalis product	10 (20.4)	13 (27.7)	0.477
Diuretic	24 (49.0)	22 (46.8)	0.841
Aldosterone antagonist	18 (36.7)	10 (21.3)	0.118
Angiotensin-receptor antagonist	16 (32.7)	20 (42.6)	0.400

DISCUSSION

Effectiveness of the intervention program

According to the process indicators, the level of compliance with a sodium-restricted diet and activities or exercise and the implementation of self-monitoring regarding weight and a deterioration of symptoms significantly improved in the intervention group, as compared to the control group, at ≥6 months. Furthermore, the data on BNP, an important clinical indicator of CHF deterioration, significantly improved at 3 and 6 months in the intervention group. Additionally, the MacNew Heart Disease Health-related QOL Instrument score significantly improved in the intervention group after 6 months. Therefore, based on this data, this program is considered to be effective as it could lead to disease management and help prevent a deterioration in symptoms.

Another reason why the program is considered to be effective is that it is based on an evidence-based guideline (Association Study Group, 2005; HFSA, 2006) and basic research that provides group characteristics (Otsu & Moriyama, 2008); thus, the program could satisfy the needs of the participants. From these results, it was thought that knowledge of CHF and self-management were easy to learn by the intervention group. Moreover, setting goals for each participant and the continuance of self-monitoring encouraged proper self-management behavior; therefore, the symptoms improved and, in turn, the QOL also improved. Hence, the evidence

Table 2 Changes in the physiological data

Variable	Intervention group (mean ± SD)					Control group (mean ± SD)					Two-way ANOVA (upper row: *F*-value; lower row: *P*-value)		
	Baseline	3 months	6 months	9 months	12 months	Baseline	3 months	6 months	9 months	12 months	Interaction	Between groups	Within groups
Systolic blood pressure (mmHg)	128.2 ± 11.9	131.0 ± 8.6	130.4 ± 12.9	129.6 ± 11.3	125.9 ± 10.9	131.2 ± 7.0	130.9 ± 11.2	130.8 ± 9.2	132.3 ± 10.3	129.3 ± 9.5	1.047 0.38	2.283 0.135	2.851 0.027*
Diastolic blood pressure (mmHg)	71.3 ± 5.5	72.7 ± 4.7	71.8 ± 5.1	71.2 ± 4.7	70.5 ± 5.5	71.5 ± 4.7	71.4 ± 3.9	70.9 ± 6.3	70.7 ± 4.4	71.7 ± 4.7	1.015 0.397	0.000 0.995	0.517 0.710
Pulse pressure (mmHg)	56.7 ± 9.3	58.0 ± 6.8	58.7 ± 9.7	58.0 ± 8.8	55.0 ± 11.0	60.1 ± 8.3	59.5 ± 9.5	60.1 ± 9.2	61.6 ± 11.1	57.7 ± 8.6	0.401 0.806	3.159 0.079	2.661 0.033*
Weight (kg)	62.1 ± 11.4	62.1 ± 11.7	61.8 ± 11.6	61.2 ± 11.7	60.6 ± 11.3	62.7 ± 10.1	62.3 ± 10.4	62.0 ± 11.0	61.8 ± 10.4	61.5 ± 11.0	0.696 0.513	0.049 0.826	10.882 0.000**
Brain natriuretic peptide (pg/mL)	153.2 ± 149.1	124.1 ± 126.1	111.2 ± 101.2	–	–	163.6 ± 198.5	165.3 ± 190.0	197.9 ± 188.2	–	–	2.423 0.128	3.220 0.051	4.234 0.022*

*$P < 0.05$, **$P < 0.01$.

Table 3 Changes in the New York Heart Association's heart function levels

New York Heart Association's heart function level	Baseline		3 months		6 months		9 months		12 months	
	Intervention group ($n = 50$) N (%)	Control group ($n = 52$) N (%)	Intervention group ($n = 49$) N (%)	Control group ($n = 47$) N (%)	Intervention group ($n = 49$) N (%)	Control group ($n = 47$) N (%)	Intervention group ($n = 49$) N (%)	Control } group ($n = 47$) N (%)	Intervention group ($n = 47$) N (%)	Control group ($n = 47$) N (%)
Grade I	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Grade II	40 (80.0)	41 (78.8)	40 (81.6)	37 (78.7)	43 (87.8)	35 (74.5)	42 (85.7)	35 (74.5)	44 (93.6)	37 (78.7)
Grade III	10 (20.0)	11 (21.2)	9 (18.4)	10 (21.3)	6 (12.2)	12 (25.5)	7 (14.3)	12 (25.5)	3 (6.4)	10 (21.3)
Grade IV	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
P-value	1.000		0.247		0.076		0.089		0.089	

Table 4 Presence of the symptoms of deterioration in chronic heart failure in the participants

		Intervention group ($n = 49$)		Control group ($n = 47$)		
Symptom	Period	Existence N (%)	Non-existence N (%)	Existence N (%)	Non-existence N (%)	*P*-value
Paroxysmal dyspnea	Baseline	0 (0.0)	49 (100.0)	0 (0.0)	47 (100.0)	–
	3 months	0 (0.0)	49 (100.0)	0 (0.0)	47 (100.0)	–
	6 months	0 (0.0)	49 (100.0)	0 (0.0)	47 (100.0)	–
	9 months	0 (0.0)	49 (100.0)	0 (0.0)	47 (100.0)	–
	12 months	0 (0.0)	47 (100.0)	0 (0.0)	47 (100.0)	–
Ankle edema	Baseline	3 (6.1)	46 (93.9)	0 (0.0)	47 (100.0)	0.242
	3 months	5 (10.2)	44 (89.8)	0 (0.0)	47 (100.0)	0.056
	6 months	2 (4.1)	47 (95.9)	1 (2.1)	46 (97.9)	1.000
	9 months	2 (4.1)	47 (95.9)	2 (4.3)	45 (95.7)	1.000
	12 months	1 (2.1)	46 (97.9)	2 (4.3)	45 (95.7)	1.000
Coughing at night	Baseline	0 (0.0)	49 (100.0)	0 (0.0)	47 (100.0)	–
	3 months	0 (0.0)	49 (100.0)	2 (4.3)	45 (95.7)	0.237
	6 months	0 (0.0)	49 (100.0)	1 (2.1)	46 (97.9)	0.490
	9 months	1 (2.0)	48 (98.0)	0 (0.0)	47 (100.0)	1.000
	12 months	0 (0.0)	47 (100.0)	0 (0.0)	47 (100.0)	–
Shortness of breath	Baseline	5 (10.2)	44 (89.8)	7 (12.8)	41 (87.2)	0.757
	3 months	3 (6.1)	46 (93.9)	10 (21.3)	37 (78.7)	0.038*
	6 months	5 (10.2)	44 (89.8)	11 (23.4)	36 (76.6)	0.104
	9 months	3 (6.1)	46 (93.9)	12 (25.5)	35 (74.5)	0.011*
	12 months	3 (6.4)	44 (93.6)	11 (23.4)	36 (76.6)	0.041*

*$P < 0.05$.

supporting the hypothesis in Figure 1 could be validated and the framework was considered to be effective.

A follow-up review 6 months after the implementation of the program was conducted and, as a result, physiological data, such as blood pressure and weight, and compliance behaviors, except for quitting smoking and drinking, improved and could be maintained. The QOL scores in the intervention group were significantly better, as compared to the control group, although the scores in the intervention group decreased after the program. For these reasons, the effectiveness of the program, which aimed to continuously reinforce the participants' knowledge of CHF and to teach behavior modification, could be maintained.

From the above, it can be shown that this program was very effective for disease management overall, as the intervention group was self-motivated to carry out primary health care and the clinical and secondary outcomes improved.

Operation of the program

The completion probability rate was 98.0%, which is a very high rate. A relationship of trust between the health professionals (including the researcher) and the participants could be established and the teamwork between the local physician and the researcher is considered to be the main reason for this very high completion probability rate.

In addition, the intervention group participants were given the task of self-monitoring and received feedback on the results of the task and examination data each month. They were praised for their efforts. This process gradually led to repeated self-examination, habitual self-monitoring, confidence, and an interest in self-management, as well as the very high completion probability.

Although many of the participants in the study were elderly, they did not feel burdened by the tasks, such as self-monitoring each month, and personally wished to continue the tasks after the intervention. Even after the completion of this study, the participants considered this program to be suitable and planned to continue the program's routine.

Moreover, the satisfaction level of the program was 78.4% and there was no reply of dissatisfaction, so the degree of participant satisfaction is considered to be very high. Only one participant felt that he could not participate sufficiently, as a result of his work commitments.

Table 5 Changes in the quality of life and level of compliance with the chronic heart failure self-management program of the participants

Variable	Intervention group (mean ± SD)				Control group (mean ± SD)				Two-way ANOVA (upper row: *F*-value; lower row: *P*-value)		
	Baseline	6 months	9 months	12 months	Baseline	6 months	9 months	12 months	Interaction	Between groups	Within groups
MacNew Heart Disease Health-related Quality of Life Instrument											
Total	6.16 ± 0.58	6.65 ± 0.61	6.41 ± 0.61	6.20 ± 0.60	6.17 ± 0.59	6.29 ± 0.48	5.87 ± 0.65	5.65 ± 0.85	10.314	10.097	26.157
									0.000**	0.002**	0.000**
Emotional	6.07 ± 0.55	6.59 ± 0.55	6.35 ± 0.59	6.08 ± 0.64	6.09 ± 0.66	6.24 ± 0.57	5.82 ± 0.59	5.53 ± 0.89	8.173	10.616	30.080
									0.000**	0.002**	0.000**
Physical	6.27 ± 0.69	6.69 ± 0.69	6.49 ± 0.66	6.29 ± 0.64	6.23 ± 0.68	6.34 ± 0.53	5.92 ± 0.74	5.68 ± 0.09	7.559	9.906	20.161
									0.000**	0.002**	0.000**
Social	6.40 ± 0.64	6.79 ± 0.61	6.64 ± 0.63	6.45 ± 0.67	6.45 ± 0.61	6.54 ± 0.48	6.15 ± 0.73	5.78 ± 0.99	10.160	8.345	21.385
									0.000**	0.005**	0.000**
Compliance											
Sodium restriction	1.72 ± 1.04	2.72 ± 0.62	2.53 ± 0.65	2.47 ± 0.69	1.71 ± 0.97	1.80 ± 0.97	1.64 ± 0.88	1.73 ± 0.96	10.654	21.150	12.467
									0.000**	0.000**	0.000**
Medicine	2.57 ± 0.62	2.85 ± 0.36	2.94 ± 0.25	2.83 ± 0.43	2.53 ± 0.69	2.71 ± 0.55	2.71 ± 0.55	2.69 ± 0.51	0.904	2.794	9.218
									0.425	0.098	0.000**
Activities/exercises	0.11 ± 0.31	2.49 ± 0.72	2.53 ± 0.65	2.36 ± 0.67	0.18 ± 0.65	1.31 ± 1.08	0.56 ± 0.66	0.73 ± 0.86	39.739	179.294	12.524
									0.000**	0.000**	0.000**
Weight-monitoring†	0.66 ± 0.76	2.49 ± 0.69	–	2.53 ± 0.62	1.07 ± 0.88	1.46 ± 1.00	–	1.22 ± 1.07	68.801	18.248	122.184
									0.000**	0.000**	0.000**

**$P < 0.01$. †Analysis of the weight-monitoring at 9 months was excluded due to a large number of missing values.

Table 6 Compliance with the self-management program for chronic heart failure

Compliance behavior	Period	Intervention group Good N (%)	Intervention group Poor N (%)	Control group Good N (%)	Control group Poor N (%)	*P*-value
Quit smoking	Baseline	42 (85.7)	7 (14.3)	46 (97.9)	1 (2.1)	0.059
	6 months	46 (93.9)	3 (6.1)	45 (95.7)	2 (4.3)	1.000
	9 months	44 (89.8)	5 (10.2)	46 (97.9)	1 (2.1)	0.204
	12 months	42 (89.4)	5 (10.6)	46 (97.9)	1 (2.1)	0.203
Quit drinking	Baseline	32 (65.3)	17 (34.7)	38 (80.9)	9 (19.1)	0.110
	6 months	28 (57.1)	21 (42.9)	32 (68.1)	15 (31.9)	0.298
	9 months	29 (59.2)	20 (40.8)	30 (63.8)	17 (36.2)	0.679
	12 months	27 (57.4)	20 (42.6)	28 (59.6)	19 (40.4)	1.000
Symptom deterioration	Baseline	14 (28.6)	35 (71.4)	11 (23.4)	36 (76.6)	0.645
	6 months	31 (63.3)	18 (36.7)	14 (29.8)	33 (70.2)	0.001**
	12 months	31 (66.0)	16 (34.0)	18 (38.3)	29 (61.7)	0.013*

*$P < 0.05$, **$P < 0.01$.

Thus, a telephone or email consultation service and educational material are also needed for working people. The development of a program that matches the lifestyle of those who are working is needed in the future.

Limitations of the study and future tasks

As the participants in this study were retired elderly persons, no problem was observed in relation to completing the program. However, other methods of consultation, such as telephone or mail, in addition to interviews, are considered necessary for future participants who are younger, still working, and/or raising children.

This program provided knowledge on CHF and was easy to implement, so it could be provided by a nurse who is not a cardiovascular specialist and, from this standpoint, it has great utilization potential. For its future adoption in nursing practise, it is assumed that a nurse can provide the program to 60–100 outpatients per month because it was possible for three-to-five outpatients to participate per day. However, implementation is thought to be difficult for hospitals with >200 beds without charging a medical treatment fee and for facilities with an insufficient number of nursing staff members. The introduction of this program requires the cooperation of the nursing staff and the business manager.

It is essential for the validation of this program that further large-scale trials are carried out in order to generalize this study, even though it was successful for 49 outpatients in the intervention group.

Some further development is necessary for future studies. For example, in regard to compliance, the data was self-reported and was left to the judgment of the individual. However, the basis for measuring compliance was ambiguous to some extent. Thus, in addition to subjective data, objective data should be developed.

CONCLUSIONS

There was no significant difference between the intervention and control groups in regard to smoking and drinking. It meant that these aspects of compliance behavior did not improve during the 6 month program. As they related to lifestyle habits, enhanced motivational programs in the long term are needed to improve such lifestyles.

Further continued long-term care is necessary for outpatients with CHF in order to prevent their deterioration and to maintain their health status, although this 6 month program did provide the participants with appropriate knowledge regarding self-care for CHF and, moreover, the program positively affected the patients' therapy results. No previous study has been reported on continued long-term care after an educational program of several months, so further research requires careful attention.

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