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ORIGINAL ARTICLE
Mobile apps

The AppCare-HF randomized clinical trial: a feasibility study of a novel self-care support mobile app for individuals with chronic heart failure

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Aims We evaluated a self-care intervention with a novel mobile application (app) in chronic heart failure (HF) patients. To facilitate patient-centred care in HF management, we developed a self-care support mobile app to boost HF patients' optimal self-care.

Methods and results We conducted a multicentre, randomized, controlled study evaluating the feasibility of the self-care support mobile app designed for use by HF patients. The app consists of a self-monitoring assistant, education, and automated alerts of possible worsening HF. The intervention group received a tablet personal computer (PC) with the self-care support app installed, and the control group received a HF diary. All patients performed self-monitoring at home for 2 months. Their self-care behaviours were evaluated by the European Heart Failure Self-Care Behaviour Scale. We enrolled 24 outpatients with chronic HF (ages 31–78 years; 6 women, 18 men) who had a history of HF hospitalization. During the 2 month study period, the intervention group ($n = 13$) showed excellent adherence to the self-monitoring of each vital sign, with a median [interquartile range (IQR)] ratio of self-monitoring adherence for blood pressure, body weight, and body temperature at 100% (92–100%) and for oxygen saturation at 100% (91–100%). At 2 months, the intervention group's self-care behaviour score was significantly improved compared with the control group ($n = 11$) [median (IQR): 16 (16–22) vs. 28 (20–36), $P = 0.02$], but the HF Knowledge Scale, the General Self-Efficacy Scale, and the Short Form-8 Health Survey scores did not differ between the groups.

Conclusion The novel mobile app for HF is feasible.

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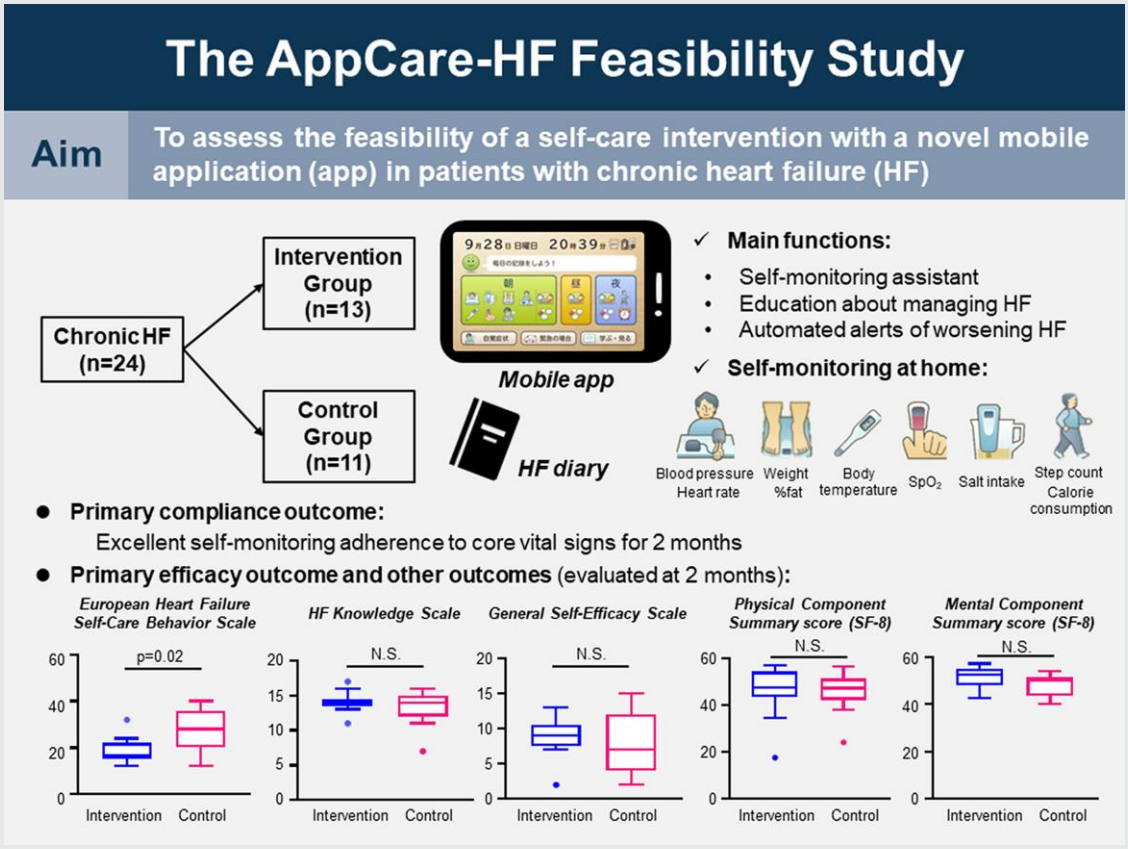
Graphical Abstract



Keywords Digital health • Feasibility • Heart failure • Mobile app • Self-care

Introduction

The morbidity and mortality of patients with chronic heart failure (HF) remain high despite the major advances in pharmacological and non-pharmacological treatments for HF, and this has led to considerable clinical and economic burdens for healthcare systems worldwide.[1] Individuals who are hospitalized for acute decompensated HF commonly suffer functional decline, rehospitalization, and death due to their HF.[2,3] Improving patients' outcomes after the onset of acute decompensated HF is a national healthcare priority in many countries.[1] In addition to the established risk factors for HF, poor self-care is significantly associated with worse clinical outcomes in patients with chronic HF.[4–6]

Multidisciplinary management programs designed to encourage patients' self-care that also provide support from healthcare professionals have been shown to improve the outcomes of patients with chronic HF.[7] It was demonstrated that a home-based self-care intervention by nurses improved HF patients' mental health and reduced the risk of hospitalizations for worsening HF.[8,9] However, human resources in healthcare are limited in many countries, and alternative strategies have thus been advocated for chronic HF patients to help them be actively involved in their own care.

Digital therapeutics using mobile technology is a promising therapeutic approach to facilitate patient-centred care in HF management. We developed a new application (app) for a smartphone or tablet personal computer (PC) to encourage HF patients' self-care behaviour at home. Several mobile health (mHealth) apps are currently available for HF patients,[10] and several studies have shown the efficacy of self-care support by mobile apps.[11–14] However, there is no mHealth app to help patients record multiple vital signs (e.g. blood pressure, heart rate, body weight, percent fat, body temperature, and oxygen saturation) plus physical activity and daily salt intake measured by sensor devices for the self-monitoring of patients' health conditions at home.

We therefore conducted the present study to (i) investigate the feasibility of the self-care intervention using our new app named 'Mimamori-cho' with various measurement devices in patients with chronic HF and (ii) examine whether this mobile app improves patient's self-care behaviour.

Methods

Study design and patients

This Mobile Application for Self-Care Support of Patients with Chronic HF (AppCare-HF) feasibility study was a three-site, randomized, controlled study of a self-care support intervention using a newly developed mobile app for outpatients with chronic HF. The study was designed to determine the feasibility of the self-care intervention using

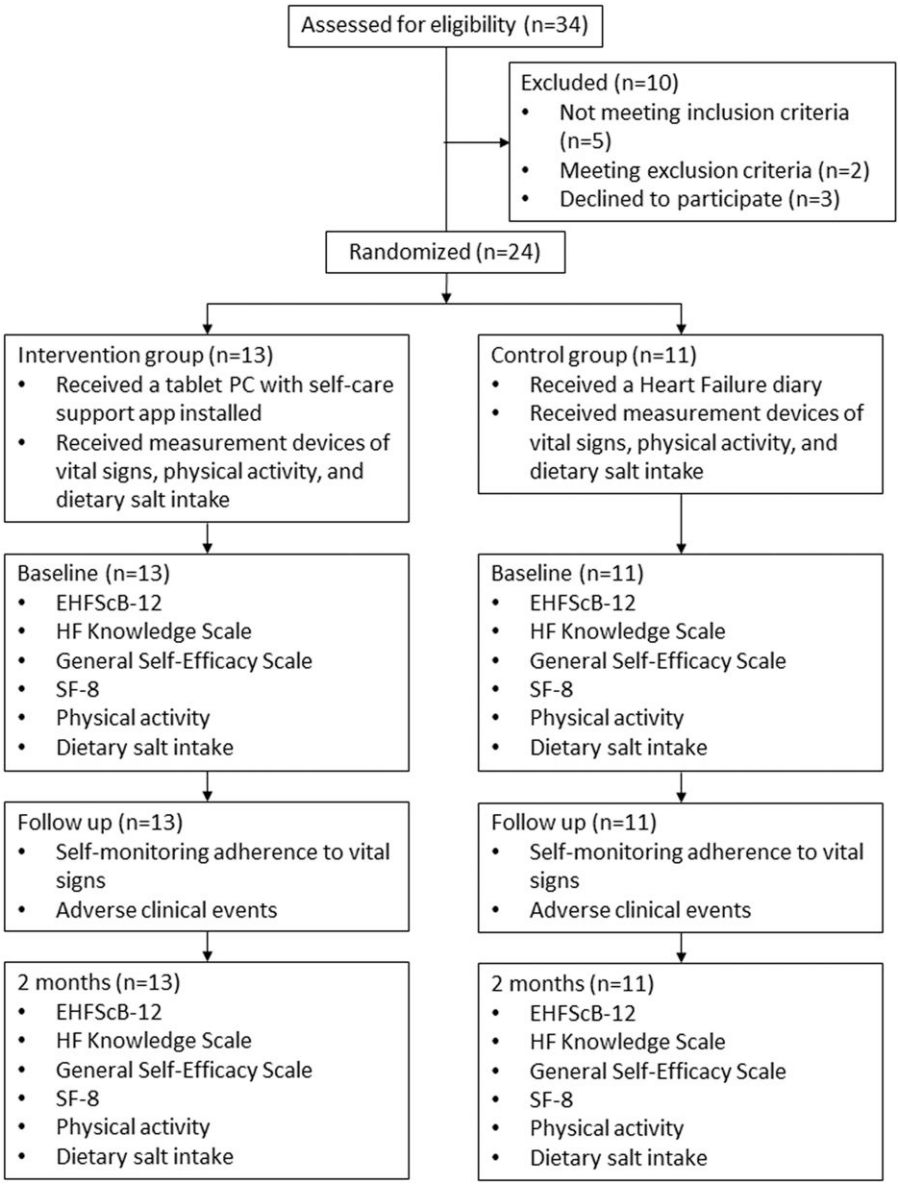


Figure 1 Flowchart of the study. EHFScB-12: the 12-item version of the European Heart Failure Self-Care Behaviour Scale, SF-8: Short Form-8 Health Survey.

this app by evaluating the patients' adherence to the self-monitoring of their vital signs at home.

Patients were eligible for participation if they were ≥20 years old and were outpatients who had a history of one or more hospital admissions for acute decompensated HF which met the Framingham HF diagnostic criteria[15] regardless of the ejection fraction. The definition of chronic HF was drawn from the 2022 American College of Cardiology American Heart Association/Heart Failure Society of America (ACC/AHA/HFSA) Guideline for the Management of Heart Failure.[16] Our study's exclusion criteria included the inability to use a tablet PC due to visual or functional impairment such as impaired cognitive function, the inability to use a urinary sodium excretion level monitor (e.g. by advanced renal failure patients undergoing dialysis), and a terminal illness other than HF.

The study was approved by the institutional review board at each participating hospital (Hokkaido University Hospital, Sapporo Municipal Hospital, and Otaru Kyokai Hospital), and the investigation conformed to the principles outlined in the Declaration of Helsinki, and the study is registered on UMIN-CTR (no. UMIN000015843). We recruited patients with chronic HF who were followed at the outpatient ward of each hospital. Written informed consent was obtained from each patient before his or her participation in the study.

After we obtained a participant's written informed consent, participants were randomly assigned in a 1:1 fashion to either the self-care support mobile app intervention group or the control (i.e. usual-care) group (*Figure 1*), using the Excel RAND function that automatically generates random numbers between 0 and 1 (for the intervention group, ≥ 0.5, and for the control group, < 0.5). Based on other studies that evaluated the feasibility of a self-care support intervention in patients with chronic HF (who had prior HF-related events including hospitalization at the enrolment) during 1.5–3 months of follow-up,[17–19] the

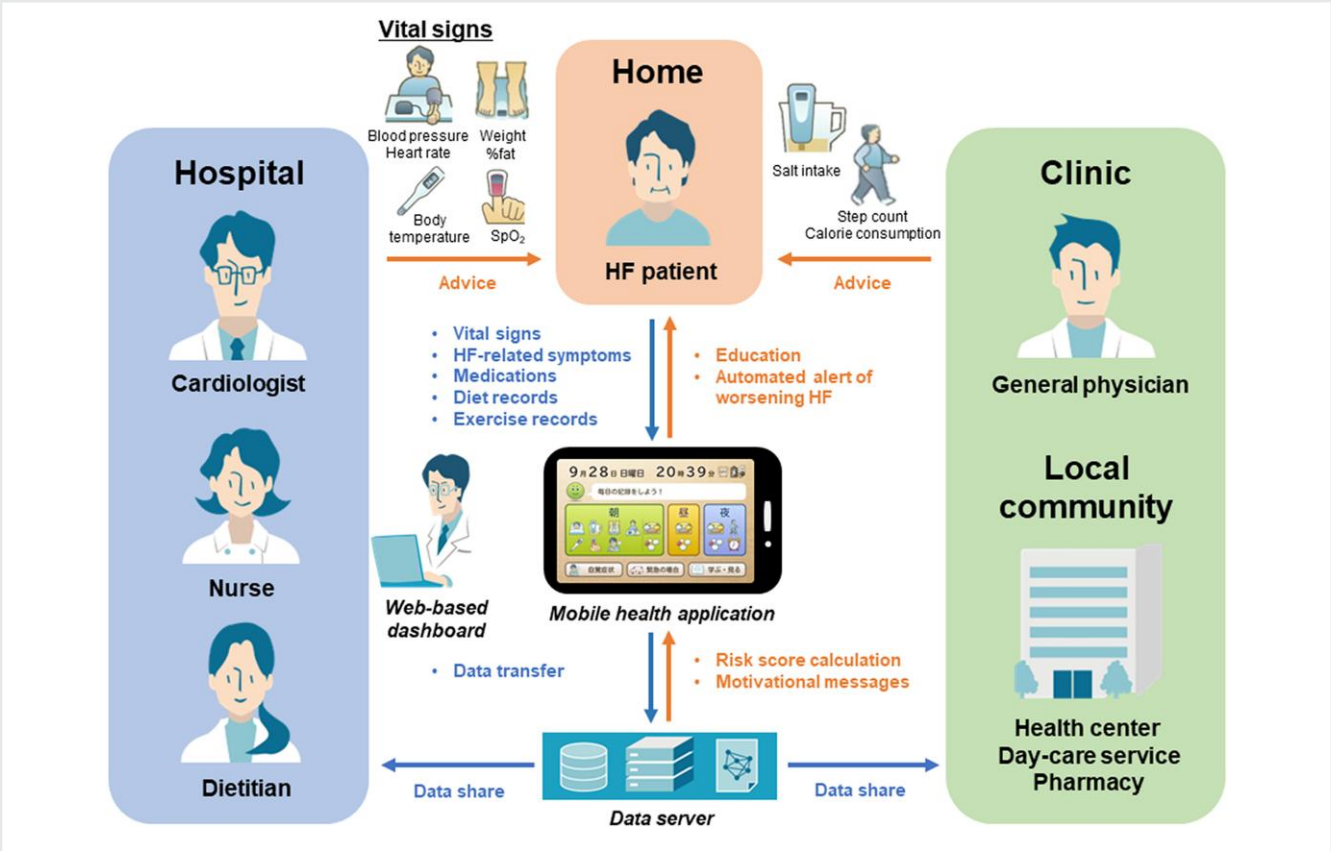


Figure 2 Overview of the self-care support system for individuals with chronic heart failure using the novel mobile app.

Table 1 Risk scores used for the calculation of automated alert algorithm for worsening heart failure (HF) in the novel app

Score	Parameter
1 point	Weight gain ≥1 kg within 1 week
	Heart rate ≥100 b.p.m.
	SBP ≥160 mmHg
	SBP ≤80 mmHg
	Body temp. ≥ 37.5°C
	Presence of either of HF-related symptoms or signs[a]
2 points	Oxygen saturation ≤93%
3 points	Weight gain ≥2 kg within 1 week
	Presence of orthopnoea[b]
	Presence of near-fainting[c]

[a]One point is added when each HF-related symptom or sign is present for ≥3 days within a week.
[b]The additional question about whether the patient has orthopnoea is asked only when he or she selects the presence of 'shortness of breath'.
[c]The additional question about whether the patient has near-fainting (which may be related to arrhythmia) is asked only when he or she selects the presence of 'palpitation'. SBP, systolic blood pressure. The total risk score ≥3 points is defined as a potential risk of worsening HF.

present patients were followed by cardiologists at the outpatient ward of each hospital for 2 months (*Figure 1*). During the study period, two visits (at 1 month and at 2 months) were the minimum scheduled outpatient visits after the initiation of the study.

The patients' baseline demographics and clinical data were extracted from their clinical charts. The estimated glomerular filtration rate (eGFR) was calculated from the serum creatinine values and the patient's age with the use of the Japanese equation[20]: $eGFR = 194 \times (\text{serum creatinine, mg/dL})^{-1.094} \times (\text{age, years})^{-0.287} \times (0.739 \text{ if female})$. Self-report questionnaires (paper versions) were used to evaluate the patients' outcomes: the 12-item version of the European Heart Failure Self-Care Behaviour Scale (EHFScB-12), the HF Knowledge Scale, the General Self-Efficacy Scale, and the Short Form-8 Health Survey (SF-8), which were collected from the participants by our clinical research coordinators, independently of clinicians, at baseline and at 2 months later (*Figure 1*).

Self-care support intervention group

The mobile app for Android and iOS, named 'Mimamori-cho' (which means 'a diary for watching over' in Japanese), is like having healthcare professionals at home. It was newly developed by healthcare professionals including cardiologists, HF nurses, dietitians, physiotherapists, and psychotherapists at Hokkaido University (Sapporo, Japan) and Hitachi, Ltd. (Tokyo), as an adjunct to usual HF care. Its architecture consists of a mobile app to support HF patients' self-care at home, a web-based dashboard of the patient's self-monitoring data for

Figure 3 Interface of the novel mobile app for patients with chronic HF. (*A*) Menu icons are listed with simplified messages (upper side) to guide the patient's daily self-care on the display of the app. (*B*) Self-monitoring icons that should be recorded in the morning are listed on the app. *Top*: Sleep, daily salt intake, body weight, blood pressure, heart rate, and meal pictures or contents (from the left). *Bottom*: Body temperature, oxygen saturation, HF-related symptoms or signs, and medications (from the left). (*C*) The patient inputs his or her body weight value in the app.

healthcare providers, and a data server for information management (*Figure 2*).

This mobile app has three key functions: (i) a self-monitoring 'assistant' that automatically creates clear graphs of six vital signs (blood pressure, heart rate, body weight, percent fat, body temperature, and oxygen saturation), HF-related symptoms or signs (shortness of breath, palpitation, fatigue, oedema, dizziness, loss of appetite, and reduced urine output), sleep (good sleep or not), physical activity (step count and calorie consumption), daily salt intake, dietary records (meal contents), exercise records (type of exercise), and medication records (taking medication or not), enabling a review of the patient's health condition, along with motivational messages to promote optimal self-care; (ii) educations that help increase the patient's knowledge about managing his or her HF; and (iii) automated alerts of possible worsening HF that use an algorithm calculated based on predetermined risk scores (*Table 1*) according to changes in individual vital signs and the presence of HF-related symptoms or signs over the past 7 days. The details of this mobile app are shown in the Supplementary material online, *Materials*.

All of the patients randomized to the intervention group ($n = 13$) received a tablet PC (7 inch size) in which the self-care support app was pre-installed, and they were instructed by a cardiologist to engage in self-care at home using this app. To increase the generalizability of the study outcomes, the following measurement devices were also provided to all of the patients in the intervention group even if the patients had their own: a blood pressure monitor (model BP301, Tanita Co., Tokyo), a body composition monitor (model BC503, Tanita Co.) (or a weight scale for patients who had an implantable cardioverter–defibrillator), a digital thermometer (model V965CJ, Vicks Co., South Yorkshire, UK), a pulse oximeter (Pulse One PMP-100B, Pacific Medico Co., Tokyo), a pedometer with an accelerometer (Lifecorder GS, Suzuken Co., Nagoya, Japan), and a urinary sodium excretion level monitor (model KME-03, Kohno ME Institute, Kawasaki, Japan) for the evaluation of the patient's vital signs, physical activity, and daily salt intake at home.

Typically, the patients measured their blood pressure, heart rate, body weight, percent fat, body temperature, oxygen saturation, and daily salt intake (which reflects the previous day's salt intake) in the morning and recorded these values together with any HF-related symptoms or signs in the app (*Figure 3*). They also measured their physical activity during the daytime and recorded it in the app in the evening.

Control group

The patients randomized to the control group ($n = 11$) were also instructed by a cardiologist to engage in self-care at home by using the HF diary published by the Japanese Heart Failure Society. This paper-based diary consists of two elements: a booklet to record vital signs and HF-related symptoms or signs and a booklet of education to encourage the patient's self-care. Both of these booklets are widely used in clinical HF settings in Japan. The control group patients also received the same measurement devices as those described above for the intervention group, to enable them to evaluate their vital signs, physical activity, and daily salt intake at home.

Outcome measures

The primary compliance outcome measure was adherence to the self-monitoring of four core vital signs (blood pressure, body weight, body temperature, and oxygen saturation) for 2 months. The adherence to self-monitoring was evaluated by the patient's records in the app (intervention group) or in the HF diary (control group). A day of adherence to self-monitoring was defined as each of the four abovedescribed vital signs being recorded ≥1×/day, and the ratio of adherence (%) was calculated as the number of days adherent to self-monitoring/the number of days during the study period.

The study's primary efficacy outcome measure was self-care behaviour evaluated by the Japanese version of the EHFScB-12 at 2 months. The EHFScB-12 is a well-validated, self-administered questionnaire for HF patients in which each item is rated on a Likert scale ranging from 1 (*I completely agree*) to 5 (*I don't agree at all*); the combined total score ranges from 12 to 60 points, with a lower score reflecting better self-care practice.[21,22] The EHFScB-12 covers three components: (i) self-care activities including daily body weight measurement, sodium and fluid restriction, regular exercise, medications, and flu prevention; (ii) consulting behaviours,

Table 2 The characteristics of the patients with chronic heart failure at study enrolment

	Total ($n = 24$)	Intervention ($n = 13$)	Control ($n = 11$)
Age, years	60 (50–67)	55 (50–68)	60 (55–65)
Age ≥65 years	8 (33%)	5 (38%)	3 (27%)
Female	6 (25%)	3 (23%)	3 (27%)
BMI, kg/m^2	23.6 (21.0–27.4)	23.7 (20.5–28.6)	23.1 (20.9–27.4)
Living alone	6 (25%)	2 (15%)	4 (36%)
Habit of daily self-monitoring at home	14 (58%)	8 (62%)	6 (55%)
Tablet PC or smartphone use experience	9 (38%)	5 (38%)	4 (36%)
Diagnosed as having chronic HF for ≥1 year	16 (67%)	8 (62%)	8 (73%)
Hospitalized for HF in past 3 months	11 (46%)	6 (46%)	5 (45%)
NYHA class			
I/II	14 (58%)	8 (62%)	6 (55%)
III	10 (42%)	5 (38%)	5 (45%)
Primary cause of HF			
Ischaemic cause	7 (29%)	3 (23%)	4 (36%)
Dilated cardiomyopathy	5 (21%)	3 (23%)	2 (18%)
Others	12 (50%)	7 (54%)	5 (45%)
LVEF, %	32 (24–46)	33 (23–45)	32 (27–46)
Preserved EF (LVEF ≥50%)	4 (17%)	2 (15%)	2 (18%)
Comorbidities:			
Diabetes	6 (25%)	1 (8%)	5 (45%)
Dyslipidaemia	14 (58%)	6 (46%)	8 (73%)
Atrial fibrillation	8 (33%)	3 (23%)	5 (45%)
COPD	4 (17%)	2 (15%)	2 (18%)
Laboratory data			
Haemoglobin, g/dL	14.4 (12.8–15.8)	14.4 (12.8–15.8)	14.5 (13.4–14.9)
eGFR, mL/min/1.73 m^2	56.1 (38.9–66.4)	55.5 (40.7–66.4)	62.3 (35.8–71.9)
Serum sodium, mmol/L	138 (137–140)	139 (137–141)	138 (136–139)
BNP, pg/mL	110.5 (34.5–337.4)	129.3 (31.4–415.7)	56.8 (34.4–209.2)
HF therapies			
ACE inhibitor or ARB	23 (96%)	13 (100%)	10 (91%)
β-blocker	22 (92%)	11 (85%)	11 (100%)
MRA	11 (46%)	7 (54%)	4 (36%)
Loop diuretic agent	20 (83%)	11 (85%)	9 (82%)
CRT	1 (4%)	0 (0%)	1 (9%)
ICD	8 (33%)	3 (23%)	5 (45%)

Data are median (IQR) or *n* (%). ACE, angiotensin-converting enzyme; ARB, angiotensin II receptor blocker; BMI, body mass index; BNP, B-type natriuretic peptide; COPD, chronic obstructive pulmonary disease; CRT, cardiac resynchronization therapy; eGFR, estimated glomerular filtration rate; ICD, implantable cardioverter–defibrillator; LVEF, left ventricular ejection fraction; MRA, mineralocorticoid receptor antagonist; NYHA, New York Heart Association.

i.e. whether the patient contacts a physician or nurse when the patient experiences an increase in any HF-related sign or symptom (e.g. shortness of breath, swollen leg, fatigue, or weight gain); and (iii) adaptive activities such as getting enough rest for prevention of worsening HF.[21] Other measures included the HF Knowledge Scale,[23] the General Self-Efficacy Scale,[24] and the SF-8[25] at 2 months. The details of other measures are shown in the Supplementary material online, *Materials*.

The patients' daily physical activity [i.e. step count and movement-related calorie consumption (MCC)] at baseline (for ≥7 days before the start of the study) and at 2 months (for the last 7 days of the 2 month study period) was evaluated by a pedometer with an accelerometer as described.[26,27] The patients' daily salt intake at baseline (for the first 7 days of the study period) and at 2 months (for the last 7 days of the study period) was evaluated by a urinary salt excretion level monitor as described.[28,29]

We also obtained a summary of each patient's adverse clinical events (all-cause death, cardiovascular death, all-cause hospitalization, cardiovascular hospitalization, or HF-related hospitalization) and unscheduled hospital visits due to HF-related signs or symptoms from the patient's and healthcare professionals' reports as well as our review of the patient's medical records.

Statistical analysis

For the self-monitoring adherence rate, under a SD of 35%, the one-sided width of the 95% confidence interval was 32.7% for the self-monitoring

adherence rate concerning the blood pressure of HF patients,[30] which was enough to evaluate a group difference of ~30%. Finally, the sample size was set at 10 persons per group based on the present investigation's design as a feasibility study. The data are presented as the median [interquartile range (IQR)] for continuous variables and as numbers (percentages) for categorical variables.

We had planned to compare the self-monitoring adherence rates of the intervention and control groups by using the mean difference and *t*-test, but it became apparent that it was inappropriate to discuss the mean difference between the two groups because of the many patients with perfect adherence. We thus compared the self-monitoring adherence rates during the 2 months of the study period between the intervention and control groups by using the Mann–Whitney U-test. In accord with this change, Mann–Whitney U-tests were also used to compare other continuous variables between the groups. When we compared categorical variables, we used the χ^2 test. We also compared the differences in the values or scores at 2 months minus the values or scores at baseline within the group between the intervention and control groups as a post-hoc analysis by using the Mann–Whitney U-test. These values or scores at baseline and at 2 months were compared within each group by a Wilcoxon signed rank test. All analyses were performed using GraphPad Prism ver. 9 software (GraphPad Software, San Diego, CA). A two-tailed *P*-value <0.05 was considered significant.

Table 3 Adherence to self-monitoring of vital signs during the study period

	Intervention ($n = 13$)	Control ($n = 11$)	*P*-value
Blood pressure			
Adherence, %	100 (92–100)	100 (97–100)	0.95
No. of patients who achieved 100% adherence	7 (54%)	6 (55%)	0.97
Body weight			
Adherence, %	100 (92–100)	100 (97–100)	0.53
No. of patients who achieved 100% adherence	8 (62%)	8 (73%)	0.56
Body temperature			
Adherence, %	100 (92–100)	100 (97–100)	0.53
No. of patients who achieved 100% adherence	8 (62%)	8 (73%)	0.56
Oxygen saturation			
Adherence, %	100 (91–100)	100 (97–100)	0.41
No. of patients who achieved 100% adherence	7 (54%)	8 (73%)	0.34

Data are median (IQR) or *n* (%). The adherence to the self-monitoring of these four core vital signs was evaluated by the records in the app (intervention group) or in the HF diary (control group). A day of adherence to self-monitoring was defined as each vital sign being recorded ≥1×/day. The ratio of adherence (%) was calculated as the number of days adherent to self-monitoring/the number of days during the study period in each patient. A 100% adherence value is achieved when the patient records each vital sign ≥1×/day during the study period.

Results

A total of 24 stable outpatients with chronic HF were randomized into the intervention group ($n = 13$) and control group ($n = 11$). All 24 patients had stage C or stage D chronic HF based on the ACCF/AHA guidelines.[31] The baseline characteristics of the two groups are summarized in *Table 2*. The median age (IQR) was 60 (50–67) years; 18 (75%) of the patients were men, and 6 (25%) were women. Twenty-five percent of the patients were living alone. Of the total chronic HF cohort, 58% had daily habits of self-monitoring before being enrolled in the study, including the measurement of blood pressure using a diary; 38% had a tablet PC or a smartphone. Before their enrolment in the study, 46% of the patients had been hospitalized for worsening HF within the prior 3 months.

The primary cause of HF was ischaemic heart disease (29% of the patients); dilated cardiomyopathy was the primary cause in 21%, and in the remaining 50% of the patients, the causes were hypertrophic cardiomyopathy, cardiac sarcoidosis, tachycardia-induced cardiomyopathy, hypertensive heart disease, and valvular heart disease. In addition, most of the patients had a reduced left ventricular ejection fraction [median (IQR): 32% (24–46)]. The rate of diabetes was higher in the control group compared with the intervention group (45% vs. 8%).

The median study periods (IQR) were 59 (56–66) days for the intervention group and 63 (55–69) days for the control group (a non-significant difference). All 13 of the patients in the intervention group measured their blood pressure, body weight, body temperature, and oxygen saturation ≥1×/day and recorded the values in the app during the study period. In the intervention group, the median (IQR) ratio of self-monitoring adherence for blood pressure, body weight, and body temperature was 100% (92–100%) and that for oxygen saturation was 100% (91–100%) (*Table 3*). In the control group, the median

Table 4 The heart failure patients' physical activity and dietary salt intake at baseline and at 2 months

	Intervention ($n = 13$)			Control ($n = 11$)		
	Baseline	2 months	Difference	Baseline	2 months	Difference
Physical activity						
Step count, steps/day	5325 (3482–6559)	6299 (4650–8870)	1544 (356–2999)	4950 (2157–6740)	4944 (2466–7157)	137 (−496 to 387)
MCC, kcal/day	146 (80–215)	189 (124–237)	34 (9–92)	121 (50–166)	126 (57–168)	6 (−7 to 11)
Dietary salt intake, g/day	7.4 (6.7–9.7)	7.1 (6.4–8.0)	−0.3 (−1.4 to 0.1)	7.9 (7.1–9.1)	7.5 (6.7–8.3)	−0.2 (−1.3 to 1.0)

Data are median (IQR). Daily physical activity and dietary salt intake at baseline were evaluated for ≥7 days before the study and for the first 7 days of the study period, respectively. Daily physical activity and dietary salt intake at 2 months were evaluated for the last 7 days of the 2 month study period. 'Difference' represents the values at 2 months minus the values at baseline in each group. Because of a lack of data, one patient in the intervention group was eliminated from the analysis of physical activity. MCC, movement-related calorie consumption.

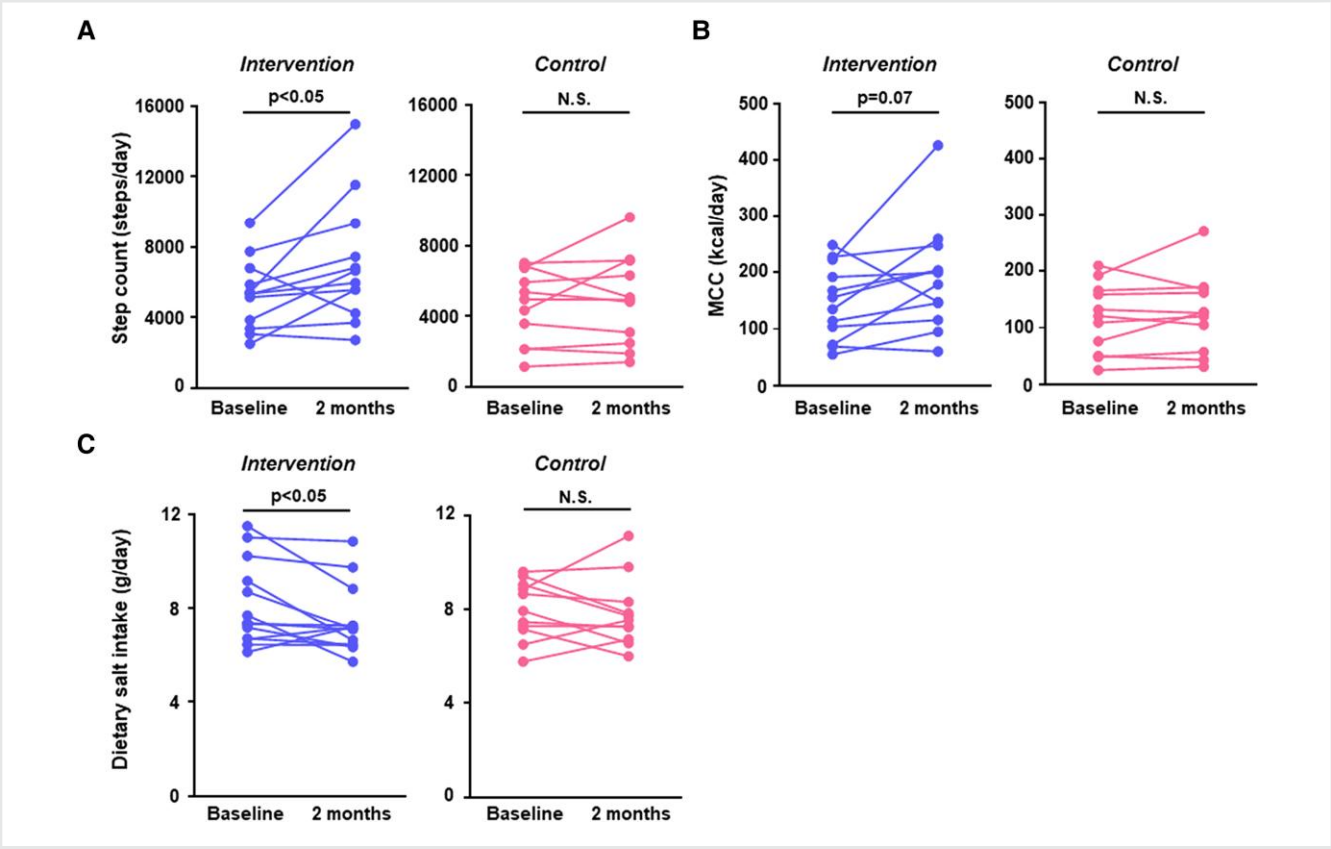


Figure 4 Physical activity [step count (*A*) and movement-related calorie consumption, i.e. MCC (*B*)] and dietary salt intake (*C*) at baseline and at 2 months in the intervention group ($n = 13$) and control group ($n = 11$). The daily physical activity and salt intake at baseline were evaluated for ≥7 days before the study and for the first 7 days of the study period, respectively. At 2 months, the patients' daily physical activity and salt intake were evaluated for the last 7 days of the 2 month study period. Because of a lack of data, one patient in the intervention group was eliminated from the analysis of physical activity. N.S., not significant.

(IQR) ratio of adherence to the self-monitoring of each vital sign (recorded in the HF diary) during the study period was 100% (97–100%) (*Table 3*). In addition, the median difference in the number of days adherent to the self-monitoring of each vital sign at 2 months minus the values at baseline was 0 days in both the intervention and control groups (see Supplementary material online, *Table S1*).

Although there was no significant between-group difference in the step count at 2 months (*Table 4*), the intervention group's step count was significantly increased after the use of the mobile app for 2 months (*Figure 4A*). However, there was no significant difference in the daily MCC at 2 months between the intervention group and the control group (*Table 4*). The differences in the step count or MCC at 2 months minus the values at baseline in the intervention group were not significantly higher than those in the control group ($P = 0.06$) (*Table 4*). The within-group comparison revealed that the daily salt intake was significantly reduced after the self-care intervention (*Figure 4C*), but there was no significant between-group difference in daily salt intake at 2 months or in the difference of daily salt intake from baseline to 2 months (*Table 4*).

At 2 months of follow-up, the patient-reported self-care behaviour score evaluated by the EHFScB-12 was significantly lower (i.e. better) in the intervention group compared with the control group, indicating that the intervention group accomplished better self-care practice towards the prevention of worsening HF (*Table 5*). In addition, the intervention group's EHFScB-12 score at 2 months was significantly decreased compared with that at baseline (*Figure 5A*). The HF Knowledge Scale score at 2 months was comparable between the two groups (*Table 5*). The General Self-Efficacy Scale score and the physical and mental health-related quality of life (QoL) scores at 2 months did not differ significantly between the intervention and control groups (*Table 5*).

During the study period, there were no clinical adverse events or unscheduled hospital visits in any of the 24 patients with HF. In addition, none of the intervention group patients reached a risk score of 3 points calculated on the basis of self-monitoring data, and thus, no warning message of possible worsening HF was displayed on the app during the study period.

Discussion

In this AppCare-HF feasibility study (a multicentre, randomized clinical trial of 24 patients with chronic HF), we examined the feasibility of our new mobile self-care support app by evaluating HF patients' adherence to the self-monitoring of core vital signs at home as well as the potential efficacy of the intervention including the encouragement of self-care behaviours. During the 2 month study period, the HF patients in the intervention group used the mobile app and showed excellent adherence to the self-monitoring of vital signs including blood pressure, body weight, body temperature, and oxygen saturation. The intervention group also showed better self-care behaviour at 2 months as assessed by the EHFScB-12 compared with the control group.

Table 5 The heart failure patients' self-care behaviour, HF Knowledge Scale, General Self-Efficacy Scale, and health-related QoL scores at baseline and at 2 months

	Intervention ($n = 13$)			Control ($n = 11$)		
	Baseline	2 months	Difference	Baseline	2 months	Difference
EHFScB-12	24 (18–36)	16 (16–22)*	−8 (−18 to 0)	32 (16–36)	28 (20–36)	−4 (−8 to 4)
HF Knowledge Scale	13 (12–15)	14 (14–15)	1 (−1 to 3)	14 (13–15)	14 (12–15)	0 (−1 to 2)
General Self-Efficacy Scale	8 (7–9)	9 (8–11)	0 (−1 to 3)	6 (4–10)	7 (4–11)	0 (−3 to 5)
SF-8						
PCS score	47.5 (40.7–53.4)	47.5 (43.6–54.2)	0.8 (−1.1 to 5.5)	44.9 (41.8–53.3)	47.2 (42.2–51.2)	0.3 (−4.2 to 5.4)
MCS score	50.0 (47.5–54.4)	52.5 (48.1–55.1)	0.3 (−5.4 to 4.2)	45.8 (39.9–48.4)	50.3 (43.6–51.6)	2.3 (−1.3 to 8.2)

Data are median (IQR). *$P < 0.05$ vs. control (at 2 months). 'Difference' represents the scores at 2 months minus the scores at baseline in each group. Because of a lack of data, one patient in the control group was eliminated from the analysis of the SF-8. EHFScB-12, European Heart Failure Self-Care Behaviour Scale; MCS, mental component summary; PCS, physical component summary; SF-8, Short Form-8 Health Survey.

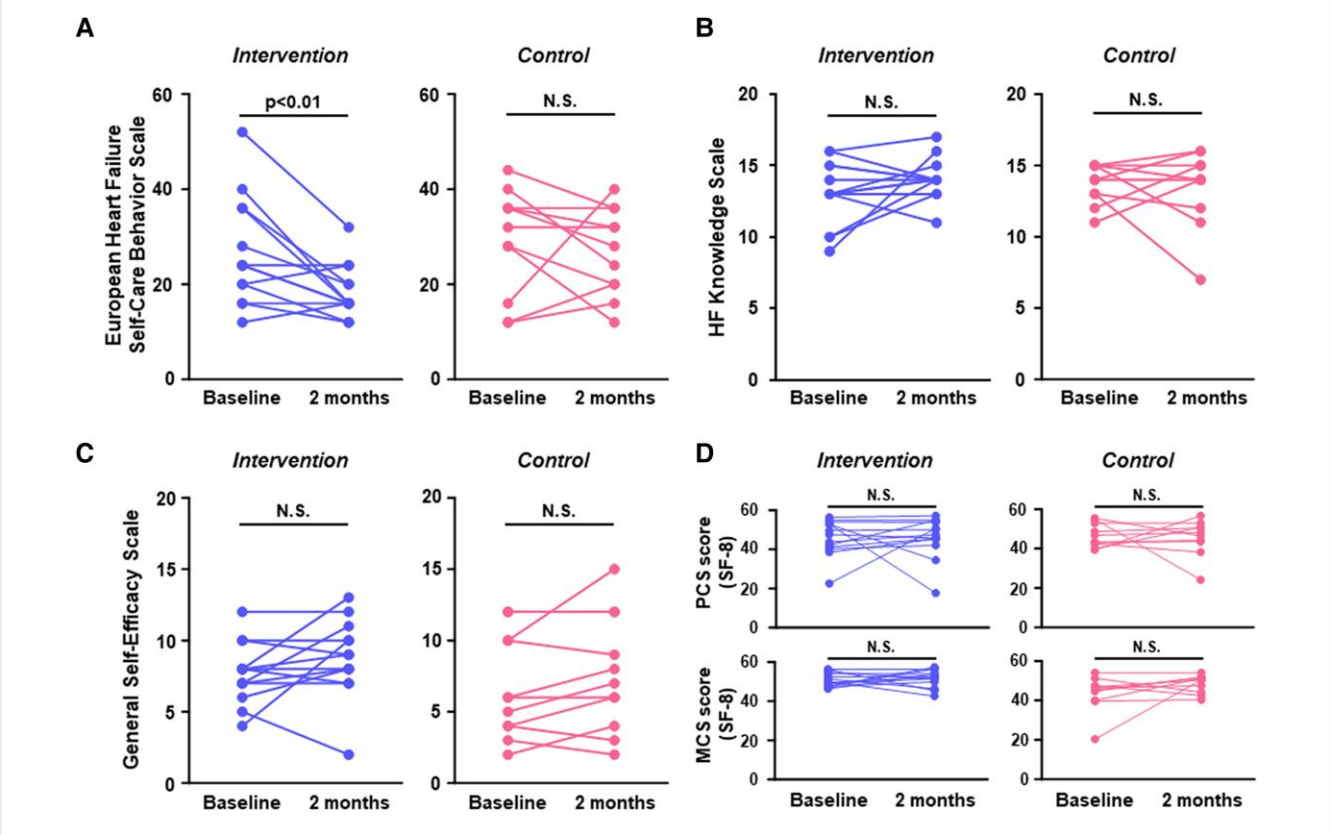


Figure 5 Self-care behaviour (*A*), HF Knowledge Scale (*B*), General Self-Efficacy Scale (*C*), and health-related QoL scores (*D*) at baseline and at 2 months in the intervention group ($n = 13$) and control group ($n = 11$). Because of a lack of data, one patient in the control group was eliminated from the SF-8 analysis. MCS, mental component summary; PCS, physical component summary; SF-8, Short Form-8 Health Survey.

With recent advances in mobile technology, the ownership rate of a smartphone or tablet PC in adults is increasing dramatically worldwide.[32] As mHealth applications have various potential advantages for health promotion including a clear display of self-monitoring data, education to gain disease knowledge and achieve optimal self-care, automated notifications or alerts, and the utilization of telemedicine or telecare, the incorporation of mHealth apps into standard HF care is expected. Moreover, the use of an mHealth app is thought to contribute to patients' active involvement in their own healthcare by providing a close partnership with clinicians and/or family members, which helps facilitate patient-centred care in HF management.[33,34]

In most of the mHealth apps that are available for HF patients, the vital signs for self-monitoring are limited to blood pressure, heart rate, and body weight.[10,35] In the present study, the intervention group

Table 6 Unique features of self-care intervention using the newly developed mobile app for individuals with heart failure

(1) Self-monitoring of multiple vital signs combined with daily physical activity and dietary salt intake monitoring by sensor devices
Vital signs
Blood pressure
Heart rate
Body weight
Percent fat
Body temperature
Oxygen saturation
Physical activity
Step count
Calorie consumption
Dietary salt intake (which reflects the previous day's salt intake)
(2) Risk score calculation for automated alerts based on changes in vital signs and the existence of HF-related symptoms or signs over the past 7 days
Vital signs (listed above)
HF-related symptoms or signs
Palpitation
Fatigue
Oedema
Dizziness
Loss of appetite
Reduced urine output

patients monitored not only these commonly used vital signs but also body temperature, oxygen saturation, physical activity, and daily salt intake by using sensor devices (*Table 6*), which is a unique feature of this self-care intervention. Although some of the patients might have found the self-monitoring time-consuming until they got used to it, all of the patients (including those with poor digital literacy) successfully maintained a high level of adherence to the self-monitoring of these vital parameters throughout the study period, suggesting the app's sustainability. This result appears to be plausible because poor digital literacy can be a strong barrier to mobile app engagement among HF patients.[36] However, the present study's follow-up was only 2 months, and further studies with a longer follow-up are necessary to evaluate the sustainability of app usage by HF patients.

It is important to note that the present self-care intervention based on the mobile app improved HF patients' self-care behaviours as assessed by the EHFScB-12 at 2 months of follow-up. One of the potential barriers to the accomplishment of optimal self-care is that most HF patients do not know the symptoms or signs of HF exacerbation, and their inability to identify symptoms/signs related to worsening HF may lead to frequent visits to an emergency department or hospital admissions.[37] Although we could not compare each item of the EHFScB-12 between the groups because of the limited number of patients, the present results indicate that our self-care intervention including the self-monitoring assistant and education can enhance HF patients' self-management skills and contribute to an improvement in the total score of patient-reported self-care behaviours. However, we did not detect any significant difference between the intervention and control groups in the HF Knowledge Scale score at 2 months, possibly because most of the patients already had sufficient knowledge about HF at baseline.

To the best of our knowledge, the present study is the first randomized controlled trial of an application-based self-care intervention in which multiple vital parameters and HF-related symptoms or signs were monitored for the recognition of individual health conditions, combined with motivation-driven messages for optimal self-care and automated alerts about potential risks of worsening HF in ambulant HF patients. In earlier randomized clinical trials of a self-care intervention using a mobile app, HF patients monitored only their body weight at home; the body weight values were used for the titration of diuretics, resulting in improved self-care behaviour and/or QoL and reduced in-hospital days during 90 to 240 day study periods.[12–14] In another randomized clinical trial, HF patients monitored their body weight and physical activity (measured using a smartwatch), which also improved their QoL at 6 months (but not at 12 months).[11]

Although such a simple HF management strategy appears reasonable for application-based interventions in a wide range of HF populations, the self-monitoring of several core vital signs with the use of simplified monitoring devices helps patients understand their own health more objectively and may be useful for the early recognition of worsening HF with the support of an automated alert system, especially in patients with advanced HF.

Our risk score calculation (*Table 1*), which was created by medical professionals including cardiologists, general physicians, and HF nurses, resembles the calculation used in other telemedicine alert systems for HF patients.[18,38,39] In these previous studies, a weight gain of ≥2.3 kg within a week[18] or ≥2 kg over 5 days[39] was defined as posing a risk of worsening HF for direct alerts to patients or medical staff or a subsequent survey of detailed risk of worsening HF. In the other study,[38] changes in systolic blood pressure (>160 or <90 mmHg) and heart rate (>100 or <50 b.p.m.) under the existence of HF-related symptoms or signs were also used for the risk calculation of the HF alert system in a smartphone app. However, there is apparently no prior study that combined the monitoring of multiple vital signs including body temperature and oxygen saturation plus HF-related symptoms or signs for the alert system in an app.

Study limitations

Several study limitations should be noted. The patient cohort was small ($n = 24$), and the median age of the patients (60 years) appears to be younger than that of real-world HF populations, and we thus cannot completely eliminate the possibility of selection bias based on the usability of the mobile app. In addition, the self-reporting used in this study may have resulted in an over-estimation effect on self-care behaviour outcomes. We used the EHFScB-12 instead of the revised version that consists of nine items of the EHFScB (i.e. the EHFScB-9),[21] because the Japanese version of the questionnaire is validated only for the 12-item EHFScB.[22]

In addition, this was a feasibility study and was not designed to thoroughly assess the efficacy of the self-care intervention using the mobile app for HF patients. Finally, we could not assess the clinical validity of the automated alert system for the notification of worsening HF, because no major adverse event occurred during the 2 months of follow-up. Our findings should therefore be considered preliminary and must be confirmed in a larger clinical trial with a longer follow-up period.

Future directions

On the basis of the findings obtained in this feasibility study, a larger multicentre randomized clinical trial, i.e. the AppCare-HF study (UMIN-CTR no. UMIN000032780), was recently launched to investigate whether the self-care intervention using this new smartphone app for 12 months improves the QoL and reduces the risks of death and HF hospitalizations in patients with chronic HF.

Conclusions

Our findings demonstrate the feasibility of a novel mHealth app in outpatients with chronic HF who have a history of hospital admissions due to worsening HF. All of the patients in the intervention group maintained good adherence to the self-monitoring of various core vital signs throughout the 2 month study period.

Supplementary material

Supplementary material is available at *European Heart Journal – Digital Health* online.

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Data availability

The data will be shared upon reasonable request to the corresponding author.

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