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松田, 美紗子

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博士論文

Effect of Daily Activity Record-Based Self-monitoring Intervention on the Perception of Physical Sensations in Patients With Chronic Heart Failure: A Randomized Controlled Trial

(慢性心不全患者における身体感覚の認知に対する
生活行動記録に基づくセルフモニタリング支援の効果：
無作為化比較試験)

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Misako Matsuda

松田 美紗子

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Abstract

Background: To prevent re-hospitalization for heart failure (HF), patients need to be able to perceive physical changes that occur at the onset of HF exacerbation and seek early help.

Objective: To evaluate the effect of a self-monitoring intervention on patients' perceptions of physical sensations during daily activities in the context of HF via a randomized controlled trial.

Methods: Participants (N=70) were randomly assigned to the intervention (received daily activity record-based self-monitoring intervention support; Group A) or control (only explained the measured results from the records; Group B) group. Group A reflected on and described the physical sensations in their daily activities within 1 month after discharge. Outcome measures were assessed at 1 month after the intervention using the European Heart Failure Self-Care Behavior Scale (EHFScBS), Evaluation Scale for Self-Monitoring by patients with Heart Failure (ESSMHF), clinical events, physical activity, and sleep.

Results: There was no significant difference in the change in the "asking for help" subscale score of the EHFScBS between the groups (+0.7 vs. +0.4 points, $p=0.716$). Group A had improved score on the self-monitoring subscale related to "concern about how movements affect body" from baseline (12.7 to 14.0 points, $p=0.026$). There was no significant effect of self-monitoring intervention support on the first re-hospitalization related to HF and all-cause death (log-rank $\chi^2=0.432$, $p=0.511$). A significant difference in

moderate-intensity physical activity between the groups was observed (+4.6 vs. -0.5 min, $p=0.029$).

Conclusions: A focused strategy that enables patients to perceive their physical sensations and promotes early help-seeking behavior is needed.

Background

The number of people living with heart failure (HF) is increasing worldwide and may increase to more than 1.3 million by 2030 in Japan, considering the increase in the aging population.¹ HF is a progressive condition, requiring repeated hospitalizations. The 1-year re-admission rates for HF in Japan have remained consistent in recent years at 23.6–26.2%.² While improved self-care can prevent HF exacerbations and improve patients' clinical outcomes,^{3–6} increased knowledge on HF has not always helped improve their self-care behaviors.⁷

Self-care has three components: self-care maintenance, symptom perception, and self-care management.⁸ Symptom perception is an essential process of the detection of physical sensations in the body and interpretation of their meaning, leading to self-care management.⁸ However, it is difficult for patients with HF to perceive subtle physical changes in the early stages of an exacerbation, especially in the early post-discharge period.⁹ Various symptoms may be experienced by patients with HF that are often non-specific to HF.^{10–15} The symptoms are also subjective¹⁶ and ambiguous, and patients often have unique physical sensations and expressions that cannot be classified into common HF symptoms that healthcare professionals refer to.^{10,14,15} However, patient-reported outcome measures, such as symptoms and physical functions, accurately reflect clinical changes in patients with HF rather than changes in the 6-min walk distance, New York Heart Association functional class, or weight.¹⁷ Therefore, to prevent severe exacerbation and subsequent re-hospitalization, we need to support patients in perceiving their unique physical changes experienced early in HF exacerbation and seeking help. There is insufficient evidence on effective nursing support strategies focused on symptom perception.^{18–20}

In our unpublished preliminary study, patients reported their symptoms during exacerbations as unusual physical sensations, often described by them using specific expressions in the context of their daily activities. A previous study also reported that during acute exacerbation, patients with HF perceive the symptoms and the actions or scenes during which they experienced such symptoms, especially, while walking, sleeping, climbing stairs, getting up, and using the toilet, when wearing pants or socks, and in the morning.¹⁰ Although hospitalized patients may already have some HF knowledge and experience, they only experience their current HF conditions in a limited hospital setting, where HF is managed by healthcare professionals and hospital staff. After discharge, the patients experience their current HF conditions in their daily lives and their own homes, and at that point, the patients themselves have to manage their conditions. The conditions will become the patients' own.²¹ To improve patients' perception of changes in physical sensations, the patients and healthcare professionals need to understand the changes in their daily activities owing to the transition from the hospital to the home and to identify the unique physical sensations that patients experience during their daily activities early after discharge. Subjective experiences associated with the daily activities of the participants may not always be abnormal or unusual, e.g., feeling well or being able to carry out some actions after discharge. Therefore, in this study, physical sensation refers to the condition associated with the participants' daily activities that they subjectively experience/express.

We developed a self-monitoring intervention using the activity tracker to enable patients to perceive the changes in physical sensations associated with their daily activities,²² focusing on symptom perception based on the theory of HF self-care.⁸ The daily activity records were measured objectively, and the patients had the

opportunity to recall and report their specific daily activities early after hospital discharge; they were asked to reflect on the physical sensations associated with them in their own words.

We hypothesized that our daily activity record-based self-monitoring intervention will improve “asking for help” self-care management behavior as a primary outcome. “Asking for help” would be improved through increased patients’ symptom perception, which was assessed by self-monitoring and preceding self-care management. Thus, it would reduce HF-related re-hospitalization and all-cause death as a secondary outcome. Additionally, we examined the changes in other aspects of patients’ self-care behavior, physical activity, and sleep as secondary outcomes.

Methods

Study design

This study was a stratified, randomized, two-arm parallel-group trial. Patients aged ≥ 20 years who were hospitalized for HF and who were scheduled to visit the outpatient department of cardiovascular medicine at the hospital after discharge were eligible to participate. Patients with Stage D HF,^{23,24} those receiving hemodialysis therapy, those who were unable to walk independently at home, those who were transferred to another hospital after being discharged, those who did not understand information concerning the study or had difficulty answering the Japanese questionnaire (severe cognitive impairment, lack of fluency in Japanese, inadequate vision and hearing), and those who were unable to participate in the study for any other reasons, were excluded.²²

The participants were recruited from a tertiary care hospital in Japan that provides multidisciplinary inpatient and outpatient cardiac rehabilitation (CR) as per the HF guidelines.^{23,24} The participants were stratified by sex and randomly allocated in a 1:1 ratio to the intervention group (Group A; self-monitoring nursing intervention) that received self-monitoring nursing intervention support based on patients' daily activity records or the control group (Group B; non-self-monitoring nursing intervention) that only received an explanation of the daily activity records. The patients were assigned to the intervention support group after the completion of baseline assessments.

The order of randomization was created by one of the researchers using a computer-generated list of random numbers. Randomization was stratified by sex, with 1:1 allocation using random block sizes of 2, 4, and 6. The allocation sequence was sealed in an opaque envelope with serial numbers.^{22,25,26} This sealed envelope was opened by a research nurse providing the intervention for the first time prior to the implementation of the assigned intervention. Our trial protocol has been previously published.²² All participants provided written informed consent. The flow of participants is shown in Figure 1.

Study intervention

The self-monitoring intervention protocol was described in a previous study.²² A trained research nurse who was not blinded to group allocation provided the interventions. All participants were asked to wear "Life Microscope" (Hitachi Ltd., Tokyo, Japan) wristwatch activity trackers, with accelerometers for 3–7 days after discharge. A daily activity record was created to visualize the measured activity counts and times as graphs. A sample of this daily activity record was published in the protocol paper.²² At the hospital visit within 1

month after discharge, the participants were explained the results of the measured activity counts, sleep/wake time, activity/sitting time, and activity intensity while viewing their daily activity records (5 min).

In addition to explaining the results, the participants in Group A received a self-monitoring intervention support session (30 min). Based on the patient–lay models of disease approach,²⁷ the research nurse had an interactive session with the participants to elicit their experiences and enhance their perceptions of their HF. The purpose of patient–lay models is to elicit actual experiences related to patients’ illness from the patient themselves and to help them perceive their own illness by having to describe it to someone else. By understanding patients’ experience with their illness, healthcare professionals can assist them with specific treatment methods tailored to the patient.²⁷ Therefore, the intervention support focused on enhancing opportunities for participants to reflect on and describe the conditions that they experienced. The research nurse shared and viewed the daily activity records with each participant. Focusing on the time of day when routine and regular daily activity counts had been high, the research nurse asked the participants the following questions: (1) “What daily activities did you perform and how did you perform them?”; (2) “When did you perform such physical activities in the day?”; (3) “For how long had you performed such daily activities?”; (4) “What physical sensations did you feel during daily activities in the current early post-discharge?.” Through these questions, participants were encouraged to reflect on and describe the daily activities and unique physical sensations they had experienced early after discharge. Then, the research nurse asked the participants the following: (5) “What are the differences between the physical sensations experienced in the course of early HF exacerbation that led to your hospitalization and physical sensations experienced in current

early post-discharge daily activities?” The nurse and each participant reviewed the unique physical sensations associated with the current daily activities after discharge and determined the changes in physical sensations that required medical consultation. For intervention fidelity, the participants’ daily activity records as well as summaries of the daily activities and associated physical sensations were reviewed by the research team at regular meetings.

Control group (Group B)

Group B only received an explanation of the measured results based on daily activity records. Incidentally, the participants in both groups had opportunities for multidisciplinary comprehensive CR.²⁸ This CR included appropriate exercise training and patient education, including lifestyle modification, medication, diet, smoking cessation, and self-monitoring. Regarding self-monitoring, the participants were educated regarding the importance of monitoring symptoms and instructed to record common symptoms of HF (i.e., dyspnea, weight, edema, and fatigue) in a diary.

Participants’ characteristics

We assessed participants’ characteristics, including age, sex, body mass index, marital status, living status, employment status, New York Heart Association functional class, left ventricular ejection fraction, B-type natriuretic peptide, etiology of HF, prior HF hospitalization, comorbidities, medications, length of hospital stay, and participation in CR at hospital discharge. Outpatient CR use was defined as participation in at least one session²⁹ from discharge to the 1-month follow-up after the intervention.

Outcome measures

The Japanese version of the European Heart Failure Self-care Behavior Scale ([EHFScBS] Cronbach's α : 0.71)³⁰ was used to assess the self-care behavior. The EHFScBS has three theoretical dimensions: 1) complying with the regimen, 2) asking for help, and 3) adapting activities (Cronbach's α for subscales: 0.56–0.85).³¹ The primary outcome was “asking for help” in EHFScBS. A low score indicates a better self-care behavior. The secondary outcomes included symptom perception, clinical events (HF-related hospitalizations and all-cause deaths) and healthcare utilization (i.e., unplanned medical consultations and emergency department visits), other aspects of self-care behavior (i.e., complying with the regimen and adapting activities), physical activity, and sleep. Symptom perception was evaluated using the Evaluation Scale for Self-Monitoring by patients with Heart Failure (ESSMHF).³² ESSMHF consists of Domain 1. Self-monitoring related to “awareness” and “measurement” (Cronbach's α for Domain 1: 0.91) and Domain 2. Self-monitoring related to “interpretation” (Cronbach's α for Domain 2: 0.89).³² Domain 1 of ESSMHF comprises six factors (21 items, Cronbach's α for the factors: 0.53–0.84) and Domain 2 comprises four factors (16 items, Cronbach's α for the factors: 0.59–0.76).³² Responses to the items are rated on a 5-point Likert scale (ranging from 1 [“I don't think”] to 5 [“I think so”]), with the higher subscale score indicating higher frequency of self-monitoring as a regimen.³²

Data collection

The EHFScBS and ESSMHF were self-administered at baseline and the 1-month follow-up after the intervention. Further, all participants wore a Life Microscope wristwatch activity tracker with a triaxial

accelerometer for 3–7 days, 24 h/d except during water-related activities (e.g., bathing), at both the baseline and 1-month follow-up after the intervention. The Life Microscope wristwatch activity tracker detects an acceleration change of 0.01 G/rad/s or more within a range of 2–3 Hz and calculates the amount of activity from the change in acceleration in 1 s.³³ The automated program ActiViewer software (Hitachi Ltd.) was used to convert each participant's activity counts to average metabolic equivalents/min. The Cole–Kripke algorithm³⁴ was used for sleep/wake identification. Days with at least 10 h of wear time were considered valid.^{35,36} Participants with at least 3 valid days were included. Based on previous studies, all wear times were classified according to time-by-activity intensity.^{35,37–39} To determine the range of valid analysis days for each patient, we calculated the time per day (minutes) by activity intensity for the valid days as follows: total time of activity intensity/valid days. We recorded the clinical events and healthcare utilization during the 12 months after discharge from the participants' medical records. Cardiologists determined the HF-related re-admission. The cardiologists who judged the causes of admission had knowledge of the included participants and the study purpose. However, they were blinded to group assignments of participants.

Statistical analysis

The sample size was determined as per unpublished data. We assumed that the “asking for help” scores of the EHFSBS at baseline and 1-month follow-up after intervention would range from 10 to 6 points for Group A and from 10 to 9 points for Group B. With a two-sided α of 5% and power of 80%, 28 patients per group (total n=56) were required to detect a 3-point difference in the score, assuming a standard deviation (SD) of 4.0. A 20% participant dropout and/or withdrawal rate was assumed based on prior studies. Therefore, 68

participants with HF were required in both groups.²²

Data were analyzed according to the intention-to-treat principle. For the baseline sociodemographic and clinical data, categorical data were presented as frequencies and percentages, and continuous data were presented as the median and first and third quartiles by group. To assess the balance of participants' baseline characteristics, the chi-square test was used for categorical variables, and the Mann–Whitney U test was used for continuous variables. A paired t-test was conducted to compare the scores of each scale (i.e., EHFSBS and ESSMHF), physical activity, and sleep before and after intervention support within each group. The significance of the mean changes in these outcomes between the groups was assessed using an independent sample t-test. Kaplan–Meier survival curve analysis with a log-rank test was used to examine the composite effects of all-cause death and HF-related hospitalization. All statistical analyses were performed using SPSS Statistics 26 (IBM Corp., Armonk, NY), and statistical significance was set at p-value of <0.05.

Results

The flow diagram of this study is presented in Figure 2. The participants were recruited between October 2019 and February 2021. However, recruitment was interrupted during the COVID-19 restriction from March to June 2020. Seventy participants were randomly allocated to Group A (n=35) or Group B (n=35). In each group, 32 participants (91%) received the allocated intervention at 15.4 ± 6.3 (mean $\pm$ SD) days after discharge; three participants in each group did not receive allocated intervention owing to re-hospitalization prior to the intervention or missing daily activity record. Thirty participants in Group A and 32 participants in Group B

provided data on the primary outcome. Outcomes were measured at 33.8 ± 12.5 (mean $\pm$ SD) days after intervention (i.e., 48.8 ± 13.6 days after discharge). As one participant in each group withdrew, and four in Group A and two in Group B had responded to the questionnaires insufficiently, five participants in Group A and three in Group B were excluded from the primary analysis.

The 34 participants in each group, excluding the one participant in each group who withdrew, were followed for 12 months after discharge to assess the clinical outcomes. Most of the participants were male (72.6%), and the median age of the sample was 71.5 years. The majority of the participants were classified as New York Heart Association functional class II or III, with a median left ventricular ejection fraction of 38%. A few participants (27.4%) had experienced prior hospitalization for HF. There were no statistically significant differences in the demographic or clinical characteristics between the two groups at baseline. There were also no differences in baseline characteristics between the participants who completed the study and those ($n=6$) who were excluded from primary analysis (Table 1).

Primary outcome

Asking for help self-care behavior (EHFScBS)

The outcomes at baseline and at 1 month after the intervention are shown in Table 2. For Group A, the mean score on asking for help of the EHFScBS was 8.3 (SD, 3.1) points at the baseline and 9.0 (SD, 2.9) points at the 1-month follow-up examination. For Group B, the mean score was 9.4 (SD, 3.6) points at the baseline and 9.8 (SD, 2.7) points at the 1-month follow-up examination. No change was observed over the study period in either Group A or Group B. Moreover, the change before and after intervention was not different

between Groups A and B ($t=0.366$, $p=0.716$).

Secondary outcomes

Symptom perception assessed by self-monitoring (ESSMHF)

The between-group differences in the changes in the scores for any factor in ESSMHF Domain 1, self-monitoring related to “awareness” and “measurement,” over 1 month were not statistically significant. Only Group A had an improved score on Factor 5, "Concerns about how movements affect body," from baseline. For Domain 2, self-monitoring related to “interpretation,” the total score in Group A remained the same (baseline, 64.3 [SD, 9.1] to 1-month follow-up, 64.7 [SD, 8.2]) at the 1-month follow-up. The total score of Group B decreased from 62.6 (SD, 8.2) to 60.3 (SD, 10.5) points. There were no statistically significant between-group changes before and after intervention ($t=1.365$, $p=0.178$).

Clinical events

Of the 70 participants, two were excluded from the analysis of clinical outcomes because they had withdrawn their consent to participate in the study and had requested to delete their data. During the 12 months after hospital discharge, seven participants (20.6%) in Group A and nine participants (27.3%) in Group B experienced at least one re-hospitalization related to HF. In Group B, one participant died. The composite mean event-free survival time to re-hospitalization for HF and all-cause death was 314.9 (standard error [SE], 19.3) days in Group A and 296.8 (SE, 19.8) days in Group B. There was no significant effect of self-monitoring intervention support on the first re-hospitalization related to HF and all-cause death (log-rank $\chi^2=0.432$, $p=0.511$) (Figure 3). In total, 10 (29.4%) participants in Group A and seven (20.6%) in Group

B had unplanned healthcare utilization (unplanned medical consultations or emergency departments). Especially, in Group A five participants had six unplanned medical consultations and six participants had eight emergency room visits. Moreover, in Group B, five participants had seven unplanned medical consultations and four participants had seven emergency room visits. They did not require re-hospitalizations in any case.

Other aspects of self-care behavior (EHFScBS)

Regarding either “complying with the regimens” or “adapting activities” in the EHFScBS, no between-group differences in the changes in the scores before and after were observed.

Physical activity and sleep

The change in sleep from baseline to the 1-month follow-up was 709.4 to 662.8 min/day in Group A and 678.7 to 704.2 min/day in Group B. There was a significant difference in the sleep changes between the two groups over 1 month ($t=-2.066$, $p=0.044$). In Group A, high-intensity light ($t=-2.868$, $p=0.008$) and moderate-intensity ($t=-2.243$, $p=0.034$) physical activity significantly increased from the baseline to 1 month, whereas in Group B, the sedentary behavior significantly decreased from the baseline to 1 month ($t=2.999$, $p=0.006$). A significant difference in the change in moderate-intensity physical activity before and after the intervention between the two groups was observed ($t=2.269$, $p=0.029$).

Discussion

To our knowledge, this is the first randomized controlled trial to evaluate the effects of self-monitoring

intervention support on patients' perceptions of physical sensations associated with daily activities in the early post-discharge period. After the intervention, the "Asking for help" self-care behavior did not show significant change.

The mean scores on "asking for help" at the baseline for both groups were better than those in previously reported in HF studies.^{7,40} This may be explained by the fact that all participants had participated in inpatient CR, including guideline-based HF education by a multidisciplinary team; furthermore, 61% also participated in outpatient CR after hospital discharge. HF programs conducted by a multidisciplinary teams lead to an increase in the patients' knowledge.⁷ We believe that the participants could have selected actions recommended for common signs and symptoms during HF exacerbations, such as increased shortness of breath, swelling, weight, and fatigue, based on the knowledge acquired from HF education in the inpatient and outpatient CR settings.

Our self-monitoring intervention support in the early post-discharge period enabled the participants to reflect on and describe the physical sensations associated with HF in their daily activities as well as those experienced in the process leading to their hospitalization. The unique individual physical sensations experienced by each patient may not always be classified as dyspnea, swelling, fatigue, or weight gain, as assessed by the "asking for help" subscale of the EHFScBS. Many studies have shown that patients experience various symptoms during exacerbation that are different from typical HF symptoms.^{10,14,15,41} Patients find it difficult to classify their conditions into general HF symptoms and often use metaphorical and onomatopoeic expressions or express feelings of distress during activities.^{10,15} Hence, it is important to assess

the changes in physical sensations reported by the patients as indicators of HF exacerbation.

Our intervention was also not sufficient to improve symptom perception as assessed by patients' self-monitoring, which precedes "Asking for help" self-care behavior as a self-care management. We provided one session of self-monitoring intervention support at the hospital visit within 1 month after discharge. A recent study⁴² suggested that symptom-monitoring behavior is an essential component of symptom perception; frequent symptom monitoring enables patients to recognize and respond to their HF symptoms quickly. Adequate self-care management is predicted by adherence to symptom-monitoring behavior.⁴³ We did not evaluate how often the participants monitored their unique physical sensations during daily activities. Thus, adherence to regular and frequent self-monitoring may have affected the asking-for-help behavior in this study. Several follow-up sessions to support participants in monitoring their physical sensations associated with their daily activities may have helped them to engage in regular and frequent self-monitoring and further enhanced their skills in detecting changes. Moreover, analysis of interview data patient behaviors during HF exacerbations showed that once the patients experienced unusual symptoms, they took a significant amount of time to evaluate the cause of their symptoms, resulting in a delay in seeking help.¹⁹ The abilities of patients with HF to detect their symptoms may not be associated with self-care management.⁴⁴ Our self-monitoring intervention allocated insufficient importance to reflection on the causes that patients had attributed to physical changes before hospitalization^{19,20} and discussion of self-care management strategies for future changes in physical sensations.^{19,45,46} Based on patient-lay models of disease approach,²⁷ our intervention was focused on eliciting actual experiences related to patients' illness. In the common-sense

model of self-regulation, which is one example of patient-lay models of disease approach, patients are asked to describe their illness representations along the five dimensions, which include the identity, cause, timeline, consequences, and controls.^{21,27,47} In this study, reflecting on and describing their physical sensations associated with daily activities included illness representations of identity (symptom experiences from patients' illness) and consequences (impact of the illness to patients' life) in the five dimensions. However, it did not include representations regarding cause, timeline, and control. Moreover, in our intervention, the reflection and description of what the patients believe is the cause of physical sensations (cause), their chronic view that changes in physical sensations can occur over time (timeline), and their confidence in how controllable their conditions are (control), may help them grasp the meaning of physical sensations and self-management behaviors when physical sensation changes occur. Future studies must examine intervention strategies that help patients interpret the meaning of the responses of their body to daily activities and associate changes in their physical sensations with early help-seeking behavior.

We observed an effect on one specific self-monitoring score related to "concern about how movements affect body" in Group A. Our self-monitoring intervention support using the daily activity record that visually displayed each patient's daily activities in the early post-discharge period; this may have helped them identify their own daily activities and monitor physical sensations associated with their daily activities. Therefore, this strategy has the potential to help patients determine changes in physical sensations during HF exacerbation based on their experience.

Group A showed a significant decrease in sleep and a significant increase in moderate-intensity physical

activity compared to Group B. The improved scores on “concern about how movements affect body” in Group A indicate that the Group A participants would have been able to self-monitor “the body when moving,” “any changes in ability to move the body as usual when exercising,” and “any physical changes after movements that exert strain on the body.”³² A previous self-monitoring intervention study¹⁸ that assessed physical functional capacity using a self-administered 6-min walk test as an objective measurement of patients’ progress found similarly improved physical activity levels. Patients with HF may decrease a level of activity to avoid symptom occurrence when monitoring their body,⁴⁸ but our results showed that monitoring and knowing the body allowed the patients to increase physical activity and control their symptoms. Decreased activity reduces the potential to notice symptoms of worsening HF.⁴⁸ By monitoring physical sensations associated with participants’ own daily activities, the increased physical activity may have helped the participants notice their triggers of HF exacerbations.

Limitations

This study had several limitations. Although there was no significant difference between the two groups in the rate of participation in CR, we did not evaluate the frequency or duration of each patient’s participation. The multidisciplinary outpatient CR program for patients with HF has shown a beneficial effect on clinical outcomes.²⁹ In this study, 61% of our sample participated in the outpatient CR, which was considerably higher than the 7% reported in a nationwide study in Japan.⁴⁹ Therefore, variables, such as whether or not the patients participated in CR and the frequency and duration of participation, may have influenced the

outcome measures.

Moreover, we assessed outcomes only once, 1 month after intervention. In the early post-discharge period, patients with HF found it difficult to identify immediate physical change.⁹ Patients with HF may need more experience in their daily activities to understand their own body's responses. Thus, we must evaluate the effectiveness of self-monitoring interventions early after discharge in the long term.

Further, This study was based on the HF self-care theory.⁸ However, we did not use the Self-Care of Heart Failure Index⁵⁰ developed according to the theory to assess symptom perception, as it was not available in Japan at the time of study protocol development. In the future, we should consider using this scale to evaluate the effectiveness of our intervention focused on symptom perception.

Finally, statistically significant differences could not be clarified because the sample size was calculated according to clinical outcomes. The HF re-admission rate at 12 months after discharge was 20.6% in Group A and 27.3% in Group B; however, the difference was not statistically significant. The non-significant but higher frequency of unplanned or emergency department visits before the onset of severe exacerbation that had prevented re-hospitalization in Group A may have resulted from early detection of changes in physical sensations through self-monitoring.

Conclusion

We evaluated the effects of self-monitoring intervention on the perceptions of physical sensations experienced during daily activities by patients with chronic HF. The self-monitoring intervention did not

improve the primary outcome of “asking for help” and did not contribute to a reduction in the re-hospitalization rate for HF and all-cause death. However, it improved a specific self-monitoring of “concern about how movements affect body” over time; it also significantly increased the moderate physical activity. Self-monitoring strategies must be improved, with a focus on facilitating patients’ perception, especially their interpretation of physical sensations associated with daily activities and promoting early help-seeking behavior.

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Ethical approval

The investigation conformed to the principles outlined in the Declaration of Helsinki, and the trial was approved by the Ethics Committee of Kobe University Graduate School of Health Sciences (No 699-2) and the conducting research facility. The trial protocol was registered with the UMIN Clinical Trials Registry (UMIN 000032509).

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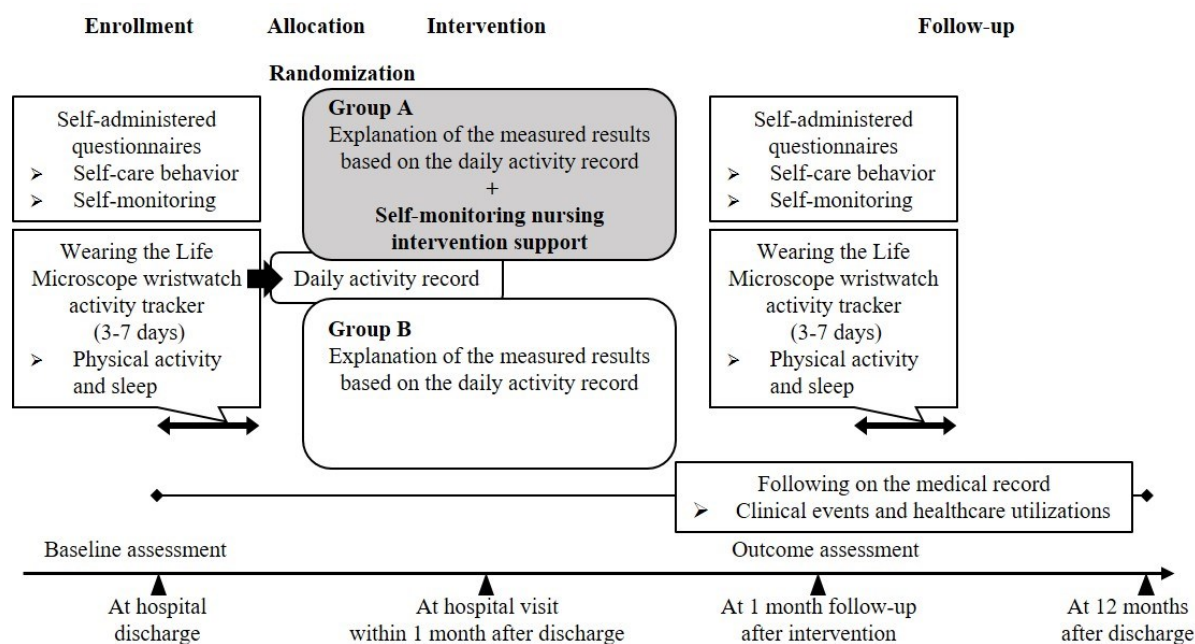


Figure 1. Participant flow chart

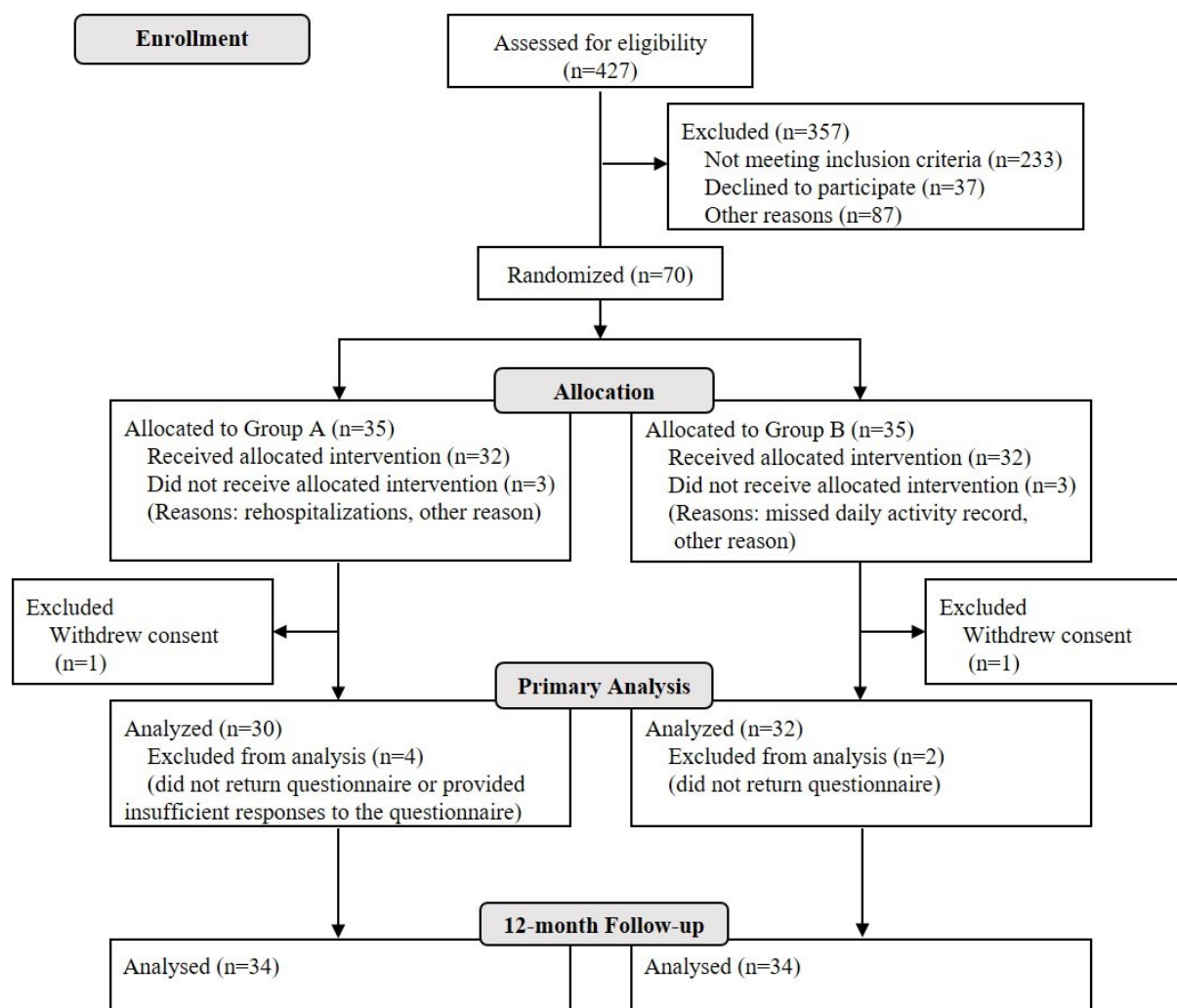


Figure 2. Flow diagram

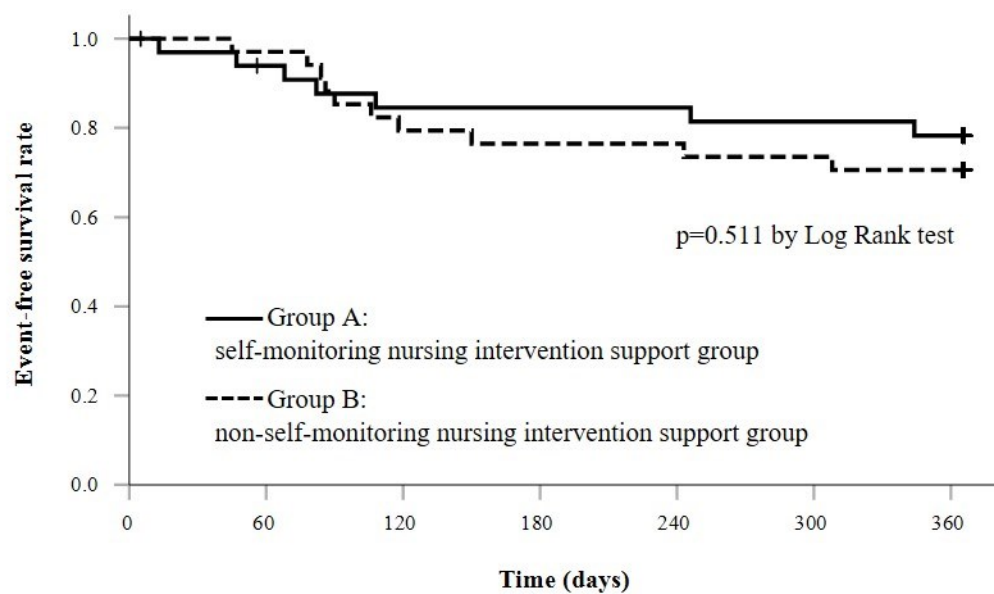


Figure 3. Kaplan–Meier survival curve for days to heart failure-related hospitalization and all-cause death

Table 1. Baseline characteristics

	Total (n=62)	Excluded (n=6)	Group A (n=30)	Group B (n=32)	p
Male sex, n (%)	45 (72.6)	6 (100)	21 (70)	24 (75)	0.659
Age, years, median (first, third)	71.5 (60.5, 78)	78.5 (57, 86)	71.5 (58.8, 79.3)	71.5 (61, 76)	0.568
BMI, kg/m ² , median (first, third)	23.9 (21.7, 26.0)	22.5 (19.3, 27.1)	23.7 (20.9, 25.1)	24.2 (22.0, 26.4)	0.278
Living alone, n (%)	15 (24.2)	0 (0)	5 (16.7)	10 (31.3)	0.180
Married, n (%)	43 (69.4)	6 (100)	23 (76.7)	20 (62.5)	0.227
Employed, n (%)	26 (41.9)	2 (33.3)	12 (40)	14 (43.8)	0.765
NYHA, n (%)					
class I	3 (4.8)	0 (0)	2 (6.7)	1 (3.1)	0.533
class II	51 (82.3)	5 (83.3)	23 (76.7)	28 (87.5)	
class III	8 (12.9)	1 (16.7)	5 (16.7)	3 (9.4)	
LVEF, %, median (first, third)	38 (29, 58.5)	34.5 (27.5, 49.3)	34 (29, 59)	44 (32, 59)	0.319
BNP, pg/mL, median (first, third)	162.6 (81.9, 249.9)	236.8 (107.2, 640.5)	171.2 (72.6, 231.3)	162 (93, 341.2)	0.724
Etiology of HF, n (%)					
Ischemic	18 (29)	2 (33.3)	8 (26.7)	10 (31.3)	0.961
Valvular	13 (21)	0 (0)	7 (23.3)	6 (18.8)	
Cardiomyopathy	14 (22.6)	0 (0)	7 (23.3)	7 (21.9)	
Other	17 (27.4)	4 (66.7)	8 (26.7)	9 (28.1)	
Prior HF hospitalization, n (%)	17 (27.4)	1 (16.7)	8 (26.7)	9 (28.1)	0.898
Comorbidity, n (%)					
Hypertension	46 (74.2)	4 (66.7)	22 (73.3)	24 (75)	0.881
Diabetes mellitus	26 (41.9)	3 (50)	10 (33.3)	16 (50)	0.184
Chronic kidney disease	35 (56.5)	1 (16.7)	16 (53.3)	19 (59.4)	0.632
COPD	6 (9.7)	1 (16.7)	2 (6.7)	4 (12.5)	0.438
Length of hospital stay (days)	13 (10, 18)	13.5 (9, 16.8)	12.5 (9.8, 18.0)	14 (10.0, 17.8)	0.340
Outpatient cardiac rehabilitation, n (%)	38 (61.3)	3 (50)	18 (60)	20 (62.5)	0.840
Medication, n (%)					
ACEI/ARB	43 (69.4)	4 (66.7)	21 (70)	22 (68.8)	0.915
Beta-blocker	57 (91.9)	6 (100)	27 (90)	30 (93.8)	0.588
Mineralocorticoid blocker	34 (54.8)	4 (66.7)	16 (53.3)	18 (56.3)	0.818
Diuretics	53 (85.5)	4 (66.7)	26 (86.7)	27 (84.4)	0.798

Baseline characteristics were collected from hospital discharge records. Values are presented as n (%) or median (first, third quartile).

P-values were calculated using the chi-square test for categorical variables or the Mann–Whitney U test for continuous variables (Group A vs. B). Note: LVEF; n=61 (A: 29, B32), BNP; n=61 (A: 30, B: 31). Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index; BNP, B-type natriuretic peptide; COPD, chronic obstructive pulmonary disease; HF, heart failure; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association.

Table 2. Primary and secondary outcomes at baseline and 1-month follow-up after intervention

	Baseline				Follow-up		Mean changes from baseline			
	Group A	Group B	t	p *	Group A	Group B	Group A	Group B	t	p *
Primary outcome	(n=30)	(n=32)			(n=30)	(n=32)				
Asking for help (EHFScBS)	8.3±3.1	9.4±3.6	-1.295	0.200	9.0±2.9	9.8±2.7	0.7±3.3	0.4±2.9	0.366	0.716
Secondary outcomes										
Symptom perception assessed by Self-monitoring (ESSMHF)										
Domain 1. Self-monitoring related to “awareness” and “measurement”	(n=30)	(n=32)			(n=30)	(n=32)				
Factor 1: Concern about signs of exacerbation	20.8±6.2	20.1±4.9	0.502	0.618	21.7±4.3	20.6±5.6	0.9±4.9	0.5±4.7	0.330	0.742
Factor 2: Regular measurement of physical condition	10.9±4.4	10.3±4.6	0.541	0.590	13.7±2.7**	13.7±2.7**	2.9±3.9	3.5±4.0	-0.599	0.551
Factor 3: Concern about the results of measurements	10.3±3.8	10.0±3.7	0.319	0.751	11.8±3.0**	11.7±2.8**	1.4±3.2	1.6±2.9	-0.286	0.776
Factor 4: Concern about volume of water	8.8±3.1	9.7±2.7	-1.122	0.266	9.8±2.6	10.1±2.7	1.0±3.6	0.5±2.3	0.699	0.487
Factor 5: Concern about how movements affect body	12.7±3.3	13.0±3.5	-0.383	0.703	14.0±3.0**	13.9±3.1	1.4±3.2	0.9±3.4	0.551	0.584
Factor 6: Concern about physician’s consultations and instructions for medications	9.5±1.0	9.1±1.6	1.157	0.252	9.5±0.9	9.4±1.1	0.0±0.9	0.3±2.0	-0.859	0.395
Domain 1 Total	72.9±14.8	72.1±16.6	0.217	0.829	80.5±12.3**	79.4±14**	7.6±11.8	7.4±12.3	0.073	0.942
Domain 2. Self-monitoring related to “interpretation”	(n=29)	(n=32)			(n=29)	(n=32)				
Factor 1: Prognostic interpretation of signs of exacerbation	16.7±2.3	16.5±2.4	0.307	0.760	17.0±2.2	15.9±2.9	0.3±2.4	-0.6±2.6	1.477	0.145
Factor 2: Interpretation of symptoms and physical condition management	31.7±4.8	31.2±4.5	0.447	0.656	32.3±4.2	30.1±5.2	0.6±4.5	-1.1±4.9	1.413	0.163
Factor 3: Interpretation of deterioration of pulse	7.6±1.8	6.8±1.9	1.634	0.108	7.6±1.8	6.7±2.1	-0.1±2.0	-0.2±1.9	0.240	0.811
Factor 4: Interpretation of water retention	8.3±1.5	8.1±1.7	0.532	0.597	7.9±1.5	7.7±2.1	-0.5±1.4	-0.4±1.4	-0.030	0.976
Domain 2 Total	64.3±9.1	62.6±8.2	0.772	0.443	64.7±8.2	60.3±10.5	0.5±7.9	-2.3±7.9	1.365	0.178

Table 2. (Continued)

	Baseline				Follow-up		Mean changes from baseline			
	Group A	Group B	t	p *	Group A	Group B	Group A	Group B	t	p *
Other aspects of self-care behavior (EHFScBS)	(n=30)	(n=32)			(n=30)	(n=32)				
Complying with the regimen	15.0±4.1	14.3±4.5	0.661	0.511	12.8±3.5**	13.2±3.4	-2.2±3.6	-1.0±3.4	-1.266	0.210
Adapting activities	4.3±1.6	4.1±1.5	0.540	0.591	4.3±1.3	4.4±1.6	-0.0±1.9	0.3±2.1	-0.689	0.493
Physical activity and sleep	(n=27)	(n=29)			(n=27)	(n=29)				
Sleep, min/day	709.4±212.2	678.7±190.9	0.569	0.572	662.8±220.6	704.2±180.1	-46.6±136.1	25.4±124.8	-2.066	0.044
Sedentary (≤1.5 METs), min/day	476.8±123.4	509.3±117.2	-1.009	0.317	451.0±114.1	475.8±114.2**	-25.8±86.8	-33.5±60.1	0.385	0.702
Low-intensity light physical activity (1.6–1.9 METs), min/day	152.5±72.5	163.9±90.8	-0.515	0.608	168.3±72.8	162.8±79.4	15.8±49.8	-1.1±60.9	1.132	0.263
High-intensity light physical activity (2.0–2.9 METs), min/day	54.2±53.1	54.2±49.1	-0.001	1.000	72.0±53.9**	60.6±48.1	17.8±32.3	6.4±30.6	1.354	0.181
Moderate-intensity physical activity (≥3 METs), min/day	6.3±8.5	9.7±12.4	-1.215	0.230	10.9±12.8**	9.3±12.3	4.6±10.6	-0.5±4.7	2.269	0.029

∞ Data are presented as means ± standard deviations. *P-values were calculated using the independent t-test (Group A vs B). **P <0.05 using the paired t-test (baseline vs 1-month follow-up). Note: Group A: Participants were provided with a self-monitoring nursing intervention support session in addition to the explanation of results based on the daily activity records. Group B: Participants were provided only with an explanation of the measured results based on the daily activity records. Abbreviations: EHFScBS, European Heart Failure Self-care Behavior Scale; ESSMHF, Evaluation Scale for Self-Monitoring by patients with Heart Failure; METs, metabolic equivalents.