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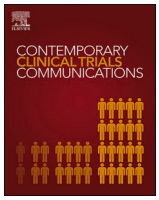

Effectiveness of daily activity record-based self-monitoring intervention for patients with chronic heart failure: A study protocol

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ABSTRACT

Background: The prevention of recurrent readmission among heart failure (HF) patients requires support for appropriate self-care behaviors to prevent exacerbation of HF and self-monitoring to allow for patients' early perception of physical changes during exacerbations. Such support may enable patients to seek early consultation. This study developed a self-monitoring intervention that aimed at increasing the perception of patient-unique physical sensations caused by HF, based on daily activity records of patients.

Method: A parallel two-arm randomized controlled trial is being conducted with 68 HF patients early after their discharge. Participants in both groups wear a wristwatch activity tracker from time-of-discharge. Participants in the self-monitoring intervention group receive support to reflect on their actual daily activities and the associated physical sensations they experienced, based on their daily activity records. The primary outcome is participants' "Asking for Help" dimension of self-care behavior, measured using the European Heart Failure Self-Care Behavior Scale at one month follow-up after intervention.

Conclusion: This study is the first trial to use an activity tracker as a tool for symptom perception among HF patients. The problem of delayed consultations during exacerbations may be resolved by assisting patients in improving their perception of their unique physical sensations associated with specific daily activities, based on their daily activity records. If the effect is clarified, it could lead to the construction of new nursing interventions for continuous disease management that aim towards re-hospitalization prevention.

1. Background

Heart failure (HF) is characterized by recurrent exacerbations and a high rate of hospital readmission (>20% within one year of discharge) [1,2]. One cohort study identifying patterns of self-care behaviors and their association with clinical events in HF patients reported that clinical events, including readmission, were less likely to occur in patients who were able to recognize HF symptoms and seek consultation, in addition to practicing self-care behaviors to prevent exacerbation [3]. Therefore, to prevent recurrent readmission, it is necessary for patients to practice appropriate self-care behaviors to prevent exacerbations (e.g., adherence to medications, a salt-restricted diet, and exercise), and to provide self-monitoring support for patients to perceive physical changes that occur during exacerbations.

Since symptoms caused by HF are diverse, such as dyspnea, fatigue, and edema [4,5], each patient presents with unique physical sensations for these symptoms [4]. Therefore, it is difficult for patients to associate their own physical sensations with those that are indicators of HF exacerbation. This inability to differentiate symptoms often results in delayed consultations, until symptoms become severe, such as orthopnea, consequently leading to hospitalizations [4–7]. Conventional, knowledge-based, in-hospital self-care interventions have improved self-care behaviors related to patients' adherence to treatment. However, these interventions have not been effective in self-care behaviors related to patients' consultation-seeking during exacerbation [8]. Notably, re-hospitalization rates have been reported to be especially high among patients in early post-discharge phase [9]. Furthermore, it is difficult to identify the kinds of sensations of HF symptoms that might occur in an individual's body.

Riegel et al. [10,11] proposed that HF self-care is a naturalistic decision-making process comprising: 1) self-care maintenance, 2) symptom perception, and 3) self-care management. Symptom perception has been shown to be an important process that directs patients toward self-care management Fig. 1). To allow for appropriate

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consultation behavior during exacerbation of HF, it is necessary for patients to be more perceptive of their own unique HF-related changes before the occurrence of severe symptoms. However, specific nursing support to increase symptom perception in HF patients has not been sufficiently studied.

Based on Riegel et al.'s [10] theory, we developed a self-monitoring intervention to increase patients' symptom perception that focuses specifically on patients' physical sensations associated with their daily activities early after hospital discharge. In our unpublished preliminary studies, patients' perceived symptoms associated with HF exacerbation tended to be reported as "unusual" physical sensations. For example, "a feeling of breathing being 'strange', rather than 'having trouble breathing'" or "a discomfort that I can move (i.e., can move as usual but experiences fatigue later)." These physical sensations were often expressed in the context of patients' daily activities. The intervention support approach developed in this study focuses on physical sensations that are described in participants' own expressions, involving their own daily activities. They reflect on how physical sensations associated with patients' daily activities early after discharge were experienced differently from physical sensations they experienced in the process of HF exacerbation that led to hospitalization. It is hoped that this reflection would enable them to detect unusual physical sensations that occur at the onset or during the early stage of HF exacerbations. To assist the participants in recalling and describing their specific daily activities, without being limited to their memory or selective parts of their daily activities, we use daily activity records obtained from accelerometer measurements.

Interventions that support patients throughout their experience are an important part of the educational support approach [12]. It is also more effective to start interventions with patients describing their own illnesses [12]. Our self-monitoring intervention support is deemed an approach that can improve patients' skills in perceiving physical sensations they personally experience, rather than simply increasing knowledge of, for example, common HF symptoms and/or the importance of daily weighting. The goal of this approach is to allow patients to seek medical consultation, that is, practice self-care management, early on when they experience HF exacerbations.

Thus, this randomized controlled trial tests the effectiveness of a self-monitoring intervention in improving physical sensation perception associated with daily activities in chronic HF patients in the early post-discharge phase, based on daily activity records.

2. Method

2.1. Study design

This is a stratified, randomized, two-arm, parallel-group study conducted in Japan. Participants are stratified by sex and randomized in a 1:1 ratio into intervention Group A, which receive self-monitoring nursing intervention support based on patients' daily activity records, or Group B, which only receive an explanation of the daily activity records. Given the nature of the intervention, it is not possible to blind participants and the research nurse providing intervention support. Researchers involved in the collection of outcome data and data analysis will be blinded to treatment allocation to minimize potential bias. This study is conducted at a tertiary care hospital in Japan. This facility provides multidisciplinary inpatient and outpatient cardiac rehabilitation, as recommended by the HF guidelines [13].

2.2. Eligibility criteria

Clinical nurses identify hospitalized HF patients, followed by their physician and research nurse screening them for inclusion and exclusion criteria (Table 1). Patients who meet the eligibility criteria are informed of the study by the research nurse at the time the patient's prospect of discharge is set. Those who provide consent will participate in the study.

2.3. Intervention

All participants are required to wear a wristwatch activity tracker ("Life Microscope") equipped with a 3-axis accelerometer for 3–7 days post hospital discharge. Participants return the tracker via post after the wearing period. With this device, the researchers can obtain data on various human movements for each participant during the wearing period. This data enables graphical visualization of each participant's rhythm of daily activities, based on activity counts and time measured,

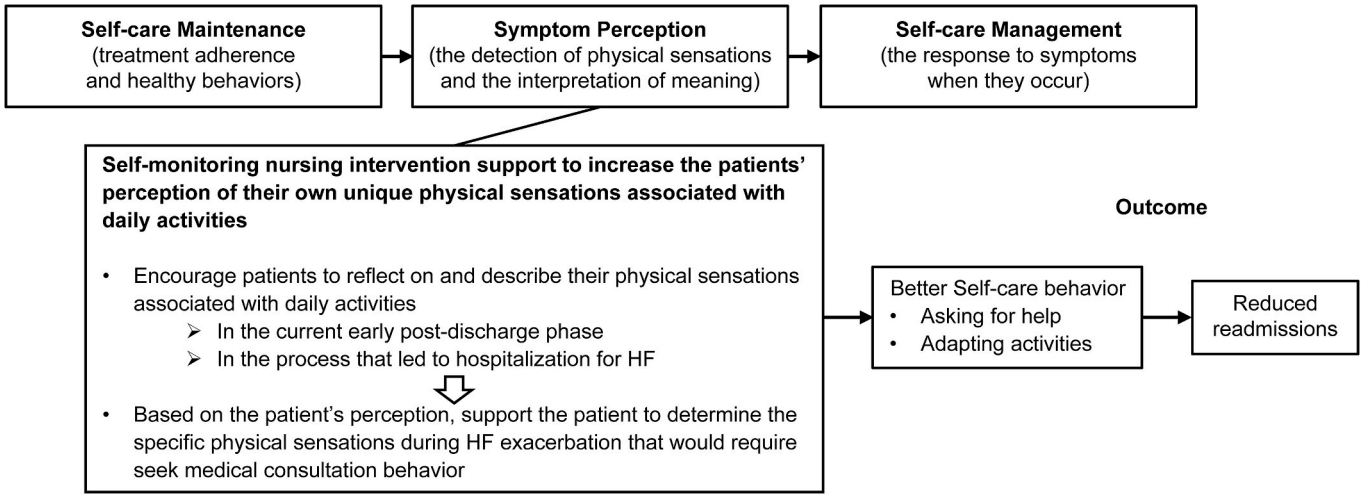

Fig. 1. Self-monitoring nursing intervention support protocol based on the Situation-Specific Theory of Heart Failure (Self-Care of Heart Failure Model) Self-care entails three separate but linked concepts (self-care maintenance, symptom perception, self-care management) that often are mastered in sequence [10]. Symptom perception, which is supported with our self-monitoring intervention in this study, is a process that precedes self-care management. Thus, self-monitoring intervention support may increase the perception of patients' own unique physical sensations associated with their daily activities and, thereby, promote self-care behaviors, especially with respect to early consultation (self-care management). Such actions, in turn, may reduce readmission. Modified with permission from Wolters Kluwer Health, Inc.: [B. Riegel, V.V. Dickson, K.M. Faulkner, The situation-specific theory of heart failure self-care: Revised and updated, J. Cardiovasc. Nurs. 31 (3), pp226–235, https://journals.lww.com/jcnjournal].

Table 1
Inclusion and exclusion criteria.

Inclusion criteria	1)	Patients aged at least 20 years or older
	2)	Patients who are scheduled to visit the outpatient department of cardiovascular medicine at the hospitalized facility after discharge
Exclusion criteria	1)	Patients with Stage D HF
	2)	Patients receiving hemodialysis therapy
	3)	Patients unable to walk independently at home
	4)	Patients transferred to another hospital after being discharged
	5)	Patients who do not understand information about the study or who have difficulty answering the Japanese questionnaire (e.g., severe cognitive impairment, non-speaking, and non-reading Japanese, inadequate vision and hearing)
	6)	Patients unable to participate in the study for any other reasons

Note. HF: Heart failure.

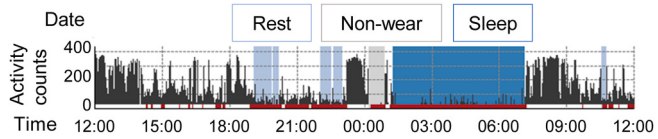

Fig. 2. Sample of visualized daily activity record based on activity counts and time.

to create a daily activity record (Fig. 2). To understand the rhythm of the participants' daily activities, the period of accelerometer use is at least three days.

On the day of each participant's hospital visit within 1 month after discharge, participants are briefed (5 min) on their measured activity counts, sleep and wake time, activity and sedentary time, and activity intensity. They are provided with daily activity records to peruse during this briefing, so that they can objectively grasp their daily activities as measured early after discharge. Participants in Group B only receive an explanation of the measured results using daily activity records.

2.3.1. *Self-monitoring intervention support*

Intervention Group A participants, in addition to the briefing of the results, also undergo a support session (30 min). The purpose of our self-monitoring intervention support is to enable participants to perceive physical sensations associated with their daily activities post hospital discharge and to capture any changes in their bodies during exacerbations of HF. Such identification is based on individual experiences, thereby enabling participants to take appropriate consultation actions to prevent rehospitalization (Fig. 1).

This study's approach uses patient-lay models of disease [12]. The purpose of patient-lay models is to elicit actual experiences related to patients' illness from the patient themselves and to help the patients perceive their own illness by having to describe it to someone else. By understanding patients' experience with their illness, healthcare professionals can better assist them with a specific treatment method that is specifically required for and by the patient [12]. The intervention support in this study, therefore, focuses on enhancing opportunities for participants to reflect on and describe the illness that they experience.

Prior to providing intervention support to the participants, a research nurse uses the measured data from each participant to understand their rhythms of daily activities and activity intensity. To assist the participants in recalling and describing their specific daily activities, without being limited to their memory or selective parts of their daily activities, the research nurse shares a daily activity record with each participant. Based on the characteristics of the rhythms of daily activities presented in this record and activity intensity, each participant is asked 1) when, 2) in what kind of daily activity, 3) how long, and 4) what physical sensation did they feel during this daily activity. Such questions would help participants describe their sensations using their own expressions. Participants are then asked about any differences between physical sensations experienced in the process of HF exacerbation that led to their hospitalization and physical sensations experienced in their current early post-discharge daily activities. By having participants reflect on and describe their own experiences during this interactive session with the research nurse, the researcher provides an opportunity to increase perceptions of participants' specific daily activities and associated unique physical sensations when living with HF. With this intervention support, both the nurse and participants will be able to confirm unique physical sensations associated with each participant's current daily activities after discharge. This will assist both parties to determine the kind of physical sensation that needs medical consultation. For intervention fidelity, intervention support is provided by one research nurse trained and verified by the protocol development members.

2.4. *Outcome measures*

The study is conducted according to the trial flow shown in Fig. 3 and Table 2. Baseline data are collected at the time of the participants' discharge. Outcome data are assessed at 1 month after the intervention support and self-care behavior is measured as the primary outcome. Self-monitoring, health literacy, and physical activity are measured as secondary outcomes. The long-term effects of the intervention support will be assessed using clinical events and healthcare utilization during the 12 months after discharge.

2.4.1. *Primary outcome*

Self-care behavior is measured using the Japanese version of the European Heart Failure Self-Care Behavior Scale (EHFScBS) [14]. The EHFScBS is the most versatile assessment tool for evaluating self-care behaviors and the effects of educational interventions among patients with HF [15]. The reliability (Cronbach's α: 0.71) and validity of the Japanese version of the scale have also been confirmed [14]. Conceptually, this self-administered questionnaire has three theoretical dimensions: 1) complying with the regimen, 2) asking for help, and 3) adapting activities (Cronbach's α for the subscales was between 0.56 and 0.85) [16]. A prior study examined self-care behaviors for each dimension among Japanese patients with HF [17]. Although all three dimensions of the EHFScBS are measured in this study, the primary outcome is "Asking for help."

2.4.2. *Secondary outcomes*

Self-monitoring is measured using the Evaluation Scale for Self-Monitoring by patients with heart failure (ESSMHF) (Cronbach's α coefficients for the subscales were between 0.53 and 0.84. The internal consistency of the scale was 0.91 for domain1and 0.89 for domain2) [18]. Health literacy is measured using the 14-item Health Literacy Scale for Japanese adults (HLS-14) (Cronbach's α for the subscales ranged from 0.76 and 0.85. The internal consistency of the scale was 0.81) [19]. Physical activity is measured using a wristwatch activity tracker (Life Microscope, Hitachi Ltd., Tokyo, Japan), which consists of a continuous daily activity recording system that is incorporated into a wristwatch. The measurement starts at the time of discharge and a month after the intervention support. The participants are required to wear the tracker on their wrists for 3–7 days, throughout the day without water-related activities (e.g., bathing) time. This device is equipped with a triaxial accelerometer with a resolution of 11.7 mG 20 Hz. The meter 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 1 s [20]. The trackers from the Life Microscope brand have been used as a reliable and valid tool in previous studies [21]. The automated program ActiViewer software (Hitachi Ltd., Japan) is used to convert each participant's activity counts to average metabolic equivalents (METs) per minute. For sleep/wake identification, the Cole-Kripke algorithm [22] is used. Days with at least 10 h of wear time will be considered valid [23,

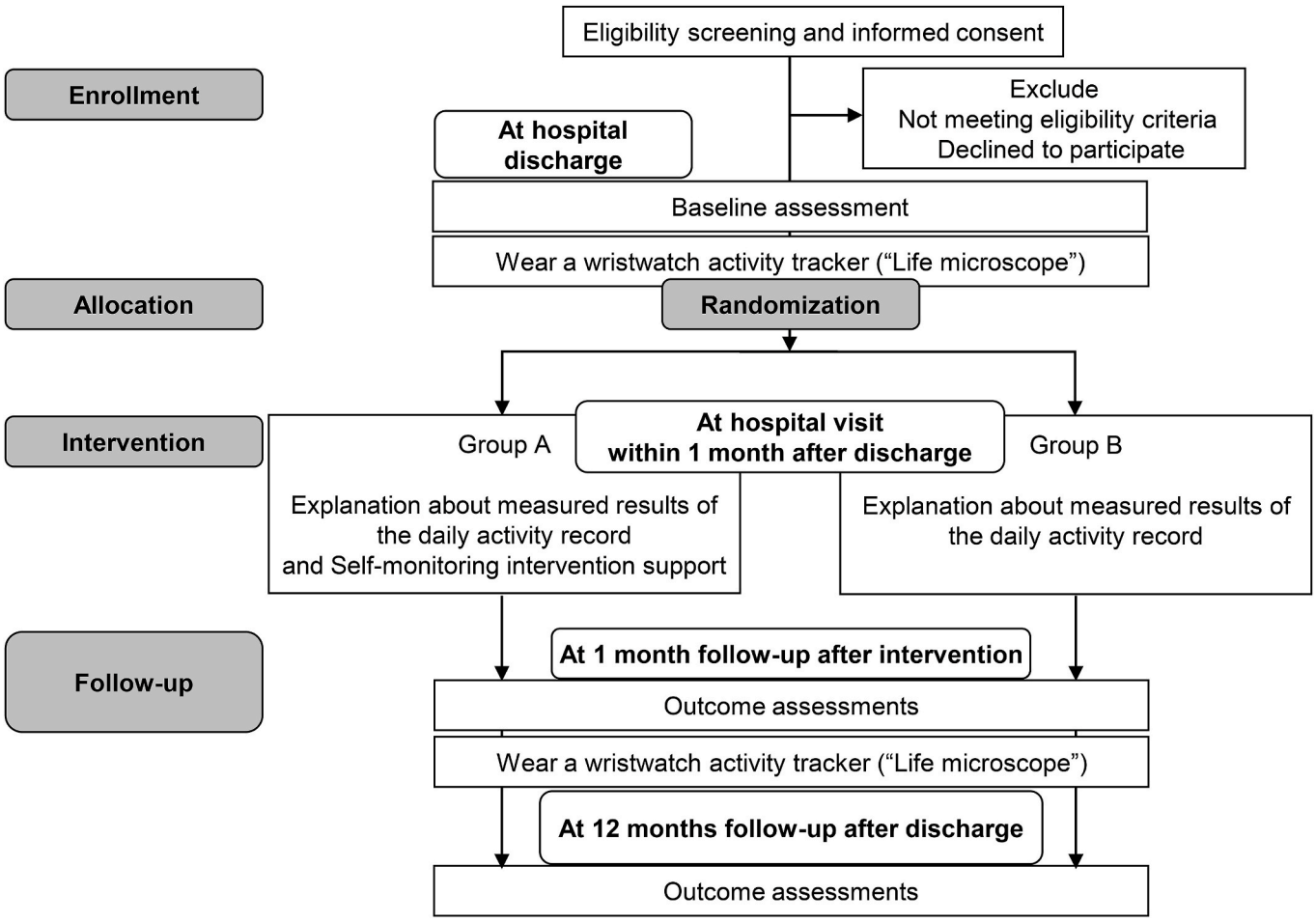

Fig. 3. Trial flow.

Table 2
Baseline and follow-up assessment schedule.

Time point	Baseline	Follow-up	
	At hospital discharge	At 1 month after intervention	At 12 months after discharge
Characteristics of participants	●		
Self-care behavior	●	●	
Self-monitoring	●	●	
Health literacy	●	●	
Physical activity	●	●	
Clinical events and healthcare utilizations	←	—	→

24]. Participants with at least 3 valid days will be included in the analysis. Based on previous studies, all wear time will be classified as the time by activity intensity [23,25–27]. To address the range of valid analysis days, for each patient, we will calculate the time/day (minutes) by activity intensity for the valid days as follows: total time by activity intensity/valid days. Data on clinical events (deaths, HF-related hospitalizations) and healthcare utilization (unplanned medical consultations and emergency department visits) during the first 12 months after discharge will be recorded as further data used in this study. These data will be gathered from medical records.

2.4.3. *Characteristics of participants*

Information on sociodemographic characteristics (age, sex, height and weight, marital status, living status, employment status), clinical data (NYHA function class, echocardiography, blood test results, etiology of HF, history of HF, medications and non-pharmacological

treatment), and comorbidities (hypertension, diabetes mellitus, chronic kidney disease, COPD) are collected from medical records and demographic questionnaire at discharge.

2.5. Sample size

The sample size was determined based on our prior unpublished data. We assumed that the "Asking for help" scores of the EHFScBS at baseline and at one month after the support intervention would range from 10 to 6 for Group A and from 10 to 9 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 of the "Asking for help" dimension, assuming a standard deviation of 4.0. A 20% participant dropout and/or withdrawal were assumed based on prior studies. Therefore, the total target sample size was set to 68 HF patients.

2.6. Allocation

The assignment of the intervention support group that occurs after the baseline assessment is completed and before the intervention support is provided. The order of randomization was created by one of the researchers using a computer-generated list of random numbers. The randomization is stratified by sex, with a 1:1 allocation using random block sizes of 2, 4, and 6.

The allocation sequence was sealed in an opaque envelope with serial numbers. This sealed envelope is opened for the first time just before the intervention support provider offers to confirm and implement the allocated intervention.

2.7. Recruitment and retentions strategies

This study is conducted at the outpatient department of participants' hospitalized facility. Participants do not require visits to another site for study participation. Participants are provided envelopes with postage paid to return accelerometers by post. We show and explain measured results of the daily activity record to all participants (including Group B) wearing accelerometers. Participant adherence to the protocol is defined as wearing time on wristwatch activity tracker for at least 3 days and attendance at intervention support session.

2.8. Data management

Data collected at the hospital is recorded on study case sheets by the researchers. Completed case sheets and participants' answered questionnaires are posted to our research team institution. One of the two researchers responsible for data management enters these data points into the study database and the other verifies them with the paper case sheets and questionnaires. Accelerometer data are imported directly into the study database. The files of study database are locked with password, and no one except the two researchers responsible for data management are informed of the file password. These study data are stored in a locked cabinet within a locked office at the research team's institution.

2.9. Data analysis

In this study, the baseline data will be reported descriptively by each intervention support group. For continuous variables, an independent sample *t*-test or Mann-Whitney *U* test will be used to assess the balance of baseline data between groups. For categorical variables, Fisher's exact test or chi-square test will be used.

To assess changes in the score of each scale (i.e., EHFScBS, ESSMHF, and HLS) and the physical activity before and after intervention support between the two groups, the researchers will use a paired *t*-test or Wilcoxon signed-rank test. The significance of the differences between the support groups in these outcomes will be assessed using an independent sample *t*-test or Mann-Whitney *U* test. When any unbalanced variables in the baseline data between the two groups require adjustment, analysis will be performed using the analysis of covariance. To examine the clinical event data, Kaplan-Meier survival curve analysis with the log-rank test and the Cox proportional hazards regression model will be used.

All analyses will be based on initially assigned groups. Statistical analysis is performed using SPSS Statistics 26, and statistical significance is defined as a p-value <0.05.

2.10. Ethical approval and consent to study participation

The study was approved by the Ethics Committee of Kobe University Graduate School of Health Sciences (No 699–2). This study was started after approval by both the ethics committee of the research organization and the ethics committee of the facility where the research is being conducted (note that this facility is not involved in protocol development). The clinical trial was registered in the UMIN Clinical Trials Registry (UMIN 000032509) before participant enrollment began. Written informed consent for study participation is obtained from all participants prior to study entry. Participants are informed that participation in this study is voluntary and that they can withdraw at any time, even after giving consent. The participants are also informed that the data collected from them would only be used for the purposes of this study. Possible participant risks associated with this study include fatigue and burden of time loss associated with answering questionnaires and attending session to gain the correct nursing intervention support are informed to the participants. In addition, wearing a wristwatch activity tracker may cause some physical and/or mental strain on some participants. If a participant is too fatigued or has limited time to respond during this waiting period, they are asked to respond at home and return the questionnaire by post. With respect to wearing the wristwatch activity tracker, participants are assured that they can discontinue depending on their physical condition.

3. Discussion

This study aims to test the effectiveness of self-monitoring nursing intervention support based on daily activity records for patients with chronic HF during the early post-discharge phase.

Patients with HF experience a wide range of physical symptoms, including dyspnea, breathlessness, fatigue, edema, sleep problems, palpitations, pain, cough, and poor appetite [4–6], as well as mental symptoms such as depression, anxiety, and fear [4,5]. Other reported symptoms relate to reduced physical capacity [5], a general feeling of being "unwell", and a difference that cannot be clearly explained in words [5]. Even if patients felt some differences in their normal condition 3–7 days before hospital admission, less than half of the patients were able to relate the cause to HF or heart problems [4–7]. Rather, most tend to attribute this change to being overworked [4,7,28], stress [4,6], aging [4], comorbidities [4,6,28], or unknown causes [5,6]. Consequently, many patients delay consultation until their symptoms become severe, usually at the point where it becomes difficult to manage them at home (e.g., orthopnea) [4–7]. These diverse symptoms are also expressed as patients' unique physical sensations, which are often quite distinct from the expressions used by medical professionals [4]. "Symptoms" are defined as the subjective physical and mental experiences appraised and defined by the patient, and reflective of an altered health state or change therein [29]. Therefore, medical professionals must consider that symptoms of HF exacerbation may be related to abnormal physical sensations experienced subjectively by patients, which is different from the norm. To enable patients to seek medical consultations at an early stage of HF exacerbation, it is necessary to provide support to increase the perception of patients' unique physical sensations upon and soon after being discharged. Such support should then serve as a criterion for patients to determine the exacerbation of HF post discharge.

Most self-care intervention programs used to reduce re-hospitalization of HF patients tend to focus on increased knowledge of HF and its symptoms, treatments, and self-care, improved adherence to self-care behaviors (i.e., medical recommendations), or nurses' assessment of their signs and symptoms, (telephone follow-up, home care, messaging, and tele-monitoring) [30–37]. Early after their discharge, patients tend to have difficulties identifying immediate physical effects caused by their behavior, and often do not even perceive changes during exacerbation until their health status worsens to the point that they have to be readmitted [38]. In relation to current trends regarding HF patient readmission, many patients were found to be readmitted at early post-discharge and pre-fatal time periods [9]. Indeed, 19%–24.5% of patients who were admitted with HF [39–42] tend to be readmitted within 30 days after their initial discharge.

Previous intervention studies aimed at increasing patients' perception of changes during exacerbation of HF have used a 6-min walk test. This assesses changes in the sensations of symptoms at rest and immediately after activity [43] and change in walk distance [44], respectively. However, to our knowledge, self-monitoring support to manage physical sensations experienced by HF patients' daily activities early after discharge has not yet been researched. In her explanation of illness perceptions for chronic illness, Larsen [45] suggested that even when medical professionals (who have some knowledge of the disease) experience illness, their perceptions of that illness may instantly change, followed by their emotional responses and behaviors. Thus, even though patients may have already gained some knowledge and experience about HF through in-hospital education or physical activity, hospitalized patients only experience HF in a limited hospital setting. In this setting, HF is managed by a variety of medical professionals and staff. By comparison, in the early stages of discharge, the same patient experiences HF in their daily activities and at their own home, with such conditions becoming "their own." Thus, early in discharge, patients' perception of themselves with HF is likely to change dramatically when compared with their perceptions during hospitalization. Therefore, it is considered more effective to increase patients' perception of physical sensations based on their own daily activities as they live with HF in their own homes and in their own situations at the early stage of discharge. This is important to improve patients' perceptions of unusual physical sensations experienced in the early stage of exacerbation, which may require hospitalization if these become severe.

The daily activity records obtained from the participants who wore activity trackers will serve as a tool for both patients and nurses. It will help nurses to objectively understand each patient's daily activities after discharge and help patients to reflect on their specific daily activities. Physical activity assessment tools generally include self-report-type measures (e.g., questionnaires and detailed diaries) and direct measures using motion sensors (e.g., accelerometers and pedometers) [46]. Thus, direct measurement tools can solve patient self-reported recall and accuracy problems. Moreover, they can objectively measure and grasp individual patients' daily activities. Furthermore, the accelerometer tracker (Life Microscope) used in this study does not require a complicated set-up and/or operation and can easily be worn on the wrist in the same way one would wear a wristwatch. This tracker can also constantly measure the movement of an individual for 24 h/1 week with a full charge, including sleep time, from changes in the acceleration sensor. Displaying the measured data in a visible form helps both the patient and the nurse who provides support to the patient during this study, to easily understand and assess the rhythm of daily activity of each patient during the early stage of discharge. The accelerometer is most often used to assess physical capacity and/or the amount of physical activity for HF populations [27,47,48]. In this study, it is novel to use an accelerometer as a tool for symptom perception in patients with HF. The records gained from accelerometer data can be used to help patients recall their specific daily activities and link how they felt about the physical sensations they experienced during different daily activities. In this way, the use of accelerometer data may aid patients in acquiring self-care management skills to better respond to symptoms, based on an increased perception of physical sensations associated with their daily activities.

Authors believe that increasing the perception of daily activities and associated physical sensations based on daily activity records can lead patients to gain a better understanding of their own illness. Therefore, it resolves many issues associated with delayed consultation in the event of exacerbating HF.

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CRediT author statement

Misako Matsuda: Conceptualization, Methodology, Writing - Original Draft, Funding acquisition. **Nao Saito:** Conceptualization, Methodology, Writing - Review & Editing, Supervision. **Ikuko Miyawaki:** Conceptualization, Methodology, Writing - Review & Editing, Supervision, Project administration.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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