

# **Protocol for the Developing a Self-Administered Eating Behavior Scale for Patients with Heart Failure Living at Home**

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# Protocol for the Developing a Self-Administered Eating Behavior Scale for Patients with Heart Failure Living at Home

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## Abstract

**Background:** The prevalence of heart failure (HF) is increasing worldwide, with the associated mortality rates rising consistently. Preventing HF progression requires adherence to restricted sodium intake alongside sufficient and balanced nutritional consumption. For patients at home, the preparation of nutritionally balanced meals is essential, either self-assisted or with the aid of close individuals. Patients with HF frequently experience decreased exercise tolerance, depression, anxiety, and social isolation. These concurrent conditions interfere with eating behaviors, leading to inadequate dietary habits. Despite these reasonable hypotheses, measures focusing on the determinants of eating behavior among patients with HF are currently lacking.

**Objective:** This study aims to develop a self-administered scale to assess the eating behaviors of patients with HF living at home (SEBS-HF).

**Methods:** The first phase of this study commenced in September 2023, and by May 2024, seven patients with HF and six expert professionals were enrolled as study participants. This study encompasses three phases: Phase 1 involves semi-structured interviews to be conducted with medical experts and patients with HF to identify factors influencing eating behaviors in patients with HF. A preliminary scale will be created based on the information gathered in Phase 1. In Phase 2, cognitive interviews will be conducted with patients with HF and experts; the preliminary scale will be employed to evaluate its content validity. After validation, the scale will be employed in Phase 3 to conduct a cross-sectional study involving patients with HF. The reliability and validity of the scale will be assessed using statistical methods.

**Results:** The first phase of this study commenced in September 2023, and by May 2024, seven patients with HF and six expert professionals were enrolled as study participants. This study is scheduled to complete the evaluation of reliability and validity (Phase 3) by late 2025, after which the SEBS-HF will be published.

**Conclusions:** Developing and utilizing this scale will enable a more comprehensive evaluation of the factors affecting eating behaviors in patients with HF. Therefore, medical and welfare professionals should provide appropriate support tailored to their patient needs.

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## Original Manuscript

## Original Paper

# Protocol for the Developing a Self-Administered Eating Behavior Scale for Patients with Heart Failure Living at Home

## Abstract

**Background:** The prevalence of heart failure (HF) is increasing worldwide, with the associated mortality rates rising consistently. Preventing HF progression requires adherence to restricted sodium intake alongside sufficient and balanced nutritional consumption. For patients at home, preparing nutritionally balanced meals is essential, either self-assisted or with the aid of close individuals. Patients with HF frequently experience decreased exercise tolerance, depression, anxiety, and social isolation, which interfere with eating behaviors, leading to inadequate dietary habits. However, measures focusing on the determinants of eating behavior among patients with HF are currently lacking.

**Objective:** This study aims to develop a self-administered scale to assess the eating behaviors of patients with HF living at home (SEBS-HF).

**Methods:** The first phase of this study commenced in September 2023, and by May 2024, seven patients with HF and six expert professionals were enrolled as study participants. This study encompasses three phases: Phase 1 involves identifying factors influencing eating behaviors in patients with HF. First, a literature review will be conducted using PubMed and CINAHL databases. The specified literature will be analyzed qualitatively and inductively. Additionally, verbatim transcripts obtained from semi-structured interviews of patients with HF and medical experts will be qualitatively analyzed. Based on the Phase 1 results, a preliminary scale will be constructed. In Phase 2, cognitive interviews will be conducted with patients with HF and experts; the preliminary scale will be employed to qualitatively evaluate its content validity. After validation, the scale will be employed in Phase 3 to conduct a cross-sectional study involving patients with HF. In Phase 3, data will be collected from clinical records and self-administered questionnaires or scales. After conducting a preliminary survey, the main survey will be conducted. The reliability and validity of the scale will be assessed using statistical methods.

**Results:** For the first phase of the study targeting HF and experts, approval was obtained on August 30, 2023, from the Ethics Review Board of the Graduate School of Nursing at Sapporo City University (No. 4, 2023). As of May 2, 2024, seven patients with HF and six experts have already been enrolled as study participants.

The draft creation of the scale will be completed in 2024, and the content validity evaluation of the draft scale is expected to be finished by early 2025. The third phase will begin its investigation in mid-2025 and is expected to be completed by late 2025, after which is the publication of the SEBS-HF.

**Conclusions:** The development and utilization of this scale will enable a more comprehensive evaluation of the factors influencing eating behaviors in patients with HF. Thus, medical and welfare professionals should provide appropriate support tailored to the specific needs of patients with HF.

**Keywords:** heart failure; eating behavior; self-care; Patient Reported Outcome Measures

## Introduction

Heart failure (HF) is a clinical syndrome characterized by signs and symptoms resulting from a structural or functional impairment in ventricular filling or blood ejection [1]. HF is a global pandemic, with its prevalence steadily increasing globally, coupled with a consistent increase in associated mortality rates [2]. The prevalence of HF in Japan is estimated to be between 2.2% and 6.5% [3], with HF-related deaths accounting for 6.3% of all mortalities [4]. Given the context of a super-aged society, Japan is currently facing an HF pandemic [5].

Effective self-care for patients with HF primarily involves medication adherence, dietary habits, and physical activity [1]. Self-care measures, such as the European Heart Failure Self-care Behavior Scale (EHFScBS) [6] and the Self-Care of Heart Failure Index (SCHFI) [7], are widely recognized. A Japanese version of the EHFScBS has been developed and used [8]. Patients who adhered to appropriate self-care, as indicated by their EHFScBS scores, had significantly fewer hospitalizations due to all causes than those who did not [9]. The EHFScBS and SCHFI, which include dietary habits as part of self-care, primarily evaluate patient adherence.

Dietary recommendations for preventing HF progression and its associated adverse events are based on balancing sodium restriction with adequate nutrient intake [1]. Concerning low-sodium diets, large-scale randomized controlled trials have demonstrated that stringent sodium restrictions have limited benefits [10]. Therefore, a moderately low-sodium diet and adequate nutritional intake are recommended. However, a low-sodium diet often leads to inadequate intake of macronutrients and micronutrients [11,12]. HF comorbidities, including malnutrition, are known to affect prognosis adversely [13]. In addition, maintaining a balanced diet after discharge from the hospital is crucial to prevent HF progression. Home dietary management entails selecting suitable ingredients and meals, purchasing and preparing them, and making associated decisions. The term “eating behavior” broadly encapsulates these series of actions and decision-making processes [14].

The Brief Dietary Psychosocial Scale (BDPS) is an instrument that targets adolescents and adults, focusing on psychosocial factors and external environments that influence healthy dietary habits, such as the consumption of fruits, vegetables, fiber/whole grains, and fats [15]. The BDPS assesses whether individuals perceive the benefits they derive from a healthy diet, whether they are trying to maintain or change to a healthy diet, whether they are receiving social support for the diet, whether healthy food ingredients are physically and economically accessible, and whether they are enjoying following a healthy diet. The reliability of this scale has previously been evaluated in patients with HF [16].

The Dietary Sodium Restriction Questionnaire (DSRQ) is designed to assess attitudes, subjective norms, and perceived behavioral control related to dietary sodium restriction in patients with HF and hypertension [17]. Of the three DSRQ subscales, the subjective norms are predictive factors for adherence to a low-sodium diet [18].

The Burden Scale In Restricted Diets (BIRD) is a specific instrument developed to assess the burden of low-sodium diets in patients with HF [19]. This questionnaire comprises 14 candidate items for the following dietary-related domains: organization, pleasure, leisure, social life, vitality, and self-rated health.

The International Classification of Functioning, Disability, and Health (ICF) is a framework developed by the World Health Organization that categorizes and describes the health and disability status of individuals [20]. Under the ICF framework, eating behavior pertains to activities and participation domains. Patients with HF often experience decreased exercise tolerance [21], depression, and anxiety [22], which fall under the domains of body function and structure, and social isolation [23], included in the environmental factors domain. These conditions among patients with HF may hinder the eating behaviors necessary for proper home dietary management, potentially leading to acute decompensated HF.

Existing measures, such as the BDPS, DSRQ, and BIRD, focus on factors influencing healthy eating and low-sodium diets but lack a perspective on eating behaviors and do not focus on the body functions and structures domain in the ICF, corresponding to decreased exercise tolerance in HF.

Despite these reasonable hypotheses, measures focusing on the eating behavior determinants among patients with HF are currently lacking. Therefore, this study aims to develop and validate the Self-Administered Eating Behaviors Scale for Heart Failure (SEBS-HF) to assess the dietary habits of patients with HF living at home.

## Methods

### Design and Study Population

This study was designed in accordance with the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) Study Design checklist for Patient-reported outcome measurement [24] and the COSMIN methodology for evaluating the content validity of patient-reported outcome measures [25]. The qualitative descriptive investigation in this study adheres to the guidelines outlined in the Consolidated Criteria for Reporting on Qualitative Research checklist [26]. The criteria for identifying patients with HF in this study are defined as follows. The eligible population includes patients aged  $\geq 18$  with **symptomatic** HF (stage C), according to the American College of Cardiology/American Heart Association/Heart Failure Society of America guidelines [1]. Under the Japanese long-term care insurance system, individuals aged  $\geq 65$  are assessed and classified into seven levels of care needs based on their activities of daily living, cognitive function, and medical conditions. For patients aged  $\geq 65$  years, only those yet to receive long-term care certification or those who fall within the range of “Requiring Help 1” to “Long-term Care Level 1” will be included. This is because SEBS-HF is aimed at home-based patients with HF who can self-manage their diet to some extent, focusing on individuals who are relatively independent but may still require minimal assistance.

The exclusion criteria are as follows: living in care facilities, assisted living facilities, or nursing homes; aged  $\leq 65$  years with a disability certificate unrelated to cardiac dysfunction; undergoing hemodialysis because of dietary restrictions different from those of patients with HF; chronic respiratory diseases because of symptoms similar to HF such as reduced exercise tolerance; and mental illnesses because of the potential impact on eating behaviors.

**Patients with HF eligible for this study will be recruited from either outpatients or inpatients at the medical institutions where the co-researchers are affiliated and the medical institutions collaborating in this study. Specifically, patients who are attending or admitted to the cardiology departments of these medical institutions will be included.**

**Experts will be recruited through the network of the principal investigator, co-researchers, and snowball sampling of the initially recommended experts.**

### Study Composition

This study is composed of three phases (Table 1).

Table 1. Composition of the study.

Phase 1: Scale draft creation using qualitative descriptive method
1. Extraction of factors influencing eating behavior through literature review
2. Extraction of factors influencing eating behavior through semi-structured interviews with patients
3. Extraction of factors influencing patients' eating behavior through semi-



structured interviews with experts

4. Itemization and creation of the scale draft from the scale items obtained

### **Phase 2: Evaluation of the scale draft's content validity by patients and experts**

1. Evaluation of the scale draft's face validity and revision of the draft through semi-structured interviews with patients
2. Evaluation of the comprehensibility, relevance, and inclusiveness of the scale draft and revision of the draft through semi-structured interviews with patients
3. Evaluation of the relevance and inclusiveness of the scale draft and revision of the draft through semi-structured interviews with experts

### **Phase 3: Evaluation of the reliability and validity of the scale draft through a cross-sectional survey**

1. Preliminary investigation
2. Primary investigation
3. Analysis of the data obtained from the primary survey using statistical methods and evaluation of the reliability and validity of the scale draft

### **Phase 1**

In Phase 1, a qualitative descriptive investigation will be conducted to create a preliminary scale.

#### **Phase 1-1**

A literature review will be performed to identify factors influencing eating behaviors. For this literature review, the approach by Sascha [27] will be followed, and PubMed and CINAHL databases will be utilized as literature sources. We will consider primary research articles written in English, published within the last 10 years, and available as full texts for our analysis. Keywords such as "heart failure," "eat," "behavior," "diet," "food," "meal," "sodium," and "preparation" will be incorporated in the search to specifically target relevant articles in the context of this study. **Additionally, references cited within the selected literature will be manually searched, and any articles identified as relevant to the eating behaviors of patients with HF will be included in the analysis based on their context or titles.** The selected literature will be analyzed qualitatively and inductively. **Descriptions of factors influencing the eating behaviors of patients with HF will be extracted from each source. To maintain the meaning and content, these descriptions will be standardized consistently to illustrate how various factors influence the eating behaviors of patients with HF.** The extracted descriptions will be categorized based on their similarities and differences. Multiple researchers will review and verify the categorization to ensure reliability and validity.

#### **Phase 1-2**

Semi-structured interviews with patients with HF will be conducted to gather insights into the factors influencing their eating behaviors. Interviews will be conducted in person according to an interview guide. Verbatim transcripts generated from the interviews will be returned to the participants for verification and to obtain their comments. Demographic and clinical information, such as age, sex, New York Heart Association (NYHA) functional classification [1], height, weight, HF history, hospitalization due to HF, other medical conditions or history, details of medications, and whether patients received nutritional guidance, will be extracted from their medical records. Information on participants' living arrangements, employment status, perceived financial status, utilization of community resources, means of transportation to grocery stores, frequency of cooking meals and meal delivery services, presence of cohabitants, and essential characteristics of cohabitants will be collected using a self-administered questionnaire to obtain more data. The age distribution of the targeted patients will encompass the entire age range susceptible to HF, including a minimum of one

participant <50 years, one participant in their 60s, and two participants each in their 70s and 80s, totaling at least six individuals.

Data obtained from medical records and self-administered questionnaires will be analyzed using simple aggregation. Interview transcripts will be collected verbatim and analyzed using Sandelowski's qualitative descriptive approach. The analysis will commence once the data from the six patients with HF have been collected. Transcript data collected verbatim from subsequent participants will be included in the analysis, and the process will continue until theoretical saturation is achieved. The analyses will be conducted independently by two researchers.

### Phase 1-3

Semi-structured interviews will be conducted with experts to gather insights into the factors influencing the eating behaviors of patients with HF. The interviews will be conducted following an interview guide, either in person or online. Transcripts generated verbatim from the interviews will be returned to the experts for verification and to obtain their comments. The target experts for the interviews will consist of six members, one from each specialization area:

- (i) Certified physicians of the Japanese Society for Clinical Nutrition, specializing in cardiology
- (ii) Certified nurse in chronic HF care
- (iii) Clinical nurse specialist in chronic disease care
- (iv) Certified HF educator
- (v) Nutrition support team (NST)-specialized therapist
- (vi) Visiting nurse

The NST-specialized therapist and visiting nurse will target individuals with extensive experience caring for patients with HF. Verbatim transcripts from the interviews will be analyzed using Sandelowski's qualitative descriptive approach. The analysis will be conducted independently by two researchers.

Based on the results obtained in Phase 1, a set of scale items and a Likert rating scale will be constructed as preliminary scales.

### Phase 2

In Phase 2, cognitive interviews with patients with HF and experts will be conducted, employing a preliminary scale to evaluate its content validity. **The COSMIN guidelines recommended having a sample size of at least seven participants for qualitative evaluation of content validity [25].** If any issues with the scale are identified through the assessments conducted in Phases 2-1-3, they will be modified as appropriate.

#### Phase 2-1

The surface validity of the preliminary scale will be assessed through semi-structured interviews with patients with HF. Patients with HF will be recruited from a population different from the one used in the previous investigation. The participants will consist of at least seven individuals, including one individual in their 50s and 60s and two individuals each in their 70s and 80s. Cognitive interviews and analysis will follow the approach proposed by Willis [28]. **Cognitive interviewing allows us to understand respondents' thought processes and identify issues with the scale. This approach involves asking participants to verbalize their thought processes while answering, allowing researchers to detect misunderstandings, ambiguities, and cognitive difficulties. This method ensures the face validity of the scale.** The interview guide will be developed based on the questionnaire items created for the preliminary scale. The interviews will be conducted in person following this procedure.

- i. Explaining the purpose of measuring the scale to the patients.

- ii. Showing patients the items on a preliminary scale and requiring them to provide written responses to each question.
- iii. Once responses are obtained, we will orally confirm the thought process that the patients underwent when answering the questions (think-aloud).
- iv. We will verbally probe and confirm the content of the question items in more detail, checking if the initial responses align (verbal probing).
- v. Steps (ii) to (iv) will be repeated for all question items.
- vi. Verifying that no important content relevant to the patient is missing across the entire scale.

The verbatim transcripts obtained from the interviews will be analyzed from the following perspectives:

- i. Were there any doubts or concerns regarding the content of the questions?
- ii. Were the intended responses obtained from the question items?
- iii. Were there any ambiguities or unclear language expressions in the question items or response choices?
- iv. Were there any deficiencies in the questions regarding important content relevant to the participants themselves?

The analysis will be conducted independently by two researchers.

#### Phase 2-2

The clarity, relevance, and comprehensiveness of the preliminary scale will be assessed through cognitive interviews, **involving at least seven patients** with HF included in the previous investigations. The interview guide will be developed based on the questionnaire items created for the preliminary scale. The interviews will be conducted in person following this procedure.

- i. Participants will read and respond to the paper-based scale.
- ii. Orally confirming how participants understood the content of the scale questions.
- iii. Verbally confirming if the scale questions were relevant to their own experiences.
- iv. Steps (ii) to (iii) will be repeated for all the question items.
- v. Verifying that no important missing content in the scale is relevant to the participant's experiences.

Transcripts will be created verbatim from the interviews, and the assessment will revolve around examining the clarity of each question item, its relevance to patient situations, and the presence of any pertinent information that might be missing. The analysis will be conducted independently by two researchers.

#### Phase 2-3

The relevance and comprehensiveness of the preliminary scale will be assessed through cognitive interviews with experts. The investigation will involve seven experts, including six experts identified in Phase 1-3, and an additional expert who is a nursing faculty member experienced in scale development. These seven experts will be the target participants and will be distinct from those involved in previous investigations. Interviews will be conducted either in person or online.

- i. Participants will read the scale on paper.
- ii. The questionnaire items will be checked for their relevance to patients with HF.
- iii. If any questionnaire item is perceived as lacking relevance, its reasons will be investigated.
- iv. The overall scale will be reviewed to ensure that important content related to patients with HF is not missing.
- v. The reasons for perceiving the content as insufficient will be confirmed if it was perceived as such.

Transcripts will be created verbatim from the interviews, and the assessment will revolve around examining its relevance to the patients' situations and the presence of any pertinent information that might be missing. The analysis will be conducted independently by two researchers.

### Phase 3

We will employ the scale scrutinized in Phase 2 to conduct a cross-sectional study involving patients with HF. Data will be collected from the clinical records and self-administered questionnaires or scales. The items are listed in Table 2. A cross-sectional survey consisting of preliminary and primary investigations will be conducted. **The collection of clinical records data will be conducted with the approval of the medical institution's ethics review board. After obtaining this approval, consent from the eligible patients for their participation in the study will be requested. Clinical records will then be collected from the medical institutions where the co-researchers are affiliated or from the collaborating medical institutions, with the cooperation of both the co-researchers and collaborating researchers.**

Table 2. Inventory of data obtained from the cross-sectional survey in Phase 3.

<b>Clinical record</b>
Age, sex, NYHA classification [1], height, weight, HF history, hospitalization due to HF, other existing medical conditions, medical history, medications, and whether nutritional guidance was provided
<b>Self-administered questionnaire of lifestyle situations</b>
Living arrangements, employment status, perceived financial status, utilization of community resources, means of transportation to grocery stores, frequency of cooking meals on own, frequency of using meal delivery services, presence of cohabitants, essential characteristics of cohabitants, and frequency of meals prepared by a cohabitant or home helper
<b>Self-administered scale</b>
Preliminary SEBS-HF
The Japanese version of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)
The Japanese version of the European Heart Failure Self-care Behavior Scale (EHFScBS)
Established scales for assessing criterion-related validity

### Preliminary Investigation

Data will be collected using clinical records, self-administered questionnaires, and preliminary SEBS-HF. To confirm normality, the sample size will be approximately 30 [29]. In addition, data will be collected from patients attending collaborating medical institutions. The principal investigators collaborating at these institutions will select patients based on established eligibility criteria. Once informed consent has been obtained, the patient's clinical records will also be collected. A survey set, which includes the self-administered questionnaire and preliminary SEBS-HF, will be provided along with a return envelope for data collection. Calculations will be made from the acquired data to determine the mean scores, standard deviations, and individual item score distributions. Normality tests will be also performed. Moreover, potential ceiling and floor effects will be examined based on the mean and standard deviation.

### Primary Investigation

The reliability and validity of the data acquired from the primary investigation will be examined using statistical methods (Table 3).

Table 3. Statistical analysis procedures and considerations for assessing reliability and validity.

<b>Descriptive statistics</b>	<b>Measures means, standard deviations, and frequencies</b>
<b>Normality assessment</b>	Conduct a Shapiro–Wilk test, which calculates a test statistic based on the observed data and compares it against the Shapiro–Wilk distribution.
<b>Item analysis</b>	Evaluate ceiling and floor effects and perform item-total correlation analysis. Items with a correlation coefficient $r < 0.3$ or $> 0.7$ may be considered for removal or integration[30].
<b>Internal consistency</b>	Calculate Cronbach’s alpha coefficient. A coefficient of $\geq 0.7$ is considered to indicate internal consistency[31].
<b>Structural validity</b>	Perform an exploratory factor analysis to ascertain the degree of shared variance among the items and elucidate potential factor groupings. The factor structure established through exploratory factor analysis is assessed with confirmatory factor analysis to check its fit with data from a different population.
<b>Criterion validity</b>	Calculate descriptive statistics for the external criterion scale and confirm normality. Then, calculate the correlation coefficient between the criterion scale and the scale under development. The validity is evaluated based on the value of the correlation coefficient.
<b>Construct validity</b>	Calculate the correlation coefficient between subgroups to verify hypotheses. In this scale, it is assumed that aging and the decline in physical and mental functions due to HF symptoms will affect eating behavior negatively. Therefore, verification will be done using age, NYHA classification [1], and certification of care-need level subgroups.
<b>Measurement error</b>	Calculate the intra-class correlation coefficient, standard error, and detectable minimum change for the total scale and sub-scale scores obtained from the first and second tests. The sample size should be $> 50$ participants to verify measurement error. An intra-class correlation coefficient of $\geq 0.7$ is considered to indicate stability[32].

In addition to the data collection methods used in the preliminary investigation, the primary investigation will incorporate the test-retest method to assess measurement error and establish scales to evaluate criterion-related validity. In the test-retest method, participants will initially respond to the SEBS-HF and then provide their responses again 2 weeks later. To assess the criterion-related validity of the SEBS-HF, we will select the SF-36 [33] and the EHFSBS [8] as external measures. We will request the study participants to provide their responses to these instruments. If more suitable external measures are available when the survey commences, we may opt to use them. The maximum likelihood method and promax rotation will be used in the exploratory factor analysis. The factor loadings obtained will enable commonality assessment among the questionnaire items. Items with a factor loading exceeding a certain threshold will be selected. Consideration will be



given to the excluded items that did not meet this threshold or loaded on multiple factors. If items are excluded, a factor analysis will be performed again.

The factor structure established by exploratory factor analysis will be examined to fit the data collected from different populations. This will be performed using goodness of fit indices (Goodness of Fit Index, Adjusted Goodness of Fit Index, Comparative Fit Index, and Root Mean Square Error of Approximation) to evaluate the appropriateness of the model. If the fit does not meet specific standards, a review of the questionnaire items or reconsideration of the exploratory factor analysis will be needed.

According to the COSMIN guidelines [24], the sample size should be five to seven times the number of scale items and not <100. Assuming the scale had 30 items, we planned to include over 150 participants in the primary investigation. Data from different populations are required to conduct exploratory and confirmatory factor analyses. Therefore, the total sample size should exceed 300 participants.

## Results

In the first phase of this study, a literature review was conducted to extract factors influencing eating behavior in patients with HF. On January 26, 2024, a comprehensive search using keywords such as “HF,” “diet,” “eating behavior,” “meal prep\*,” and “culinary” was performed in databases including PubMed and CINAHL. This search yielded a total of 4,145 articles. Relevant literature was selected based on the examination of titles and abstracts to extract the factors influencing eating behavior among patients with HF.

For the first phase of the study targeting HF and experts, approval was obtained in

**August 30, 2023**, from The Ethics Review Board of the Graduate School of Nursing at Sapporo City University (No. 4, 2023). **As of May 2, 2024**, seven patients with HF and six experts have already been enrolled as study participants.

The draft creation of the scale is scheduled to be completed in 2024, and the evaluation of the content validity of the draft scale is expected to be finished by early 2025. The third phase will begin its investigation in mid-2025 and is expected to be completed by late 2025, after which is the publication of the SEBS-HF.

## Discussion

This study aims to develop a SEBS-HF to evaluate the eating behaviors of patients with HF living at home. This section discusses how SEBS-HF development might improve the eating behaviors of patients with HF living at home.

Given the concerns surrounding the relationship between malnutrition and adverse outcomes in patients with HF, proper dietary management has emerged as a pivotal factor in enhancing prognosis [34].

Minimal barriers to eating are desirable to maintain appropriate dietary management. **According to the ICF framework, negative aspects of body functions and structures, environmental, and personal factors, can affect eating behaviors, which are included in the activities and participation domains. In other words, characteristics specific to heart failure patients, such as frailty[35], depression, and social isolation[36], are expected to influence eating behaviors negatively. Therefore, the SEBS-HF will be designed to quantitatively evaluate and assess the impact on eating behaviors specific to heart failure patients through self-administered evaluations.**

Through self-administered evaluations, patients can identify their strengths and weaknesses. Additionally, Sharing the evaluation results from the SEBS-HF with medical and welfare professionals can pave the way for individualized patient-centric support. Such assistance enhances the patient’s ability to manage their diet appropriately and leads to improved well-being.

Furthermore, as the SEBS-HF is quantified using a Likert scale, if a correlation between the results and adherence to dietary habits and readmission due to acute decompensated HF becomes evident, it could serve as a potent predictor.

Notably, a significant number of patients with HF may have dementia, which affects their self-care. The SEBS-HF is specifically designed for patients with HF who manage their diet at home, without accounting for those patients who require additional assistance because of conditions such as dementia.

## Limitations

This study will verify the reliability and validity in accordance with the COSMIN guidelines [24,25], but there are some limitations. First, a longitudinal study must evaluate the responsiveness of the measure or the process of validating the ability of the instrument to detect changes in the measured construct over time. Second, interpretability, which implies setting cutoff values, will not be measured. Following SEBS-HF development, we aim to evaluate the clinical importance of factors such as adherence to dietary habits and readmission due to acute HF to determine appropriate cutoff points. Finally, the cross-cultural validity of the SEBS-HF, explicitly designed for Japanese, remains to be assessed in different linguistic and cultural contexts.

## Conclusions

The development and utilization of this scale will enable a more comprehensive evaluation of the factors influencing eating behaviors in patients with HF. Patients will be able to conduct self-assessments using this scale. Sharing the results with healthcare professionals will allow patients to identify eating behavior issues, potentially improving dietary adherence. Therefore, medical and welfare professionals will provide appropriate support tailored to their patients' needs.

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## Authors' Contributions

Conceptualization: Kashiwakura Daisaku, Hiyama Akiko, Muramatsu, Masumi, Hinotsu Atsuko. Funding acquisition: Kashiwakura Daisaku, Hiyama Akiko, Muramatsu, Masumi, Hinotsu Atsuko. Methodology: Kashiwakura Daisaku, Hiyama Akiko, Muramatsu Masumi, Hinotsu Atsuko, Takeda Michiko, Kida Keisuke, Suzuki Norio, Akiyama Sachie, Kurihara Sayuri. Project administration: Kashiwakura Daisaku. Supervision: Hiyama Akiko, Muramatsu Masumi, Hinotsu Atsuko. Writing - original draft: Kashiwakura Daisaku. Writing – review, and editing: Kashiwakura Daisaku, Hiyama Akiko, Muramatsu Masumi, Hinotsu Atsuko.

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## Consent for publication

Not applicable.

## Availability of Data and Materials

The data collected or analyzed during the course of this study will not be made available to third parties. However, upon reasonable request, associated questionnaires and protocols used in the study may be provided by the corresponding author.

## Ethics Approval

In Phases 1 and 2, before starting interviews of patients with HF and experts, the research participation details will be explained using a document and written informed consent will be obtained. Consent can be withdrawn within certain time limits by signing and returning a withdrawal form or by email. As compensation for participating in the research, a gift card worth ¥3,000 was given to patients with HF, and a gift card worth ¥5,000 was given to experts upon the completion of each interview.

In Phase 3, when distributing the set of survey forms to the eligible patients with HF, the research participation details will be explained using a document, and consent will be obtained in a similar manner. The set of survey forms will include a small gift as a token of appreciation for participating in the research.

The Ethics Review Board of the Graduate School of Nursing at Sapporo City University approved this study. The first phase of the investigation had already been approved by the Ethics Review Board (No. 4, 2023). This study will be conducted in accordance with the principles outlined in the Declaration of Helsinki.

## Conflicts of Interest

None declared.

## Abbreviations

BDPS: Brief Dietary Psychosocial Scale

BIRD: Burden Scale in Restricted Diets

COSMIN: Consensus-based Standards for the selection of health Measurement Instruments

DSRQ: Dietary Sodium Restriction Questionnaire

EHFScBS: European Heart Failure Self-care Behavior Scale

HF: heart failure

ICF: International Classification of Functioning, Disability, and Health

NST: nutrition support team

NYHA: New York Heart Association

SCHFI: Self-Care of Heart Failure Index

SEBS-HF: Self-Administered Eating Behaviors Scale for Heart Failure



## References

1. Writing Committee Members; ACC/AHA Joint Committee Members. 2022 AHA/ACC/HFSA guideline for the management of heart failure. *J Card Fail* 2022;28(5):e1-e167. PMID:35378257
2. Savarese G, Becher PM, Lund LH, Seferovic P, Rosano GMC, Coats AJS. Global burden of heart failure: A comprehensive and updated review of epidemiology. *Cardiovasc Res* 2023;118(17):3272-3287. PMID:35150240
3. Zhang L, Ono Y, Qiao Q, Nagai T. Trends in heart failure prevalence in Japan 2014–2019: A report from healthcare administration databases. *ESC Heart Fail* 2023;10(3):1996-2009. PMID:37016908
4. Ministry of Health, Labour and Welfare. Patient Survey. 2022. URL: <https://www.e-stat.go.jp/dbview?sid=0003464100> [accessed 2024-04-01]
5. Isobe M. The heart failure “pandemic” in Japan: Reconstruction of health care system in the highly aged society. *JMA J* 2019;2(2):103-112. PMID:33615020
6. Jaarsma T, Årestedt KF, Mårtensson J, Dracup K, Strömberg A. The European Heart Failure Self-care Behaviour scale revised into a nine-item scale (EHFScB-9): A reliable and valid international instrument. *Eur J Heart Fail* 2009;11(1):99-105. PMID:19147463
7. Riegel B, Lee CS, Dickson VV, Carlson B. An update on the self-care of heart failure index. *J Cardiovasc Nurs* 2009;24(6):485-497. PMID:19786884
8. Kato N, Ito N, Kinugawa K, Kazuma K. Validity and reliability of the Japanese version of the European Heart Failure Self-Care Behavior Scale. *Eur J Cardiovasc Nurs* 2008;7(4):284-289. PMID:18221917
9. Wagenaar KP, Broekhuizen BDL, Rutten FH, Strömberg A, van Stel HF, Hoes AW, et al. Interpretability of the European Heart Failure Self-care Behaviour scale. *Patient Prefer Adherence* 2017;11:1841-1849. PMID:29138538
10. Ezekowitz JA, Colin-Ramirez E, Ross H, Escobedo J, Macdonald P, Troughton R, et al. Reduction of dietary sodium to less than 100 mmol in heart failure (sodium-HF): An international, open-label, randomised, controlled trial. *Lancet* 2022;399(10333):1391-1400. PMID:35381194
11. Uysal H, Öz Alkan HÖ, Enç N, Yiğit Z. Assessment of dietary habits in patients with chronic heart failure. *J Nurs Res* 2020;28(1):e65. PMID:31107776
12. Jefferson K, Ahmed M, Choleva M, Mak S, Allard JP, Newton GE, et al. Effect of a sodium-restricted diet on intake of other nutrients in heart failure: Implications for research and clinical practice. *J Card Fail* 2015;21(12):959-962. PMID:26497756
13. Li H, Zhou P, Zhao Y, Ni H, Luo X, Li J. Prediction of all-cause mortality with malnutrition assessed by controlling nutritional status score in patients with heart failure: a systematic review and meta-analysis. *Public Health Nutr.* 2021 Jun 30;25(7):1-8. PMID: 34187615
14. Mahmood L, Flores-Barrantes P, Moreno LA, Manios Y, Gonzalez-Gil EM. The influence of parental dietary behaviors and practices on children’s eating habits. *Nutrients* 2021;13(4):1138. PMID:33808337

15. Norman GJ, Carlson JA, Sallis JF, Wagner N, Calfas KJ, Patrick K. Reliability and validity of brief psychosocial measures related to dietary behaviors. *Int J Behav Nutr Phys Act* 2010;7:56. PMID:20594360
16. Marolt C, Miller A, Carlozzi NE, Karmally W, Helmke S, Teruya S, et al. Assessing barriers to healthy eating in hospitalized older adults with heart failure: Psychometric properties of two questionnaires. *J Card Fail* 2020;26(3):223-226. PMID:31580890
17. Bentley B, Lennie TA, Biddle M, Chung ML, Moser DK. Demonstration of psychometric soundness of the Dietary Sodium Restriction Questionnaire in patients with heart failure. *Heart Lung* 2009;38(2):121-128. PMID:19254630
18. Wu JR, Lennie TA, Dunbar SB, Pressler SJ, Moser DK. Does the theory of planned behavior predict dietary sodium intake in patients with heart failure? *West J Nurs Res* 2017;39(4):568-581. PMID:27756851
19. Audureau E, Guellich A, Guéry E, Canouï-Poitaine F, Benedyga V, Duchossoir H, et al. Development and validation of a new tool to assess burden of dietary sodium restriction in patients with chronic heart failure: The BIRD questionnaire. *Nutrients* 2018;10(10):1453. PMID:30301251
20. World Health Organization. International Classification of Functioning, Disability and Health. I.M.B. Community Foundation. 2001. URL: <https://www.who.int/standards/classifications/international-classification-of-functioning-disability-and-health> [accessed 2024-04-01]
21. Del Buono MG, Arena R, Borlaug BA, Carbone S, Canada JM, Kirkman DL, et al. Exercise intolerance in patients with heart failure: JACC state-of-the-art review. *J Am Coll Cardiol* 2019;73(17):2209-2225. PMID:31047010
22. Celano CM, Villegas AC, Albanese AM, Gaggin HK, Huffman JC. Depression and anxiety in heart failure: A review. *Harv Rev Psychiatry* 2018;26(4):175-184. PMID:29975336
23. Goodlin SJ, Gottlieb SH. Social isolation and loneliness in heart failure: Integrating social care into cardiac care. *JACC Heart Fail* 2023;11(3):345-346. PMID:36889882
24. Terwee CB, Prinsen CAC, Chiarotto A, Westerman MJ, Patrick DL, Alonso J, et al. COSMIN methodology for evaluating the content validity of patient-reported outcome measures: A Delphi study. *Qual Life Res* 2018;27(5):1159-1170. PMID:29550964
25. Mokkink LB, Prinsen CA, Patrick DL, Alonso J, Bouter LM, de Vet HC, et al. COSMIN study design checklist for patient-reported outcome measurement instruments. 2019. URL: [https://www.cosmin.nl/wp-content/uploads/COSMIN-study-designing-checklist\\_final.pdf](https://www.cosmin.nl/wp-content/uploads/COSMIN-study-designing-checklist_final.pdf) [accessed 2024-04-01]
26. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. *Int J Qual Health Care* 2007;19(6):349-357. PMID:17872937
27. Kraus S, Breier M, Lim WM, Dabić M, Kumar S, Kanbach D, et al. Literature reviews as independent studies: Guidelines for academic practice. *Rev Manag Sci* 2022;16:2577-2595. doi:10.1007/s11846-022-00588-8

28. Willis G. Cognitive Interviewing as a Tool for Improving the Informed Consent Process. *J Empir Res Hum Res Ethics* 2006;1(1):9-23. PMID:19385864
29. Kwak SG, Kim JH. Central limit theorem: The cornerstone of modern statistics. *Korean J Anesthesiol* 2017;70(2):144-156. PMID:28367284
30. Henrysson, S. Correction of item-total correlations in item analysis. *Psychometrika* 1963;28(2):211-218. doi: 10.1007/BF02289618
31. Taber, K.S. The use of Cronbach's alpha when developing and reporting research instruments in science education. *Res Sci Educ* 2018;48:1273-1296. doi: 10.1007/s11165-016-9602-2
32. Landis, J. Richard, and Gary G. Koch. The measurement of observer agreement for categorical data. *Biometrics* 1977;33(1):159-174. doi: 10.2307/2529310
33. Fukuhara S, Ware JE, Kosinski M, Wada S, Gandek B. Psychometric and clinical tests of validity of the Japanese SF-36 Health Survey. *J Clin Epidemiol* 1998;51(11):1045-1053. PMID:9817122
34. Yamamoto K, Tsuchihashi-Makaya M, Kinugasa Y, Iida Y, Kamiya K, Kihara Y, et al. Japanese Heart Failure Society 2018 scientific statement on nutritional assessment and management in heart failure patients. *Circ J* 2020;84(8):1408-1444. PMID:32655089
35. Li J, Han J, Luo N, Ding X, Hao X, Li K. Frailty affects self-care behavior in congestive heart failure. *Clin Nurs Res* 2022;31(4):615-623. PMID:35168389
36. Sbolli M, Fiuzat M, Cani D, O'Connor CM. Depression and heart failure: The lonely comorbidity. *Eur J Heart Fail* 2020;22(11):2007-2017. PMID:32468714

## Supplementary Files

## **Related publication(s) - for reviewers eyes onlies**

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