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# Psychometric evaluation of the heart failure somatic perception scale in Iranian heart failure patients: a cross-sectional study

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**Background:** This study aimed to evaluate the psychometric evaluation of heart failure somatic perception scale (HFSPS) in Iranian heart failure patients.

**Materials and methods:** A total of 220 heart failure (HF) patients were enroled in the study. Data gathering was conducted via consecutive sampling from August 2022 to April 2023. Face validity, content validity, construct validity, and internal consistency were used to evaluate the validity and reliability of the Persian version of the HFSPS. Construct validity was done through confirmatory factor analysis and convergent validity. Convergent validity between HFSPS and symptom status questionnaire-heart failure was measured using Pearson's correlation coefficient. Cronbach's alpha and Macdonald's omega coefficient were used to evaluate the reliability of instruments.

**Results:** A total of 220 HF patients participated in this study. Their mean age was 66.46 (SD = 11.40). Among the participants, 70% were men. The results of the confirmatory factor analysis evaluation showed the goodness of fit indices of the final HFSPS model after modification was within an acceptable range ( $\chi^2$  = 306.18 *P* < 0.001, Minimum Discrepancy Function Divided by Degrees of Freedom = 2.47, Comparative of Fit Index = 0.91, Tucker-Lewis index = 0.90, Adjusted goodness of fit index = 0.81, Parsimonious norm fit index = 0.70, root mean square error of approximation = 0.082). Convergent validity between HFSPS and symptom status questionnaire-heart failure indicated a positive and significant correlation. Cronbach's alpha coefficient in the HFSPS was 0.868, and McDonald's omega coefficient in the HFSPS was 0.832.

Conclusion: Overall, the Persian version of the HFSPS was determined to be a reliable and valid scale among Iranians with HF.

Keywords: heart failure, psychometric, reliability, sign, symptom, validity

# Introduction

Heart failure (HF) is a severe chronic and progressive illness that affects about 26 million people worldwide<sup>[1]</sup>. HF is estimated to affect 1–2% of individuals and more than 10% of people over 70 in European countries<sup>[2]</sup>. Additionally, forecasts show that by 2030, the prevalence of HF in the United States will rise by 46%<sup>[3]</sup>. HF is also common in developing countries; for instance, in Iran, it is estimated that 3.5% of the population will soon have the condition<sup>[4]</sup>.

Patients with HF frequently experience multiple symptoms at once, including shortness of breath, exhaustion, vertigo, and sleep disturbances. The physical symptoms that patients with HF experience hasten the disease's progression and impair the person's performance<sup>[5–7]</sup>. Patients with HF are under considerable pressure to manage their illness and frequently struggle to identify their initial symptoms. These patients are either accustomed to their symptoms or unaware they are worsening<sup>[8–12]</sup>. The pressure and burden of symptoms may rise depending on the frequency and intensity of activity and how these affect a person's activities of daily living. However, physicians and other medical professionals, such as nurses, evaluate and record patients' symptoms differently since patients' perceptions of and reporting HF symptoms and signs vary significantly<sup>[6]</sup>.

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One of the most crucial self-care activities is managing one's perception of symptoms. Poor comprehension of symptoms might result in a recurrence of HF symptoms and a delay in receiving treatment<sup>[13,14]</sup>. To help identify at-risk patients with poor knowledge of illness symptoms, It is necessary to operationalize the concept of patient perception of disease symptoms to identify at-risk patients with poor knowledge of their conditions. This will be important when planning to better understand symptoms<sup>[15]</sup> and the disease trajectory. Therefore, a valid and reliable scale is crucial for adequately assessing the patient's symptoms, signs, and disease burden<sup>[6,16]</sup>.

Jurgens and colleagues created the heart failure somatic perception scale (HFSPS) in 2017. This scale assesses the presence and severity of HF's physical symptoms. The HFSPS scale assesses 18 items, which include the subscales for dyspnoea (six items), chest discomfort (two items), early and subtle symptoms (seven items), and oedema (three items)<sup>[6]</sup>. Although the HFSPS has been approved for use in many countries, Iran's population of HF patients has not yet benefited from this scale due to nonvalidation and approval for use in Iran.

Precise scales are required to assess treatment outcomes, forecast survival rates, and be utilized for clinical decision-making to assess the intensity and complexity of HF symptoms. Since the HFSPS has recommended criteria for evaluating symptoms and no validated standard scale has been used to assess patient perception of physical HF symptoms in Iran, a thorough review and psychometric evaluation of this scale are necessary. This study aimed to ascertain the psychometric properties of the Persian translation of the HFSPS in Iran and measure its reliability and validity in the Iranian HF patient population.

# Methods

The HFSPS consists of 18 items designed to assess the presence and severity of HF signs and symptoms in patients. These items are divided into four subscales: shortness of breath (six items), early and sybtle symptoms (seven items), chest discomfort (two items), and oedema (three items), all pertaining to the past week. Each item offers six possible response choices, ranging from 0 (indicating an absence of symptoms) to 5 (indicating severe symptom impact). The total score is calculated by summing up all item scores, resulting in a score range of 0–90. A higher score reflects a greater perception of the symptoms experienced by the patient<sup>[6]</sup>.

#### Phase 1

Permission was obtained from the original author of the HFSPS questionnaire (Ms Jurgens) to translate and validate the questionnaire in Iran. This questionnaire was translated from English to Farsi based on WHO guidelines using the Forward & Backward method. The procedure known as the "Wild and colleagues forward and backward method" involves several steps for the translation process. The method was followed as outlined below: (1) Preparation of the tool intended for translation; (2) Translation of the tool into the target language by a minimum of two individuals; (3) Comparison and correction of the translations; (4) Back translation: The translated tool is retranslated back into the original language by an impartial individual; (5) Examination and assessment of the back-translated version by the research

# HIGHLIGHTS

- The results of the confirmatory factor analysis evaluation showed the goodness of fit indices of the final heart failure somatic perception scale (HFSPS) model after modification was within an acceptable range ( $\chi^2 = 306.18 \ P < 0.001$ , Minimum Discrepancy Function Divided by Degrees of Freedom = 2.47, Comparative of Fit Index = 0.91, Tucker-Lewis index = 0.90, Adjusted goodness of fit index = 0.81, Parsimonious norm fit index = 0.70, root mean square error of approximation = 0.082).
- Convergent validity between HFSPS and symptom status questionnaire-heart failure indicated a positive and significant correlation.
- Cronbach's alpha coefficient in the HFSPS was 0.868, and McDonald's omega coefficient in the HFSPS was 0.832.
- Overall, the Persian version of the HFSPS was determined to be a reliable and valid scale among Iranians with heart failure.

team; (6) Harmonization and alignment of the translations with the original tool, resolving any inconsistencies; (7) Verification of the tool's concepts for clarity and understanding by the intended audience; (8) Evaluation of the perceived concept comprehension; (9) Rectification of any errors present in the tool; and (10) Compilation of the final report summarizing the translation process. This process ensures accurate translation and comprehension of the tool's concepts within the target language and culture<sup>[17]</sup>. After translation, the research team compiled the final version and translated it into English. Ms Jurgens received this English translation of the HFSPS to verify the accuracy of the translations and the consistency between the English translation and the original HFSPS. The scale's final version included all comments.

# Face validity

As a pilot study, the final scale was administered to twenty HF patients at this stage. These patients were asked to comment on the suitability of the appearance, the degree of clarity and ambiguity of the chosen terms, and the logic of the order of the items to fulfil the scale's objectives. The final version considered the opinions of this group.

# Content validity

The items' content validity ratio (CVR) and content validity index (CVI) was computed to evaluate the quantitative content validity. On a three-point scale, fifteen faculty members who were educators in cardiac care were asked to rank the HFSPS items' essentiality: Not essential: 1, useful but not essential: 2, and essential:  $3^{[18,19]}$ . A minimum acceptable CVR of 0.62 is necessary when there are up to 10 panellists<sup>[20]</sup>.

The CVI indicates the degree to which the scale's intended items are relevant, and it can be determined for both the scale's items (Item level or I-CVI) and the entire scale (Scale-level or S-CVI). Therefore, the researchers asked the ten faculty members to rank the HFSPS items' relevance on a scale of 1–4. For instance, "Not relevant," "Somewhat relevant," "Quite relevant," and "Highly relevant" were the four ratings for the items' relevance. The items with an I-CVI value of 0.7 or higher were considered appropriate<sup>[21]</sup>.

# Phase 2

#### Normal distribution, outliers, and missing data

For the normal distribution of data, skewness ( $\pm$  3) and kurtosis ( $\pm$  7) were used to analyze the univariate and multivariate distribution of data. Mahalanobis d-squared (P < 0.001) and the Mardia coefficient of multivariate kurtosis (>8) were used to determine the presence of multivariate outliers and multivariate normality, respectively<sup>[22]</sup>. The average participant response was used to replace the missing data after they had been analyzed using multiple imputations<sup>[23]</sup>. SPSS version 26 and AMOS version 24 software were used for data analysis.

# Survey development

The present study was reported in line with the STROCSS criteria<sup>[24]</sup>. Two hundred twenty HF patients enroled in the study. Data gathering was conducted via consecutive sampling from August 2022 to April 2023. The inclusion criteria of the studied patients were outpatients and inpatients with HF, class II to IV HF according to the New York Heart Association (NYHA) classification, the ability to read, write and understand the Persian language, willing to participate voluntarily, and the absence of cognitive and mental difficulties.

The researchers visited the site after obtaining hospital management's permission and the ethics clearance certificate presentation. The researchers explained the objectives of the present study to the participants and obtained informed consent. The participants' names were not mentioned in the questionnaire and responses to ensure information confidentiality.

# Construct validity

Construct validity was examined using confirmatory factor analysis (CFA) and convergent validity. CFA and goodness of fit (GoF) indices were used to evaluate the four factors extracted by the primary developer of the HFSPS. A good model fit should have a non-significant  $\chi^2$  (If the sample size is large, it will not be considered), Minimum Discrepancy Function divided by Degrees of Freedom (CMIN/DF) less than 3, Comparative of Fit Index (CFI), Tucker-Lewis index (TLI) greater than 0.9, Adjusted goodness of fit index (AGFI) greater than 0.8, Parsimonious norm fit index (PNFI) greater than 0.5, and root mean square error of approximation (RMSEA) less than  $0.08^{[25,26]}$ .

Symptom status questionnaire-heart failure (SSQ-HF) was used to evaluate the convergent validity. This questionnaire consists of seven items that assess common physical symptoms of HF, including daytime dyspnoea, orthopnea, fatigue, chest pain, oedema, difficulty sleeping, and dizziness or loss of balance in HF patients. Patients are requested to identify the presence of each symptom experienced over the past 4 weeks. In cases where there is no indication of a symptom, a score of 0 is assigned. If a symptom is reported, patients are further queried about its frequency, intensity, and level of discomfort. Responses are categorized on a scale from 1 (occurring less than once a week) to 4 (almost daily) for frequency, 1 (slightly) to 4 (very much) for intensity, and 0 (not at all) to 4 (very much) for distress. For each physical symptom, a cumulative score is computed by adding up the ratings assigned to that symptom. These scores range from 0 to 12. The overall score for the entire assessment tool is derived by summing the total scores for all symptoms. This overall score spans from 0 to 84, where higher scores correlate with more pronounced and severe symptoms<sup>[27]</sup>. Pearson's correlation coefficient was used to evaluate the correlation between HFSPS and SSQ-HF.

#### Reliability

The internal consistency of CAPS was assessed using Cronbach's alpha and McDonald's omega<sup>[28]</sup>. The scale's internal consistency was considered appropriate if it was more than  $0.7^{[29]}$ .

#### Ethical approval

The Guilan University of Medical Sciences ethics committee approved the study in Rasht, Iran. The patients were informed of the study's objectives and methodology. All study participants were assured that all reporting and publication of results would be done anonymously.

#### Results

#### Phase 1

#### Face and content validity

Regarding face validity, the results showed that every item on the scale was relevant, clear, and simple to use. According to the CVI results, every item had an index of more than 0.79 and had been deemed appropriate without additional testing in the final edition. According to 10 professionals' assessments of the outcomes of the scale's CVR, every item had a CVR higher than the minimum threshold of 0.62 in the Lawshe table<sup>[20]</sup>.

#### Phase 2

#### Participants' characteristics

As shown in Table 1, 220 HF patients participated in this study. Their mean age was 66.46 (SD = 11.40). Among the participants, 70% were men, and 88.6% were married. 73.2% of participants were university graduates, and 35.5% were self-employed. The average EF in these patients was 24.75% (SD = 11.94). 51.8% of patients had a history of hospitalization due to HF, and 66.4% were in NYHA functional class III.

## Normal distribution and HFSPS mean score

As shown in Table 2, all HFSPS items had a normal distribution. The mean score in the dyspnoea subscale was 23.45 (SD = 6.81), the chest discomfort subscale was 6.40 (SD = 3.10), the early and subtle symptoms subscale was 20.92 (SD = 6.59), and the oedema subscale was 6.59 (SD = 6.22). Overall, the mean HFSPS score was 57.36 (SD = 16.80).

## Construct validity

As shown in Table 3 and Fig. 1, the GoF indices of the final HFSPS model after modification were within an acceptable range ( $\chi^2 = 306.18 \ P < 0.001$ , CMIN/DF = 2.47, CFI = 0.91, TLI = 0.90, AGFI = 0.81, PNFI = 0.70, RMSEA = 0.082). All factor loadings were significant and ranged from 0.24 (item 4) to 0.92 (item 11).

Table 1		
Demograph	ic and clinical characteristics of participants (/	N = 220)

	Participants
Age (year)	66.46 (SD = 11.40)
Sex	
Male	154 (70.0)
Female	66 (30)
Marital status	
Single	1 (0.5)
Married	195 (88.6)
Divorced	5 (2.3)
Widow	19 (8.6)
Level of education	
Under diploma	161 (73.2)
Diploma	50 (22.7)
Above the diploma	9 (4.1)
Employment status	
Employee	4 (1.8)
Worker	4 (1.8)
Unemployed	5 (2.3)
Housewife	58 (26.4)
Farmer	30 (13.6)
Self-employed	78 (35.5)
Retired	41 (18.6)
History of hospitalization for HF	18.08 (SD = 31.70)
Yes	114 (51.8)
No	106 (48.2)
EF (%)	24.75 (SD = 11.94)
NYHA functional class	
l	38 (17.3)
III	146 (66.4)
IV	36 (16.4)

Data are presented as numbers (percentage) and mean (SD).

EF, Ejection Fraction; HF, heart failure; NYHA, New York heart association.

#### Convergent validity

As shown in Table 4, Pearson's correlation coefficient between four subscales of the HFSPS and SSQ-HF questionnaire in the dyspnoea subscale was 0.707, the chest discomfort subscale was 0.521, the early and subtle symptoms subscale was 0.658, the oedema subscale was 0.585. HFSPS was 0.867, and all were significant.

#### Reliability

As shown in Table 5, the internal consistency of the HFSPS was calculated using Cronbach's alpha and McDonald's omega coefficient. Cronbach's alpha coefficient in the dyspnoea subscale was 0.871; the chest discomfort subscale was 0.572; the early and subtle symptoms subscale was 0.665; the oedema subscale was 0.929; and the whole scale was 0.868. McDonald's omega coefficient in the dyspnoea subscale was 0.852, the early and subtle symptoms subscale was 0.600, the oedema subscale was 0.942, and the whole scale was 0.832.

# Discussion

This study was conducted to investigate the psychometric properties of the Persian version of the HFSPS. According to the obtained results, HFSPS is a valid and reliable scale to measure

# Table 2Item descriptive statistics of the HFSPS (N = 220)

Items	Mean (SD)	Skewness	Kortosos
1. I could feel my heartbeat get faster	3.43 (SD = 1.81)	- 0.92	- 0.52
2. I could not breathe if I lay down (flat)	3.87 (SD = 1.76)	- 1.43	0.76
3. I felt discomfort or pain in my chest	2.97 (SD = 1.89)	- 0.52	- 1.17
4. I had an upset stomach	2.00 (SD = 1.88)	0.20	- 1.47
5. I had a cough	2.69 (SD = 1.92)	- 0.28	- 1.41
6. I was tired	4.08 (SD = 1.25)	- 1.82	3.33
7. I could not catch my breath	4.45 (SD = 0.97)	- 2.41	6.04
8. My feet were swollen	2.41 (SD = 2.25)	- 0.002	- 1.82
9. I woke up at night because I could not breathe	3.42 (SD = 1.89)	- 0.94	- 0.64
10. My shoes were tighter than usual	2.33 (SD = 2.26)	0.08	- 1.83
11. I gained weight in the past week	1.85 (SD = 2.13)	0.45	- 1.57
12. I could not do my usual activities because I was shortness of breath	4.21 (SD = 1.22)	- 1.97	3.81
<ol> <li>Getting dressed made it hard to breathe</li> </ol>	3.20 (SD = 1.89)	- 0.76	- 0.89
14. My clothes felt tighter around my waist	1.91 (SD = 2.14)	0.39	- 1.64
15. I woke up at night because I had to urinate	3.84 (SD = 1.44)	- 1.35	1.14
16. I had to rest more than usual during the day	4.34 (SD = 0.98)	- 2.00	4.98
17. It was hard for me to breathe	4.30 (SD = 1.14)	- 2.08	4.64
18. I did not feel like eating	2.05 (SD = 2.00)	0.18	- 1.61
Mardia coefficient of multivariate kurtosis			73.590
Dyspnoea subscale	23.45 (SD = 6.81)	- 1.25	1.06
Chest discomfort subscale	6.40 (SD = 3.10)	- 0.60	-0.73
Early and subtle symptoms subscale	20.92 (SD = 6.59)	- 0.60	- 0.63
Oedema subscale	6.59 (SD = 6.22)	- 0.25	- 0.50
HFSPS	57.36 (SD = 16.80)	- 0.25	- 0.50

Data are presented as mean (SD).

HFSPS, heart failure somatic perception scale.

patients' perception of the physical symptoms of HF in the Iranian HF community.

The results of CFA in our study showed that the four factors extracted (dyspnoea, chest discomfort, early and subtle symptoms, and oedema) by Jurgens and colleagues were confirmed in the HF community in Iran. In this study, the initial fit of the model was not satisfactory, but by plotting the covariance between some errors of the items, the GoF indices became satisfactory. Covariance was plotted between items 7 and 9 in the dyspnoea subscale, items 4 and 5, 14 and 15, 15 and 16 in the early and subtle symptoms subscale, and items 8 and 10 in the oedema subscale. Incorporating covariance within the framework of CFA carries important implications in terms of refining model fit and bolstering the precision of the inherent structural connections.

Table	e 3						
Model Fit Indices for HFSPS (N = 220)							
Models	χ²	CMIN/DF	CFI	TLI	AGFI	PNFI	RMSEA
HFSPS	306.18*	2.47	0.91	0.90	0.81	0.70	0.082

AGFI, Adjusted Goodness-of-Fit Index; CFI, Comparative Fit Index; CMIN/DF, Minimum Discrepancy Function by Degrees of Freedom divided; HFSPS, heart failure somatic perception scale; PNFI, Parsimonious Normed Fit Index; RMSEA, Root Mean Square Error of Approximation; TLI, Tucker-Lewis Index. \*P < 0.001.



Covariance, a metric quantifying the extent of co-variation between two variables, encapsulates the level of interrelation or correlation they share. In the context of CFA, covariance plays a pivotal role as a vital information source, aiding in the evaluation of the degree to which the proposed model harmonizes with the actual observed dataset<sup>[30,31]</sup>. In the study of Pucciarelli and</sup> colleagues on the psychometric evaluation of the HFSPS in the European HF Society, CFA was used to check the construct validity. In this study, to improve GoF, covariance was drawn between items 6 and 7 in the dyspnoea and early and subtle symptoms subscales, items 11 and 14 in the early and subtle symptoms and oedema subscales, and items 8 and 10 in the oedema subscale<sup>[16]</sup>. Plotting covariance in items 8 and 10 in the oedema subscale aligned with our study. According to the results of plotting the covariance in items 8 and 10, it is theoretically acceptable because item number 8 examined oedema in the foot, and item number 10 examined the tightness of the patient's shoes. Therefore, these two items measured similar concepts and had the same measurement error. Other covariances in our study were drawn between the items of similar factors, which can be considered the reason for drawing the similarity of the measurement error in the items of these factors. It is reasonable to assume that the remaining items were to be correlated in a CFA when these correlations are theoretically or methodologically viable, provided that they do not affect estimations of other model parameters<sup>[32]</sup>. In the study of Hayashi et al.<sup>[33]</sup> on the cross-

Table 4					
Convergent	validity o	of HFSPS	with SS	Q-HF	

	SSQ-HF r
Dyspneae subscale	0.707*
Chest discomfort subscale	0.521*
Early and subtle symptoms subscale	0.658*
Oedema subscale	0.585*
HFSPS	0.867*

HFSPS, heart failure somatic perception scale; SSQ-HF, symptom status questionnaire-heart failure. \*P < 0.001. cultural validity of the HFSPS instrument in the Japanese HF community, CFA was used to examine the construct validity. Unlike the present study, in the reported results of the Japanese study, none of the reported GoF indices were within the acceptable range. Ultimately, through the depiction of the specified covariances, the GoF indices in this investigation exhibited notable enhancement, affirming the adequacy of the final HFSPS model consisting of four subscales and 18 items.

In this study, construct validity was additionally examined using convergent validity. Convergent validity was performed between HFSPS and SSQ-HF. Investigating the correlation between the HFSPS and SSQ-HF subscales, it was found that all were moderately and significantly correlated with the SSQ-HF. The total correlation of HFSPS with SSQ-HF was high and significant, and the Persian version of HFSPS had good convergence with SSQ-HF. In the study of Pucciarelli et al.[16], criterion validity was used to evaluate the correlation of HFSPS with the Kansas City Cardiomyopathy Questionnaire as a gold standard, the results of which showed a strong and significant correlation between the two instruments. In the study of Hayashi et al.<sup>[33]</sup>, criterion validity was used to examine the correlation between HFSPS and the Patient-Reported Outcomes Measurement Information System, and the two scales had a negative correlation. A study was conducted by Okviasanti and colleagues to investigate the validity and reliability of the Indonesian version of the HFSPS. For criterion validity, the Indonesian version of the Minnesota Living with Heart Failure Questionnaire (MLHF) was used as a gold standard, where the HFSPS had a positive and

Table 5 Reliability of HFSPS

	α	Ω
Dyspneae subscale	0.871	0.852
Chest discomfort subscale	0.572	
Early and subtle symptoms subscale	0.665	0.600
Oedema subscale	0.929	0.942
HFSPS	0.868	0.832

HFSPS, heart failure somatic perception scale.

significant correlation with both the physical domains and the total score<sup>[34]</sup>. Due to the lack of a valid and reliable scale in connection with the evaluation of HF symptoms in Iran, it was impossible to perform criterion validity to check the correlation of the Persian version of the HFSPS with a gold standard scale. For this reason, in this study, convergent validity was conducted using another similar standard questionnaire, which showed a positive and significant correlation between the two scales.

The internal consistency of HFSPS was measured using Cronbach's alpha coefficient and Macdonald's omega coefficient, and the full scale's internal consistency was reasonable. The internal consistency of the subscales of dyspnoea and oedema was also good, and the subscales of chest discomfort and early and subtle symptoms were average. In the study of Pucciarelli et al.<sup>[16]</sup>, the internal consistency of the whole scale and the subscales of shortness of breath, oedema, and initial symptoms were good, and the chest discomfort subscale was moderate. The results of Hayashi's study in Japan and Okviasanti's study in Indonesia were also in the same direction as this study<sup>[33,34]</sup>. Based on this, it can be concluded that the Persian version of the HFSPS had good reliability. Considering that Cronbach's alpha coefficient is sensitive to the number of items, the reason for the average internal consistency coefficient of the two-item chest discomfort subscale can be attributed to the low number of items<sup>[35]</sup>.

# Limitations

This study had some limitations. The sampling of this study was done only in one of the provinces of Iran, which may affect generalizability. The fact that this study confirmed the original factorial structure of the HFSPS is a reasonable justification for the generalizability of its findings. Some of the patients in this study were in class IV of the NYHA classification. Considering the physical condition of this group of patients, their patience and ability to answer the scale items may have been impacted negatively.

#### Implication for healthcare providers

Healthcare providers can use this scale to determine which signs and symptoms impact HF patients' overall health. The HFSPS can also be a valuable scale for determining how significant HF signs and symptoms are to enhance provider management.

#### Conclusion

Overall, the Persian version of the HFSPS was determined to be a reliable and valid scale among Iranians with HF. Considering the comprehensive measurement of symptoms in HFSPS, it can be used to identify HF patients at risk of having a lower quality of life and to determine appropriate interventions.

# **Ethical approval**

The Guilan University of Medical Sciences ethics committee approved the study in Rasht, Iran. The patients were informed of the study's objectives and methodology. All study participants were assured that all reporting and publication of results would be done anonymously.

# Consent

Written informed consent was obtained from the patient for publication and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

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None.

#### **Author contribution**

Study concept and design by all authors; Data acquisition by all authors; Data interpretation by all authors; drafting the manuscript by all authors; Revision of the manuscript by all authors; the final version of the manuscript is approved by all authors.

# **Conflicts of interest disclosure**

The authors declare no conflict of interest.

# Research registration unique identifying number (UIN)

We could not register our manuscript in the Research Registry UIN: www.researchregistry.com due to internet access restrictions and international sanctions. we live in Iran. We hardly even meet the basic needs of our daily life. We do not receive any funding for our research and we cannot pay for our research. Please excuse us from registering this manuscript in the Research Registry UIN: www.researchregistry.com.

## Guarantor

Nazila Javadi-Pashaki (PhD).

# Data availability

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

# **Provenance and peer review**

Not commissioned, externally peer-reviewed.

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