Original Article



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Psychometric evaluation of the Heart Failure Somatic Perception Scale in a European heart failure population

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Abstract

Background: The Heart Failure Somatic Perception Scale (HFSPS) is a four-factor instrument used to assess how bothersome are 18 physical signs and symptoms of heart failure. To date, construct validity and reliability of the HFSPS have been evaluated in only one American study and never in a European population.

Aim: To evaluate psychometric properties (validity and reliability) of the HFSPS in a European heart failure population. **Methods:** This was an Italian multicentre study in which the HFSPS factorial structure was assessed using confirmatory factor analysis. Criterion related validity of the HFSPS was evaluated by correlating its factor scores with the Kansas City Cardiomyopathy Questionnaire (KCCQ) scores using Pearson's *r*. The HFSPS internal consistency reliability was evaluated using the factor score determinacy coefficient, Cronbach's α and model-based internal consistency index.

Results: Most of the participants (n=321) were male (56.6%), with a mean age of 71.48 years (SD, 12.75) and in New York Heart Association class II (61.8%). The confirmatory factor analysis, testing the original HFSPS four-factor structure (dyspnoea, chest discomfort, early and subtle, and oedema), resulted in the following supportive fit indices: χ^2 (126, N=321)=337.612, p<0.001, comparative fit index =0.920, Tucker–Lewis index =0.903, root mean square error of approximation =0.072 and standardized root mean square residual =0.045. With regard to the criterion related validity, all the correlations with the KCCQ were statistically significant. The HFSPS reliability resulted in factor score determinacy coefficients ≥ 0.87 and Cronbach's $\alpha \geq 0.75$, with the exception of the two-item chest discomfort subscale; the model-based reliability coefficient was 0.914.

Conclusion: The validity and reliability of the HFSPS were supportive in this European sample. The HFSPS can be used to assess how bothersome heart failure signs and symptoms are in order to improve their management.

Keywords

Heart failure, signs, symptoms, psychometrics, validity, reliability

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Introduction

Heart failure is a major public health problem that affects approximately 26 million people worldwide.¹ Heart failure is characterized by several symptoms and often the escalation of these symptoms is associated with recurrent hospitalizations^{2–4} and poor quality of life (QOL).⁵

How the symptoms of heart failure are perceived and reported by patients is variable, and this variation influences the symptom assessment and documentation by clinicians.^{4,6} Because heart failure symptoms can predict ¹Department of Biomedicine and Prevention, University of Rome Tor Vergata, Rome, Italy

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morbidity and mortality, a precise assessment of these symptoms by patients using reliable and valid instruments is important.^{7,8} Furthermore, evidence has shown that better and faster identification of heart failure symptoms can reduce mortality by 40–50%.⁹

Despite the well-known relationship between heart failure symptoms and survival, several of the existing instruments to evaluate heart failure symptoms have limitations.^{10–12} Often they do not assess the early indicators of heart failure decompensation (e.g. fatigue) or they measure dyspnoea, a hallmark symptom of heart failure decompensation, with only a single item.⁷ Several investigators or clinicians evaluate heart failure symptoms with QOL disease-specific instruments, which are focused not on the burden or perception of heart failure signs and symptoms, but on the effects of the heart failure symptoms or treatments on an individual's physical and psychological QOL.^{8,13} Thus, it is difficult to evaluate the unique effects of the common heart failure symptoms on the patient outcomes.¹¹

Differently, the Heart Failure Somatic Perception Scale (HFSPS)⁷ assesses the presence and severity of 18 common physical signs and symptoms of heart failure (e.g. oedema and chest pain), and assesses dyspnoea and its effects on daily activities with six items. In addition to physical symptoms, signs of heart failure (e.g. oedema) are evaluated in the HFSPS because signs, bothersome to some patients, contribute to the patient perception of burden.14,15 The HFSPS was developed based on the literature and the Theory of Unpleasant Symptoms acknowledging that the interactions among multiple symptoms are influenced by the pathology, situational factors and outcomes.^{16,17} Also, the HFSPS reflects the five criteria proposed by Lee and Moser¹² to evaluate symptom instruments: 1) comprehensiveness, which means that the instrument includes the symptoms as well as the dimensions assessed with regard to the prevalence, frequency, severity and distress; 2) simplicity, which means that the instrument should be easy to complete and suitable for clinical and research purposes; 3) not burdensome during completion; 4) psychometrically sound for accuracy (i.e. internal consistency reliability) and precision (i.e. criterion and construct validity); and 5) information related to the clinical implications, such as the prognosis (e.g. survival).

The original HFSPS,¹⁶ called the Heart Failure Somatic Awareness Scale, included 12 items corresponding to 12 physical heart failure symptoms. Because the original scale did not evaluate the complexity of the dyspnoea and other heart failure symptoms, Jurgens et al. expanded the scale from 12 to 18 items to include dyspnoea upon exertion, fatigue, nocturia and symptoms associated with rightsided congestion (e.g. abdominal swelling and loss of appetite).⁷ Psychometric analysis of the HFSPS was conducted with a convenience sample of 378 patients with chronic heart failure and resulted in a four-factor solution: dyspnoea (six items), chest discomfort (two items), early and subtle (seven items) and oedema (three items). Convergent and discriminant validity also were evaluated, and the results showed significant correlations (r = 0.39 to 0.54, p < 0.0001) between the HFSPS factors and the sixitem physical limitation subscale of the Kansas City Cardiomyopathy Questionnaire (KCCQ).¹⁸ Predictive validity testing showed that higher HFSPS scores predicted increased heart failure-related clinical events at the one-year follow-up. The global reliability of the HFSPS indices was also supportive, ranging from 0.76 to 0.77.

Although the construct validity and reliability of the HFSPS have been found supportive for measuring heart failure symptoms, the psychometric properties of the 18-item version have been evaluated in only one American study.¹⁰ Consequently, its validity and reliability are still in their infancies in the literature, which does not report any other psychometric works on the HFSPS conducted in other countries. Since robust and rigorous measures are needed to assess the complexity of the heart failure symptoms, and the evidence suggests that a quality assessment of a broad range of heart failure symptoms may be useful in evaluating therapeutic outcomes, predicting survival and informing clinical decision making,⁷ the purpose of this study was to evaluate the validity and reliability of the HFSPS in a population of Italian heart failure patients.

Methods

Design

In this study, we used the baseline data collected until February 2018 of the Motivational Interviewing to Improve Self-care in Heart Failure Patients (MOTIVATE-HF) study.¹⁹ The MOTIVATE-HF study is an Italian three-arm randomized controlled trial designed to evaluate the effects of motivational interviewing on the patient's and caregiver's self-care. A detailed description of the study has been reported elsewhere.¹⁹ Briefly, in the MOTIVATE-HF study, patients were enrolled if they had a diagnosis of heart failure, were symptomatic with New York Heart Association (NYHA) classes II-IV, performed less than adequate self-care, did not have severe cognitive impairment or coronary syndrome during the last three months, and did not live in a residential setting (e.g. nursing home). The study also enrolled the patients' informal caregivers, who were defined as those persons, inside or outside the family, identified by the patient as providing most of the informal care.

Measures

The HFSPS v.3⁷ is composed of 18 items that quantify the extent to which the main signs and symptoms of heart failure bothered the patient during the last week. Each item

has five possible answers, ranging from 0 ('I did not have this symptom') to 5 ('extremely bothersome'). The HFSPS scores are obtained by adding the scores of all the items, with a range from 0 to 90. A higher score indicates a greater impact of the heart failure symptom on the patient's life. Before its use in this study, the HFSPS underwent a commonly accepted method for instrument translation and back-translation that we used in prior studies.^{20,21} First, the HFSPS was translated into the Italian language by two heart failure nurses who were fluent in English. Second. the Italian translation of the HFSPS was back-translated into English by an Italian-English teacher with expertise in medical/scientific English, without seeing the HFSPS in its original English version. Third, the back-translated scale was assessed by the original author (C Jurgens) in order to check whether the intended meaning of each item was kept. During this phase, minimal changes were discussed by email before reaching the final Italian version of the HFSPS.

The KCCQ¹⁸ is a 23-item disease-specific scale that evaluates the physical function, symptoms, social function, self-efficacy and QOL of patients with heart failure. The KCCQ is a reliable and valid measure of the health status responsive to changes in the clinical status. We used the KCCQ for criterion related validity purposes because the literature reports that heart failure patients with more heart failure symptoms have lower QOL.^{5,22} Higher scores on the KCCQ mean better QOL.

Data collection procedures

Participants were enrolled during both hospitalization and outpatient appointments. After identifying the potential participants based on the inclusion and exclusion criteria, the research assistants, who were all nurses, met the participants and explained the study objectives and data collection procedures. If the patient gave his/her written consent, the battery of MOTIVATE-HF study tools, including the HFSPS, was administered. The battery also included sociodemographic (e.g. age) and clinical (e.g. NYHA functional class) data. The clinical variables were extracted from the patient's medical record.

Data analysis

We performed data analysis in six steps. First, we analysed sociodemographic (e.g. age) and clinical (e.g. ejection fraction) characteristics of the study participants using descriptive statistics (e.g. mean and standard deviation (SD)). Second, we examined missing data of the HFSPS items using Little's missing completely at random test.²³ Third, we analysed HFSPS items by calculating their means and SDs and by checking their normal distribution with indices of skewness and kurtosis; Bulmer²⁴ recommends concern if skewness and kurtosis are higher than ± 1 .

To overcome the problems of item non-normality, we used Geomin (oblique) rotation and the weighted least square parameter estimation method to assess confirmatory factor analysis (CFA). The model chosen for testing was the one tested by Jurgens et al., with the following four factors: dyspnoea (items 2, 7, 9, 12, 13 and 17), chest discomfort (items 1 and 3), early and subtle (items 4, 5, 6, 14, 15, 16 and 18) and oedema (items 8, 10 and 11). Using a multifaceted approach to evaluate the model fit, while taking into account the recommendations by Hu and Bentler,²⁵ we considered the following fit indices: χ^2 , comparative fit index (CFI), Tucker-Lewis index (TLI), root mean square error of approximation (RMSEA) and standardized root mean square residual (SRMR). With the above statistics, a good model fit should have: a non-significant χ^2 (even though in a large sample size a significant χ^2 is not considered), a CFI and TLI > 0.90 (or better, > 0.95), a RMSEA < 0.08 (or better, < 0.05) and an SRMR <0.08. To estimate the model parameters the full information maximum likelihood procedure provided in Mplus 7 was applied, and all available information, including information from participants with missing data, was used.²⁶

Fifth, we evaluated the criterion related validity of the HFSPS by correlating its factor scores with the KCCQ scores using Pearson's r.²⁷ Sixth, we evaluated the internal consistency reliability of the HFSPS factors using the factor score determinacy coefficient and Cronbach's α . Moreover, since Jurgens et al. proposed to have a total score of the 18-item HFSPS, we used, as done by previous researchers,^{28,29} the model-based internal consistency index to estimate the reliability of the total multidimensional scale. All the above reliability estimates should have a value above 0.70.

We used IBM SPSS Statistics for Windows version 21.0 (IBM Corp., Armonk, New York, USA) and Mplus version 7 (Muthén & Muthén, Los Angeles, California, USA) for the data analyses. For all the analyses, a p value < 0.05 was considered to be statistically significant.

Results

Of the 343 patients who met the inclusion and exclusion criteria and were asked to participate in the study, 321 agreed to participate and signed the informed consent form. Most of the 321 participants (Table 1) were males (56.6%), married (64.1%) and retired (82.1%), with a mean age of 71.48 years (SD = 12.75). Most (61.8%) were in NYHA class II, and ischaemic cardiomyopathy (38.2%) was the main heart failure aetiology.

Missing data of the HFSPS items were only 0.07%. A comparison between participants with completed HFSPS data versus those without yielded a non-significant difference in Little's missing completely at random test (χ^2 (50) =29.29, *p*=ns). Table 2 presents the item descriptive analysis of the HFSPS. The average scores of the responses to the 18

Table.	Characteristics	of sample	(N=321)).
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Patients characteristics	M (SD) or n (%)
Age	71.48 (12.75)
Gender	
Male	185 (57.6)
Female	136 (42.4)
Education	
Less than high school	240 (74.8)
High school	58 (18.1)
University degree	23 (7.1)
Marital Status	
Single	16 (5)
Married	197 (61.4)
Widower	99 (30.8)
Divorced	9 (2.8)
Job status	
Employed	57 (17.9)
Retired	262 (82.1)
Time with heart failure, months	64.8 (74.22)
NYHA functional class	
Class II	197 (61.3)
Class III	103 (32.0)
Class IV	19 (5.7)
Left ventricular ejection fraction, %	44.54 (9.4)
Aetiology	$\textbf{35.20} \pm \textbf{7.4}$
Ischaemic	123 (38.2)
Not ischaemic	78 (24.3)
Idiopathic	74 (23.0)
Other	46 (14.5)

NYHA: New York Heart Association.

items from all participants ranged from 0.83 to 2.56. The items with the lowest mean were 'I did not feel like eating' and 'I gained weight in the past week'; the items with the highest mean were 'I was tired' and 'I woke up at night because I had to urinate'. In line with recommendations by Bulmer,²⁴ some items had a non-normal distribution, with skewness and kurtosis higher than \pm 1 (Table 2).

Confirmatory factor analysis of the HFSPS

The CFA testing of the original four-factor model identified by Jurgens et al. (2017) showed unsatisfactory fit indices, as follows: χ^2 (129, N=321) = 441.701, p<0.001, CFI=0.882, TLI=0.860, RMSEA=0.087 and SRMR=0.056. An inspection of the modification indices revealed that the misfit was due to the existence of excessive covariance between the residuals of items 11 and 14 (which investigated gaining weight in the past week and clothes feeling tighter around the waist, respectively), items 6 and 7 (which investigated tiredness and difficulty 'catching' one's breath, respectively) and items 8 and 10 (which investigated swollen feet and shoes feeling tighter, respectively). By letting the residuals of the above items freely correlate, the following satisfactory fit indices were obtained: χ^2 (126, *N*=321) = 337.612, *p*<0.001, CFI=0.920, TLI=0.903, RMSEA=0.072 and SRMR=0.045. The graphical representation of the CFA is shown in Figure 1. All factor loadings were statistically significant and ranged from 0.42 (item 18) to 0.87 (item 17). All the correlations among the four factors were statistically significant as well, and ranged from 0.783 between the chest discomfort and the oedema factor.⁷

Criterion related validity of the HFSPS

The criterion related validity, which was tested by correlating (with Pearson's *r*) the four factors of the HFSPS with the KCCQ dimensions, showed the correlations reported in Table 3. All the correlations were statistically significant, and ranged from -0.773 between the HFSPS total and the KCCQ total symptom scores to -0.158 between the HFSPS oedema dimension and the KCCQ self-efficacy scores.

Reliability of the HFSPS

The HFSPS factors' reliability, tested with the factor score determinacy coefficient, resulted in the following: 0.96 for dyspnoea, 0.87 for chest discomfort, 0.94 for early and subtle and 0.90 for oedema factor. The HFSPS factors' reliability, tested with Cronbach's α , resulted in the following: 0.90 for dyspnoea, 0.53 for chest discomfort and 0.75 for early and subtle and oedema factors. Finally, the model-based internal consistency index was 0.914 for the entire scale.

Discussion

The aim of this study was to evaluate the psychometric properties of the HFSPS in a sample of Italians affected by heart failure. Our analysis confirmed the results obtained by Jurgens et al.,⁷ which showed that the HFSPS is a valid and reliable instrument for measuring the physical signs and symptoms of heart failure patients. To the best of the authors' knowledge, this is the second psychometric work conducted on this scale, and the first conducted in an European heart failure population.

Our CFA supported the four dimensions of the scale, as found by Jurgens et al.⁷ dyspnoea, chest discomfort, early and subtle and oedema subscales. In our study, the initial fit was not satisfactory, but by letting the residuals of some of the items correlate freely, we found satisfactory fit indices. The item residuals that were allowed to correlate were actually very close in content. For example, items 11 and 14 investigated gaining weight and clothes feeling tighter, respectively, and both reflect fluid retention. The correlation between the residuals of items 6 and

Items	М	SD	Skewness	Kurtosis
I. I could feel my heart beat get faster	1.56	1.400	0.349	-0.953
2. I could not breathe if I lay down (flat).	1.86	1.596	0.139	-1.335
3. I felt discomfort or pain in my chest	1.29	1.436	0.634	-0.867
4. I had an upset stomach	1.17	1.325	0.859	-0.174
5. I had a cough	1.55	1.416	0.424	-0.927
6. I was tired	2.56	1.463	-0.400	-0.791
7. I could not catch my breath	2.07	1.527	0.027	-1.128
8. My feet were swollen	1.86	1.525	0.228	-1.086
9. I woke up at night because I could not breathe	1.59	1.633	0.424	-1.300
10. My shoes were tighter than usual	1.57	1.501	0.453	-1.003
11. I gained weight in the past week	0.87	1.250	1.133	-0.022
12. I could not do my usual activities because I was SOB	1.81	1.579	0.307	-1.146
13. Getting dressed made it hard to breathe	1.60	1.501	0.389	-1.101
14. My clothes felt tighter around my waist	1.14	1.374	0.849	-0.513
15. I woke up at night because I had to urinate	2.50	1.387	-0.146	-0.806
16. I had to rest more than usual during the day	1.70	1.518	0.371	-1.033
17. It was hard for me to breathe	1.72	1.562	0.305	-1.213
18. I did not feel like eating	0.83	1.263	1.391	0.945

Table 2. Item descriptive statistics of the Heart Failure Somatic Perception Scale (N=321).

SOB: short of breath

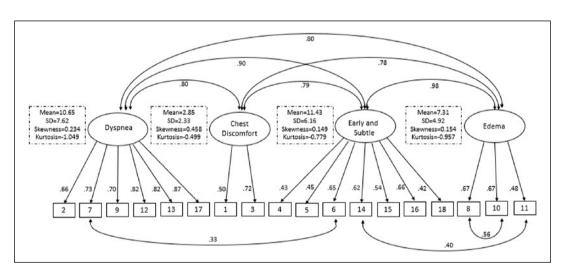


Figure 1. Confirmatory factor analysis for the Heart Failure Somatic Perception Scale with Geomin (oblique) rotation was chosen for this analysis using weighted least square parameter estimation method: final model letting the residuals of the items 11 and 14, 6 and 7, and 8 and 10 freely correlate. Fit indices: χ^2 (126, N=321) = 337.612, p < 0.001, comparative fit index =0.920, Tucker–Lewis index =0.903, root mean square error of approximation =0.072 and standardized root mean square residual =0.045.

7, which measured tiredness and 'catching' one's breath, respectively, may be due to the fact that these two symptoms may coexist in heart failure patients. Finally, the correlation between the residuals of items 8 and 10, which evaluated swollen feet and shoes feeling tighter, respectively, also reflected symptoms that are correlated. As noted by Bagozzi,³⁰ it is reasonable to let item residuals correlate in a CFA when these correlations are theoretically or methodologically plausible, and when they do not alter the estimates of the other parameters in the model, as in our case.

Our analysis showed supportive criterion related validity of the HFSPS, since the literature reports that heart failure symptoms correlate with the QOL as measured by the KCCQ.^{31,32} All the HFSPS dimension scores correlated with all the KCCQ dimension scores in this analysis. Even though all the correlations between the dimensions of the two instruments were statistically significant, these correlations were generally moderate, attesting that the HFSPS measures 'something' that is close to the QOL, but it is not the same thing. This aspect emphasizes that the burden of symptoms, as measured by the HFSPS, is not the same as

Table 3. Correlations between the KCCQ and the HFSPS.	ons betwee	n the KCC	Q and the F	HFSPS.										
	_	2	m	4	5	6	7	6	0	=	12	13	4	15
I. KCCQ Physical limitation	_													
2. KCCQ	0.198***	_												
Symptom stability 3. KCCO	0.707***	0.247***	_											
Symptom frequency	***629		0.850***	_										
Symptom burden	**104.0			**1700	_									
J. NOUCO Total symptom	17/0			102.0	_									
6. KCCQ	0.649***	0.196***	0.700***	0.727***	0.742***	_								
Quality of life 7. KCCQ	0.808***	0.230***	0.743***	0.723***	0.763***	0.747***	_							
Social limitation	0 240***	0.080	0 247***	0.210***	0 237***	0356***	0.215***							
Self-efficacy	2						2	_						
9. KCCQ	0.934***	0.262***	0.894***	0.877***	0.921***	0.749***	0.839***	0.260***						
Clinical summary	***888 U	***P3C0	***C78 U	***730 U	***P08 U	0 875***	***aco 0	0 303***	I ***U76 U					
Functional status	000.0					0.0.0	077.0	700.0	-					
II. HFSPS	-0.577***	-0.274***	-0.577*** -0.274*** -0.729*** -0.758***	-0.758***	-0.773***	-0.675***	-0.669***	-0.200*** -	-0.725*** -0.	-0.745*** I				
Total score 12. HFSPS	-0.599***	-0.300***	-0.735***	-0.599*** -0.300*** -0.735*** -0.726***	-0.760***	-0.660***	-0.662*** -	-0.159** -	-0.730*** -0.	-0.742*** 0.917***	_			
Dyspnoea 13 HFSPS	901 0 ***095 0	-0106	0 470***0 44	-0 441***			***51C 0***995 0***746 0_	- 3*** -			0 567***	_		
Chest discomfort	00000	201.0	0.120		2			214.0				-		
14. HFSPS	-0.493***	-0.192***	-0.604***	-0.493*** -0.192*** -0.604*** -0.659***	-0.657***		-0.595*** -0.594*** -0.167**		-0.617*** -0.648***	648*** 0.901***	0.725***	0.528***	_	
Early and subtle 15. HFSPS Oedema	-0.341***	-0.270***	-0.549***	-0.34 *** -0.270*** -0.549*** -0.599***	-0.597***	-0.433***	-0.433*** -0.428*** -0.158**		-0.500*** -0.	-0.495*** 0.757***	0.564***	0.434***	0.634***	_
*p<0.05 ™p<0.01 ₩P>c0.001 ₩P>cCCQ: Kansas City Cardiomyopathy Questionnaire; HFSPS: Heart Failure Somatic Perception Scale	ardiomyopatl	hy Questionr	naire; HFSPS:	Heart Failur	e Somatic Pe	rception Scal	ω							

the QOL measured by a disease-specific instrument such as the KCCQ.

In the internal consistency reliability testing, we used traditional (i.e. Cronbach's α) and non-traditional (i.e. factor score determinacy coefficient and model-based internal consistency index) estimates of reliability. The factor score determinacy coefficients were all adequate for each factor but the Cronbach's α reached a poor 0.53 for the chest comfort factor. This was not unexpected because this factor includes only two items and Cronbach's α may be lower with fewer items forming a scale.²⁸ Moreover, we used the model-based internal consistency index to estimate the reliability of the total multidimensional scale since Jurgens et al. proposed to have a total score of the 18-item HFSPS. All estimates supported the good reliability of the HFSPS, both for each single factor and for the total multidimensional scale.

This study had several limitations. First of all, we used the baseline data of the MOTIVATE-HF study, which enrolled a convenience sample. However, we balanced this limitation by enrolling patients from multiple sites. Another limitation was that this study was conducted in only one European country; therefore, caution should be taken when generalizing these results to other countries. However, since the original factorial structure of the HFSPS was confirmed in this study, we have good reason in favour of the generalizations of our finding.

In conclusion, the HFSPS was shown to be a valid and reliable instrument to measure symptom perceptions in heart failure patients in the dimensions of dyspnoea, chest discomfort, early and subtle and oedema. These symptoms limit a heart failure patient's daily activities and reduce the QOL. Having an instrument with supported validity and reliability characteristics is fundamental to identifying heart failure patients at risk of a lower QOL in order to implement specific interventions.

The HFSPS may help healthcare providers to identify which signs and symptoms influence a heart failure patient's health. Evidence suggests that heart failure signs and symptoms are often difficult for heart failure patients to identify, and they can generate confusion in the case of multiple comorbid conditions.33,34 In addition, as suggested by some investigators,^{35,36} effective heart failure self-care is largely dependent on the patient's ability to interpret and report symptoms to healthcare providers. A lower capacity for patient symptom perception is associated with a higher risk for hospitalization.³⁷ Reeder et al.³³ emphasized that little is known about the perception of a heart failure patient's somatic symptoms, and this lack of knowledge may prevent providers from gaining a good understanding of the patient's problems, and from providing them with the correct interventions to improve their health status. The HFSPS may be a good tool to assess how bothersome heart failure signs and symptoms are in order to improve provider management.

Implications for practice

- The Heart Failure Somatic Perception Scale may help healthcare providers identify which heart failure signs and symptoms are bothersome for heart failure patients.
- The Heart Failure Somatic Perception Scale is a valid and reliable instrument for measuring the perception of heart failure signs and symptoms in the dimensions of dyspnoea, chest discomfort, early and subtle and oedema.
- The Heart Failure Somatic Perception Scale is a psychometrically sound instrument that may help providers improve the management of heart failure signs and symptoms.

Declaration of conflicting interests

The authors declare that there is no conflict of interest.

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