Original Article

Development and Validation of a Tool to Assess Determinants of Nutritional Behavior in Patients with Heart Failure Based on the Theory of Planned Behavior

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Highlights

- Developing effective interventions necessitates identifying determinants of nutritional behavior in patients with heart failure.
- Valid tools are essential for measuring constructs of behavioral change theories and models related to nutritional behaviors in patients with heart failure.
- The instrument developed in this study showed suitable validity and reliability for assessing determinants of nutritional behavior in patients with heart failure, based on the Theory of Planned Behavior.

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ABSTRACT

Background: Adopting healthy nutritional behavior among patients with heart failure (HF) plays a crucial role in controlling disease symptoms. Developing effective interventions requires identifying significant determinants of nutritional behavior using theoretical frameworks from behavioral sciences and validated instruments. This study aimed to develop and validate tools to assess the determinants of nutritional behavior in patients with HF based on the Theory of Planned Behavior (TPB).

Methods: A preliminary instrument with four subscales was developed based on the TPB. An instrument for measuring the nutritional behavior of patients with HF was also created. Face and content validity were assessed using qualitative and quantitative methods. The factor structure of the TPB instrument was examined using exploratory factor analysis (EFA) in a sample of 330 patients with HF. Instrument reliability was also evaluated.

Results: During face and content validity assessment, 13 items were removed from the TPB instrument, and 14 items were modified across both instruments. The EFA revealed that the 12 items measuring TPB variables loaded onto four distinct subscales: behavioral intention, attitude, perceived behavioral control, and subjective norms. The Kaiser-Meyer-Olkin measure and Bartlett test of sphericity were acceptable. These factors accounted for 87.03% of the total variance. All TPB subscales demonstrated acceptable internal consistency, as measured by Cronbach's α. Both instruments showed satisfactory intraclass correlation coefficients.

Conclusion: The developed instruments are valid and reliable tools for assessing the determinants of nutritional behavior in patients with HF based on the TPB. They can be used for needs assessment and to develop educational interventions for this population.

Keywords: Heart Failure; Nutritional Behavior; Theory of Planned Behavior; Psychometrics, Instrument

Introduction

Heart failure (HF) is a complex clinical syndrome characterized by its chronic, progressive, and disabling course, which ultimately reduces quality of life and imposes substantial financial burdens on both individuals and society.[1]

Studies show that HF is associated with more than a 44% increase in readmission rates within 6 months after discharge.[2] In Iran, HF is a leading cause of disability and mortality. With the aging of the population, the prevalence of HF is projected to rise in the near future, affecting approximately 3500 patients per 100,000 people.[3] In addition, congestive HF accounts for 25% of hospitalizations in cardiac departments across the country.[4]

Although mortality from cardiovascular disease has declined in recent years in developed countries,[5] lifestyle changes in Iran suggest an increasing prevalence of HF. Nevertheless, reliable data on mortality trends from this condition in Iran are lacking.[6]

Evidence indicates that modifiable risk factors contribute more substantially to the development of HF than non-modifiable risk factors such as age, sex, race, and heredity.[7] Despite advances in HF management, accurate diagnosis, timely treatment, and adherence to self-care behaviors remain the most effective approaches to prevention and control.[8]

Self-care is a multidimensional concept encompassing three key components: self-care maintenance, self-care management, and self-care confidence.[9] Despite its importance in promoting favorable health outcomes, many patients with HF demonstrate inadequate self-care behaviors.[10-12] Barriers to adherence include the complexity of self-care, a perceived lack of necessity, challenges with long-term behavioral changes, and lack of motivation.[13]

Essential self-care behaviors for patients with HF include adherence to prescribed medications, following a low-sodium diet, limiting alcohol consumption, engaging in physical activity, smoking cessation, maintaining weight control, and monitoring symptoms.[14]

Evidence indicates that poor self-care and nonadherence to medication and dietary recommendations increase the risk of hospital readmission by 20% to 60% among patients with HF.[15] Excessive sodium intake is particularly detrimental, as it can lead to elevated blood pressure and fluid retention, thereby increasing cardiac workload. To mitigate these risks, patients with HF are advised to restrict daily sodium intake to no more than 2000 mg.[16]

The implementation of structured self-care programs can reinforce educational objectives and enhance patients' capacity to engage in effective self-care.[17] Furthermore, adherence to an HF-specific diet may mediate the risk of disease progression.[18]

Educational interventions have the potential to prevent many factors that exacerbate HF. [19] To design tailored educational programs that address participants' needs, behavioral theories and models are recommended. One such model is the Theory of Planned Behavior (TPB), a cognitive-social framework for behavior change.[20,21]

Originally introduced by Ajzen and Fishbein in 1998, TPB emphasizes intention as the primary determinant of behavior. Intention is, in turn, shaped by three core components: attitude, subjective norms, and perceived behavioral control.[22,23] The application of TPB has been examined in predicting and developing interventions to improve self-care behaviors among patients with cardiovascular diseases.[24,25]

To evaluate variables within behavioral theories as they relate to specific health topics, the use of valid instruments is essential. [26] Be that as it may, the literature indicates a lack of sufficient and appropriate tools for assessing nutritional self-care in patients with HF across different countries.[27,28] Some instruments have been developed to measure factors such as appetite,[29] knowledge,[30] dietary sodium restriction,[31] and medication and dietary adherence[32] in patients with HF. To the best of our knowledge, few studies have focused on the development and validation of instruments designed to assess determinants of nutritional behaviors in patients with HF, based on constructs from theories and behavioral models such as TPB.[33]

Accordingly, this study aimed to design and

validate an instrument to measure factors influencing the adoption of nutritional behaviors in patients with HF, using TPB variables.

Methods

A psychometric study was conducted in Tehran, Iran, from July through May 2023. The study protocol (IR.IUMS.REC.1402.300) received approval from the Ethics Committee of Iran University of Medical Sciences. All participants were informed about the study objectives and provided written consent. The development of instruments for assessing TPB variables and the nutritional behavior of patients with HF involved the following stages:

Item Generation

The scale development process began with item generation, employing both deductive and inductive approaches.[34] We utilized a manual to construct questionnaires based on the TPB.[35] An item pool was created to measure the dimensions of TPB and the nutritional behaviors of patients with HF. We conducted 10 semi-structured interviews with patients suffering from HF and experts in health education, nutrition, and cardiovascular diseases. During these interviews, participants were asked about items related to each dimension of the instruments. For instance, in the context of assessing the nutritional behaviors of patients with HF, participants were queried about which healthy dietary practices should be adopted to manage their HF condition. Sampling continued until data saturation was achieved. All interviews were recorded, transcribed verbatim, and analyzed using content analysis (directed method). Based on the findings, a 25-item instrument was developed to assess TPB variables, comprising four main subscales: behavioral intention (7 items), attitude (6 items), perceived behavioral control (6 items), and subjective norms (6 items). Additionally, a separate 31-item instrument was created to evaluate the nutritional behaviors of patients with HF. The validity and reliability of these initial instruments were subsequently established through several stages.

Face Validity Assessment

A group of 15 patients with HF was asked to provide feedback on the clarity, simplicity, and readability of the items in the instruments. Based on their feedback, ambiguous items were revised, and minor wording errors were corrected. Further, quantitative face validity was used to determine the impact score of each item (frequency × importance) to assess the proportion of participants who considered the item important or quite important. Items with an impact score equal to or greater than 1.5 were considered appropriate.[36] This approach was utilized to ensure that the items were suitable for use in the instruments.

Content Validity Assessment

The content validity of the instruments was evaluated in two phases: qualitative and quantitative. In the qualitative phase, a group of 10 experts, including specialists in health education, nutrition, and cardiovascular diseases, assessed the instrument in terms of wording, grammar, item allocation, and scaling. In the quantitative phase, the content validity ratio (CVR) and content validity index (CVI) were calculated for each item. For CVR, the essentiality of each item was rated on a 3-point scale (1=essential, 2=useful but not essential, 3=not essential). The CVR value for each item was determined using the formula CVR=[Ne-(N/2)] / (N/2), where Ne represents the number of specialists indicating “essential” for a specific item, and N is the total number of specialists. The Lawshe table was used to determine the acceptable CVR value, which is 0.62 or higher for a panel of 10 experts.[37] CVI assessed the relevance of each item. The CVI is calculated by counting the number of experts who rated an item as 3 or 4 and then dividing that figure by the total number of experts. The relevance of the items was evaluated using a four-point scale: (1) not relevant, (2) slightly relevant, (3) relevant, and (4) very relevant. A CVI value of 0.79 or higher was considered acceptable.[38]

Construct Validity Assessment of The TPB Instrument

To establish the construct validity of the instrument for assessing TPB variables, an exploratory factor analysis (EFA) was conducted. The literature suggests that a minimum of 300 to 450 participants is needed to ensure acceptable comparability of patterns.[39] For this study, 330 patients with HF, referred to Tehran Heart Center, affiliated with Tehran University of Medical Sciences in Iran, were randomly selected. The participants met specific inclusion criteria, including: 1) a diagnosis of HF according to hospital records, 2) no indication of following a special diet, such as vegetarianism, 3) no known food allergies or other conditions that limit their food consumption or require avoidance of certain foods, 4) residing in Tehran, 5) expressing willingness to participate, and 6) being of Iranian nationality. The study excluded individuals with language difficulties that would prevent them from answering the items of the instrument, as well as those with a history of mental illnesses that disrupt judgment and cognition, such as schizophrenia and other similar conditions.

The adequacy of the sample and the suitability of the factor analysis model were assessed using the Kaiser-Meyer-Olkin (KMO) test and the Bartlett test of sphericity. Subsequently, EFA with varimax rotation was performed to identify the main factors of the instrument.[40,41] A factor loading cutoff point of 0.4 and an eigenvalue greater than 1 were utilized in the analysis.

Reliability Assessment

The Cronbach's α coefficient was used to assess the internal consistency of the TPB instrument subscales. A total of 30 patients with HF completed the TPB instrument. Cronbach's α values equal to or greater than 0.70 were considered satisfactory.[42] Furthermore, to measure the stability of the nutrition behavior instrument and TPB subscales, test-retest correlation coefficients were calculated using data from 30 patients with HF. The tests were conducted with a 2-week interval between them. The reliability was assessed using the intraclass correlation coefficient (ICC). An ICC value≥0.70 was considered satisfactory.[43]

Statistical Analysis

Statistical analyses were performed using the SPSS software package (version 23.0; SPSS, Inc, Chicago, IL, USA). Participant characteristics were analyzed using frequencies, percentages, means, and standard deviations.

Results

The Results of Face Validity Assessments

Based on participants' feedback, 12 ambiguous items were revised, and two items were removed from the TPB instrument. Quantitative face validity analysis showed that the impact score was ≥1.5 for all remaining items (Table 2).

The Results of Content Validity Assessments

The appropriateness of wording, grammar, item allocation, and scaling of the two instruments was reviewed and deemed acceptable. Based on the CVI and CVR analyses, 11 items were removed from the TPB instrument. The CVI and CVR values for each item are presented in (Table 2); all items demonstrated a CVI of ≥0.80 and a CVR of ≥0.75 (Table 2).

The Results of The Construct Validity Assessment of The TPB Instrument

Data from 330 patients with HF were analyzed using EFA. Demographic characteristics of participants are presented in (Table 1). EFA was conducted with principal component analysis (PCA) and varimax rotation. The KMO measure of sampling adequacy was 0.835, confirming data suitability for factor analysis. Bartlett's test of sphericity was statistically significant (χ^2=5924.155; df=66; P<0.0001). All items demonstrated factor loadings greater than 0.50, indicating strong associations with the identified factors (Table 2).

Table 1. Demographic characteristics of the study participants for assessing the exploratory factor analysis (n= 330) of the TPB instrument

Variables	Mean± SD	n (%)
Age	61.53±12.61	
History of heart failure (y)	3.63±1.74	
Marital Status		
Single		87 (26.4)
Married		183 (55.5)
Divorced or widowed		60 (18/1)
Education Level		
<12th grade		274 (83)
≥12th grade		56 (17)
Sex		
Man		206 (62.4)
Woman		124 (37.6)
Self-Reported Economic Status		
Low		85 (25.8)
Moderate		188 (57)
Good		43 (13)
Very good		14 (4.2)

TPB: Theory of Planned Behavior

Table 2. The factor loading of the TPB instrument items, content validity index, content validity ratio, and impact score of the two instrument items developed

Items	Factor				Communalities (extraction)	Content Validity Ratio	Content Validity Index	Impact Score
	1 Behavioral Intention	2 Attitude	3 Subjective Norms	4 Perceived Behavioral Control				
1. I intend to implement a suitable diet for patients with heart failure in the next month, such as consuming low-sodium foods.	0.949				0.901	0.8	0.9	4.5
2. I expect from myself to adhere to the nutritional recommendations provided by a doctor or a nutritionist, suitable for patients with heart failure, in the next month.	0.927				0.859	1	0.9	4.5
3. I want to adjust my diet to be suitable for my condition in the next month.	0.961				0.924	0.9	0.9	4.5
4. Adhering to a suitable diet for heart failure patients is an action: Unnecessary 1 2 3 4 5 6 7 Necessary.		0.954			0.911	0.8	0.8	4.5
5. Adhering to a suitable diet for heart failure patients is an action: Insignificant 1 2 3 4 5 6 7 Significant.		0.832			0.692	0.8	0.9	4.5
6. Adhering to a suitable diet for heart failure patients is an action: Ineffective 1 2 3 4 5 6 7 effective.		0.942			0.887	0.8	1	3.37
7. Most of the people who are important to me ask me to adhere to a suitable diet for heart failure			0.985		0.969	0.8	0.9	2.81
			0.992		0.984	0.8	0.8	3.37
			0.987		0.973	0.7	0.8	4.5
				0.988	0.976	1	1	3.37

patients.					
8. My family and friends encourage me to follow a suitable diet for heart failure patients.	0.950	0.903	1	1	4.5
9. My doctor expects me to follow his recommendations regarding the appropriate diet for patients with heart failure.	0.986	0.972	0.8	0.9	3.37
10. I am confident that if I decide to, I can adhere to the appropriate diet for patients with heart failure.					
11. Avoiding harmful and tempting foods is easy for me.			1	1	4.5
12. Whether I adhere to a suitable diet for patients with heart failure is entirely up to me.			1	1	4.5
Nutrition Behavior			1	1	3.93
1. I do not put the salt shaker on the table during meals.			1	1	4.5
2. Instead of using ready-made sauces, I prepare salt-free tomato sauce for myself.			0.7	1	4.5
3. To reduce salt intake in my food, I flavor it with dried herbs (such as thyme), spices, lemon or lemon juice, and vinegar.			0.7	1	4.5
4. I do not use processed foods (such as sausages and salami).			0.9	1	4.5
5. When shopping, I choose ready-made food products that are low-sodium or sodium-free.			0.7	1	3.9
6. I do not use ready-made frozen foods.			0.8	0.9	4.5
7. I do not use pickles, pickled vegetables containing salt, or salted nuts.			1	1	4.5
8. I do not use smoked and canned foods.			0.7	1	3.9
9. I do not use salty snacks such as chips and popcorn.			0.8	0.9	4.5
10. I use liquid oil.			1	1	4.5
11. I do not use solid oil.			1	1	4.5
12. I do not use animal oils (eg, tallow oil or lard).			0.8	1	4.5
13. I use olive oil.			0.7	1	4.5
14. I do not use fried foods			0.8	1	4.5
15. I make my food steamed, boiled, or grilled.			1	1	3.9
16. I do not use cholesterol-rich foods such as offal, brain, liver, and egg yolk.			0.8	1	2.8
17. I do not consume high-calorie sweets (such as cream cakes).			0.8	0.9	4.5
18. I take daily supplements of B family vitamins, such as vitamin B1.			1	1	3.37
19. I take a daily supplement of folic acid medication.			1	1	4.5
20. I take a daily supplement of 2000 IU of vitamin D.			0.8	0.9	3.37
21. I consume a maximum of two liters of fluids daily (equivalent to			0.7	0.8	4.5

8 average-sized cups).			
22. Every day, I use two to three servings of low-fat dairy products (maximum 1% fat) in my meal plate. For example: Two cups of yogurt = one cup of buttermilk = one cup of milk = half a cup of sour cream = two small cheese blocks.	0.8	0.9	4.5
23. I do not use sugary and factory-made beverages.	1	1	4.5
24. I do not use flavored rice, grains, or macaroni.		0.8	4.5
25. I use whole grains (such as whole-wheat bread, whole-wheat pasta).	0.7	1	4.5
26. I use 6 to 11 servings of bread, grains, or starchy vegetables daily. For example: Half a cup of cooked corn = half a cup of cooked macaroni = four palm-sized pieces of flatbread = one palm-sized piece of Barbari or Sanghak bread = half a cup of cooked rice = one potato.	1	1	4.5
27. I consume a minimum of three to five servings of non-starchy vegetables per day (each serving is equivalent to one cup of fresh vegetables or half a cup of cooked vegetables). Examples include: lettuce, cabbage, carrots, cucumber, tomatoes, onions, zucchini, and leafy greens.	1	0.8	4.5
28. I use fresh vegetables instead of canned and frozen vegetables.	1	1	4.5
29. I consume a minimum of two to four servings of fruit per day (each serving is equivalent to one medium-sized apple). Examples include: half a cup of natural fruit juice, half a cup of grapes, one medium slice of watermelon, three apricots, one orange, and one apple.	1	1	4.5
30. I eat fish once or twice a week.	1	0.8	4.5
31. I use two to three servings of meat, legumes, and nuts daily on my meal plate. For example: one chicken leg = two eggs = one fish fillet = half a cup of cooked legumes = half a cup of nuts = 70 grams of raw or 30 grams of cooked red meat.	1	1	4.5

TPB: Theory of Planned Behavior

Exploratory factor analysis (EFA) using principal component analysis with varimax rotation was conducted to determine the dimensions of the TPB instrument.

• Qualitative content validity was assessed using the content validity ratio (CVR) and content validity index (CVI) for each item; a CVR of ≥0.62 and a CVI of ≥0.79 were considered satisfactory.

• Qualitative face validity was assessed by calculating the impact score for each item; an impact score of ≥1.5 was considered satisfactory.

The Results of Reliability Assessments

In this study, Cronbach's α values for the TPB instrument subscales ranged from 0.845 to 0.975. The ICCs for the TPB instrument subscales and the nutrition behavior instrument were also within the acceptable range (Table 3).

Table 3. The reliability and internal consistency of the TPB instrument subscales and the nutrition behavior instrument in patients with heart failure

Subscales	Number of Items	Cronbach's α	Intraclass Correlation Coefficient
Attitude	3	0.955	0.999
Perceived behavioral control	3	0.845	0.992
Subjective norms	3	0.950	0.998
Behavioral intention	3	0.975	0.992
Nutrition behavior	31	-	0.999

TPB: Theory of Planned Behavior
Cronbach's α was used to assess the internal consistency of the TPB instrument subscales; values ≥ 0.70 were considered satisfactory. Reliability was assessed using the ICC; values ≥ 0.70 were considered satisfactory.

Final Instruments and Scaling

The final 12-item instrument for assessing TPB variables consisted of four subscales: behavioral intention (3 items), attitude (3 items), subjective norms (3 items), and perceived behavioral control (3 items). In addition, a 31-item instrument to assess nutrition behavior was confirmed.

Items measuring behavioral intention, subjective norms, and perceived behavioral control were rated on a five-point Likert scale (1=completely disagree to 5=completely agree). To assess attitude toward nutrition, we employed bipolar evaluative adjectives (ie, pairs of opposites) (eg, effective 1 2 3 4 5 6 7 ineffective).

Discussion

The primary objective of this study was to conduct a psychometric evaluation of two instruments designed to assess the determinants of adopting nutrition behavior in patients with HF, based on TPB variables. As a result, a 12-item scale with four factors was developed for evaluating TPB variables, along with an instrument for assessing nutrition behavior in HF. The findings revealed that both developed instruments are valid and reliable tools for identifying these factors.

To our knowledge, there is a paucity of studies examining the development and validation of instruments for evaluating determinants of nutritional behaviors in HF patients, utilizing constructs from theories and behavioral models such as TPB.[33] Nevertheless, a notable exception is the study by Bentley et al[31] (2009), who performed a psychometric evaluation of a questionnaire on dietary sodium restriction in HF patients, designed based on TPB. Their instrument demonstrated good validity and reliability.

Furthermore, Caro-Bautista et al[44] (2019) conducted a psychometric evaluation of a tool designed to identify self-care barriers among Spanish patients with type 2 diabetes, based on TPB. Their findings suggest that a theory-based tool is effective in assessing self-care needs and providing tailored recommendations for lifestyle modifications, taking behavioral determinants into account.

Overall, the development of theory-based instruments can be advantageous for educators in designing and evaluating educational interventions related to nutrition for patients with HF. The application of theoretical frameworks provides a structured approach to understanding various individual behaviors. These instruments can assist practitioners in identifying the underlying factors contributing to individuals' engagement or non-engagement in specific health behaviors.[45,46]

The results of our study revealed that the two instruments developed in this research demonstrated favorable content validity, as evaluated by experts. Expert opinions are widely acknowledged and suitable methods for assessing

content validity in questionnaire items,[34] and they are frequently employed in psychometric studies. Previous research suggests that a range of 5 to 10 experts is sufficient for content validity assessment 47; therefore, our study included input from 10 experts. Notably, items with a CVR of <0.62 were excluded from the instruments,[37] while items with a CVI of >0.79 were retained in the instruments.[38] Similarly, Wicaksana et al[48] conducted a study to psychometrically evaluate the Indonesian version of the Sodium Restriction Questionnaire among patients with high blood pressure, utilizing content and structural validity methods. In another instance, d'Almeida et al[49] (2013) investigated the validity and reliability of the Dietary Sodium Restriction Questionnaire, using content validity. Their findings indicated that the final version of the instrument is a valid and reliable tool for measuring attitudes and behaviors related to adherence to a low-sodium diet in Brazilian patients with HF.

In another study, Mohammadi et al[50] (2019) examined the reliability and validity of the Persian version of the Simplified Nutritional Appetite Questionnaire, employing face and content validity methods. Likewise, Riegel et al[27] (2004) developed and psychometrically evaluated the Self-Care of Heart Failure Index Version 6.2 (SCHFIV6.2) questionnaire in patients with HF, utilizing content validity. This tool consists of three sections with a total of 22 items: self-care behaviors (10 items), self-care management (6 items), and self-confidence (6 items).

In our study, the face validity of the instrument items was assessed by gathering feedback from a sample of HF patients. As a result of this process, two items were removed, and 12 items were edited, confirming that the developed instrument is acceptable and easily comprehended by the target population. Similarly, Heikkilä et al[51] evaluated the face validity of an instrument designed to assess nutrition knowledge in another study. Several other studies, including those conducted by Vazquez et al,[52] El-Osta et al,[53] McNamara et al,[54] Jaarsma et al,[55] and Caro-Bautista,[44] also incorporated face validity assessments in their psychometric evaluations of respective instruments.

The results of EFA confirmed that the developed scale for assessing TPB variables had an appropriate structure. In this study, items from the TPB instrument were categorized into four factors based on EFA. Similar to our findings, Koirala et al[56] employed EFA to examine the structural validity of the Nepali Heart Failure Self-Care Index. Likewise, Bentley et al[31] and Mohammadi et al[50] utilized EFA in separate studies to evaluate the construct validity of the Dietary Sodium Restriction Questionnaire and the Nutritional Appetite Instrument in patients with HF.

Findings from this study also indicated that the ICCs and Cronbach's α values of the TPB instrument subscales were acceptable, demonstrating strong reliability and internal consistency of the developed items. The ICC for the nutrition behavior instrument was also within the acceptable range. Fromm et al[57] applied the test-retest method to assess the psychometric characteristics of the German version of a short questionnaire on dietary fat and free sugar. Similarly, Heikkilä et al[51] and Vázquez-Espino et al[52] examined the reliability and internal consistency of their instruments using the test-retest method and Cronbach's α.

Although the present findings support the usefulness of a TPB-guided framework in developing a theory-based instrument to assess determinants of nutritional behavior among Iranian patients with HF, this study had several limitations. Data were collected from a sample of patients with HF referred to Tehran Heart Center, affiliated with Tehran University of Medical Sciences. The homogeneity of this sample may limit the generalizability of findings to patients living in other socioeconomic settings across Iran. Accordingly, further research is needed to evaluate the psychometric properties of this scale in diverse racial/ethnic groups and geographic regions within the country. Another limitation was the reliance on self-reported questionnaires, which may be subject to recall bias or social desirability bias.

Conclusion

The results of the present study confirmed that the developed scales are valid and reliable tools for use among patients with HF in Tehran. These instruments may assist educators in identifying evidence-based priorities to enhance the adoption of nutritional behaviors in patients with HF and in designing tailored interventions.

Declarations:

Ethical Approval

This study was approved by the Research Ethics Committee of Iran University of Medical Sciences (IR.IUMS.REC.1402.300).

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Conflict of Interest

There are no competing interests.

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