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Translation, cross-cultural adaptation, and psychometric evaluation of the Persian version of the Symptom Distress Scale (SDS) in heart failure patients

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Abstract:

BACKGROUND: Patients with heart failure experience severe and chronic physical and psychological manifestations while the disease progresses. Assessing the degree of distress caused by manifestations of the disease in patients is the first step in designing and evaluating intervention programs to improve patients' symptoms. The aim of this study was to investigate the psychometric properties of the Persian version of the Symptom Distress Scale in HF patients.

MATERIALS AND METHODS: This study was conducted via methodological research design from March to November 2019. The translation process and cross-cultural adaptation were performed using a process recommended by the World Health Organization. The face and content validity and internal consistency were used to evaluate the validity and reliability of the instrument. The scale was evaluated by exploratory and confirmatory factor analysis in 300 patients with heart failure, and the obtained data were analyzed using SPSS-22 and AMOS-22 software.

RESULTS: The content validity of the scale was approved based on the results of the study. One-factor scale with 13 items was used in the confirmatory factor analysis, and the results showed that the instrument had high goodness-of-fit indices. Spearman correlation test for convergent validity showed a correlation between the score obtained by the Scale of Symptoms of Disease and the scores of The European Heart Failure Self-care Behavior scale (9 items) ($P < 0.0001$).

CONCLUSION: The Persian version of the Symptom Distress Scale can be used as a valid instrument for people with heart failure due to its desirable psychometric properties.

Keywords:

Cross-cultural adaptation, factor analysis, heart failure, psychometrics

Introduction

Approximately 6.2 million Americans have heart failure (HF).[1] The prevalence of this disease in Asia is between 1.26% and 6.7%.[2] The prevalence of HF in Iran is higher than that in other countries in the region (8%).[3] In 2018, 379,800 deaths were due to HF, that is, about 13.4% of all deaths,[1] and In Iran, the 1-year mortality rate of HF was 32%.[4] Advances in medical therapies and implantable cardiac devices, as well as caring for HF patients, have revolutionized the management of HF and increased survival in these patients, but increased survival is accompanied with some unintentional complications, including an increased burden of classic manifestations of the disease, such as shortness of breath and edema. While shortness of breath, edema, and fatigue are

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prominent manifestations of the disease, these patients frequently experience pain, chronic cough, gastrointestinal distress,[5,6] sexual problems, dizziness,[7] anxiety, depression,[5,8] and cognitive problems such as loss of memory and executive function. Such manifestations lead to a decrease in quality of life and an increase in the number of emergency-room visits and hospitalizations.[5,7-9] The burden of symptoms for HF patients has been compared to that of patients with advanced cancer or acquired immunodeficiency syndrome.[6] Despite the long-term manifestations of HF and reduced quality of life of patients, self-care behaviors are poor in them.[10,11] In a systematic review, it was found that self-care behaviors in HF patients depend on several factors such as manifestations associated with the disease.[12]

One of the goals of HF management is to reduce the burden of patients' symptoms. Assessing the degree of distress caused by the manifestations of the disease in HF patients is the first step in designing interventional programs and evaluating their effectiveness to improve patients' symptoms[13] that are often not properly assessed. As a result, symptoms are less likely to be diagnosed and in turn not treated properly.[6] Therefore, the presence of standard instruments to assess the manifestations of the disease in these patients is essential.

There are few instruments to assess physical and emotional symptoms in HF patients such as the Memorial Symptom Assessment Scale (MSAS), HF Symptom Survey, HF Signs and Symptom Checklist, M.D. Anderson Symptom Inventory-HF, and Memorial Symptom Assessment Scale.[14] Some of them were originally developed for the population with cancer and heart surgery. What is important in these instruments is to assess the distress of symptoms of HF and note the frequency and severity of the symptoms experienced by the patients.[13] The Symptom Distress Scale (SDS) assesses the degree of discomfort of symptoms reported by the patients. This scale was developed by McCorkle and Young (1978) to measure cancer manifestations; the instrument was evaluated in a systematic review of studies between 1978 and 2013. The results of this study showed that this instrument has an internal correlation of 0.67-0.88.[15] It has been identified as a suitable, valid, and reliable instrument for the population with cancer, immunocompromised patients, and patients with myocardial infarction.[16] Because HF patients experience signs and symptoms similar to those of cancer, this instrument has also been used in people with HF,[17-20] but instrument psychometrics has not been studied.

This instrument is easily applicable for patients and can be answered in only 5–10 min;[15] thus, it can be used in HF care centers. As there is no suitable scale in Iran to assess the burden of symptoms experienced by HF patients, the aim of the present study was to determine the psychometric properties of the Persian version of the Symptom Distress Scale (SDS) in HF patients.

Materials and Methods

Study design

This study was conducted via methodological research design from March to November 2019. The study was done in two phases: translation and cross-cultural adaptation (phase 1) and psychometric evaluation (phase 2) [Figure 1].

Phase 1: Translation and cross-cultural adaptation

This scale was translated based on the translation and cross-cultural adaptation process recommended by the World Health Organization. The steps of this method include forward translation into the target language, integration and adaptation of translations by a specialized group, backward translation into the original language, conducting a pre-testing and cognitive debriefing, preparing the final version, and finally, documenting it.[21]

After obtaining permission from the instrument developer, the instrument was simultaneously translated from English into Persian by two independent and fluent translators in English and Persian. Then, the

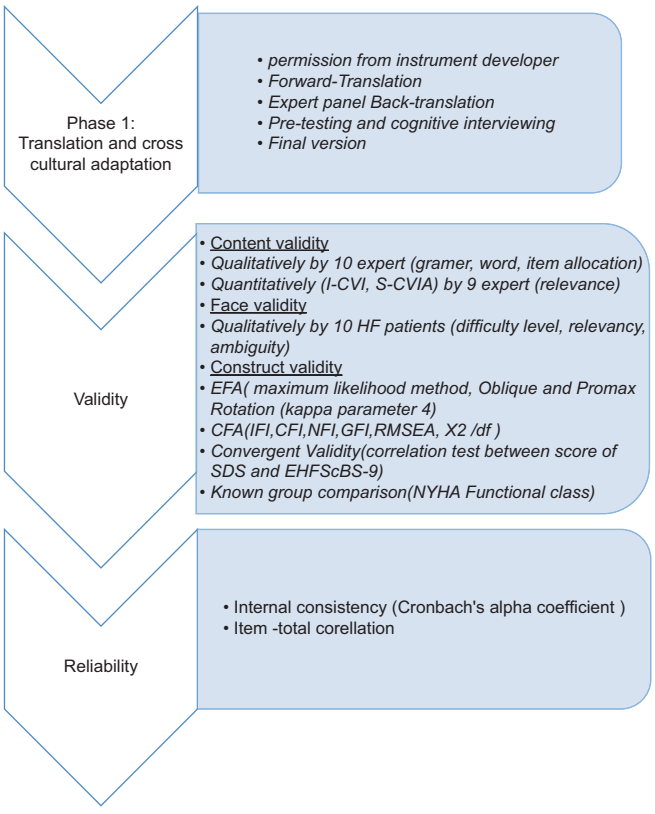

Figure 1: Flowchart depicting the process used for translation, cross-cultural adaptation, and evaluation of the psychometric properties

research team and the translators examined any differences between the original and the translated version and corrected the inappropriate phrases and concepts to achieve a unified version. Then, it was back-translated to the original language of the scale by two native translators simultaneously. After checking the back-translated version by the research team, it was returned to the main developer again.

In the next step of the study, pre-testing and cognitive debriefing were conducted via face-to-face interviews with ten HF patients that satisfied the inclusion criteria. The participants were asked to note any comments to improve their understanding of the scale's items. For example, in the question about appetite, the phrase "my appetite is usually, not always relatively good" and in the question about insomnia, the phrase "sometimes I have trouble falling asleep and staying asleep" were changed to "'My appetite is usually relatively good, but it's not always so," and "Sometimes I have trouble starting to fall asleep and staying asleep," respectively.

Phase 2: Psychometric evaluation

In this phase, the face, content, and construct validity and reliability of SDS were evaluated.

Evaluation of content and face validity

In the present study, content validity was examined qualitatively and quantitatively. In the qualitative method, the questionnaire was given to ten experts, including a cardiologist, a cardiac nurse, an English language specialist, and instrumental psychometric experts to express their opinions about grammar, appropriate words, and item allocation.[22]

In the quantitative method of content validity, the content validity index (CVI) was used. CVI was calculated in two ways: for each item and for the entire scale. To calculate CVI, the questionnaire was emailed to nine experts, and they were asked to rate the relevance of each item according to the 4-part scale (1: unrelated, 2: Somewhat related, 3: Acceptably related, 4: Fully related). The content validity index for each item was calculated by dividing the total number of specialists who gave a score of 3 or 4 depending on the relevance of each item from the total number of specialists. The values of 0.78 and above were acceptable. Then, the CVI for the whole scale was calculated using the averaging calculation method. In this method, the sum of the content validity indices of each item on the scale is divided by the total number of items. Values of 0.8 and above were acceptable. Kappa statistic (K), which is an important complement to CVI and determines the degree of agreement between evaluators without considering chance, was calculated using the modified kappa statistic, and values of 0.74 and above were considered excellent.[22]

In this study, a qualitative approach was used to assess face validity with the participation of ten HF patients. Participants were asked to comment on the understandability of items (difficulty level), the relationship of items to the concept (relevancy), and the presence of unintelligible words in items (ambiguity).[22]

Evaluation of construct validity

In the present study, factor analysis, convergent validity, and differential validity using the known groups comparison method were used to determine the construct validity.[22]

Study participants and sampling

Convenience sampling was used for gathering data on HF patients who were referred to one of the reference teaching hospitals in Tehran. The inclusion criteria were all HF patients 18 years and older, with an ejection fraction less than 40% in class I-IV New York Heart Association (NYHA) classification (Class I No limitations of physical activity, Class II Slight limitation of physical activity, Class III Marked limitation of physical activity, Class IV Unable to carry on any physical activity without discomfort), having HF for more than 3 months, not having a history of acute myocardial infarction in the last 3 months, without recently unstable angina, and/or being a candidate for a heart transplant in 6 months later.

The minimum suitable sample size for factor analysis is 5–10 samples for each item of the instrument.[23] In this way, 300 HF patients completed the questionnaires.

Data collection tool and technique

Symptom distress scale

The SDS assesses 13 common symptoms of the disease, such as nausea (presence and severity), appetite, insomnia, pain (presence and severity), fatigue, bowel, concentration, appearance, breathing, outlook, and cough experienced by the patient. Each symptom is rated on a 5-point Likert scale, where 1 indicates the absence of a problem and 5 indicates the presence of maximum problem. The overall score of distress caused by the symptoms of the disease is obtained from the sum of the responses of 13 symptoms, the range of which is between 13 and 65. Higher scores indicate more distress.[16]

European Heart Failure Self-care Behavior scale (9 items) (EHFScBS-9)

In the present study, the EHFScBS-9 questionnaire was used to assess convergent validity. This scale assesses patients' adherence to lifestyle changes and patients' consultation with a health care professional in the event of a change in signs and symptoms.[24,25] Its reliability was 0.86 by using the internal stability measurement (Cronbach's alpha).

Statistics

In this study, prior to factor analysis, the assumptions of this method, such as the absence of univariate outliers using standard Z scores and multivariate using Mahalanobis d-squared indices, the normality of univariate data distribution (skewness and Kurtosis indices), and multivariate data distribution (Mardia coefficient and critical ratio) were examined.[26] To determine the samples in factor analysis, the ratio of 20:1 and the factor load of at least 0.3 were considered.[27]

Before starting the exploratory factor analysis, the hypotheses such as Kaiser–Meier–Olkin (KMO) responsiveness index and Bartlett's test of sphericity were first examined. To determine the number of components of these instruments, the method of determining the eigenvalue was used.[27] In this study, to simplify and interpret the factor structures in order to extract the factors, the maximum likelihood method was used, assuming that the data have a natural distribution. To rotate the factors, the Oblique and Promax Rotation (kappa parameter 4) were used, assuming that the factors are inclined and correlated with each other.[23] Confirmatory factor analysis was performed using Amos software - version 22 to determine the fitness of the model.[28]

Convergent validity refers to the degree of correlation between scores obtained from two instruments that are theoretically related to each other.[22] In the present study, EHFScBS-9 was used to determine convergent validity with SDS. After determining the normal distribution of data, their scores were compared using the Pearson linear correlation test.

The discriminant validity of SDS was evaluated using the known-groups comparison method.[22] In this study, it was assumed that the Persian version of the SDS can differentiate between different NYHA functional classes so that class I has a lower score than class IV HF. In other words, class I patients experience fewer signs and symptoms.[5] A comparison of known groups was performed using one-way analysis of variance by fulfilling the condition of normal distribution and uniformity of variance of the groups.

Reliability

To assess the internal consistency of the scale, Cronbach's alpha coefficient was estimated. Alpha value consistency of 0.8 and above was considered desirable.[22]

Ethical considerations

This study was a part of the findings of a Ph.D. thesis entitled "Testing Treatment Adherence Model in People with Heart Failure Based on Roy Adaptation Model," which was registered with the code of ethics (IR.IUMS.REC.1395.95-04-28-9221199205) in Iran University of Medical Sciences. All participants in this study were aware of the purpose of the study and signed informed consent forms.

Results

Evaluation of face and content validity

In the stage of qualitative content validity, the comments of the experts were reviewed and applied by the research team. For example, in the question related to nausea,[1] option 3 "I feel nauseous almost all the time" was replaced with option 4 "I feel nauseous at least half the time."

In quantitative content validity, Scale-Content Validity Index (S-CVI) and kappa coefficient were acceptable, with values of 0.89 and 0.97, respectively.

In qualitative face validity, due to the numerous revisions made in the previous steps, no changes were made to the questions and answer options.

Evaluation of construct validity

Most participants were males (N: 175, 58.3%), aged 45–75 years (N: 186, 59.5%), and illiterate or with elementary education (N: 157, 52.3%) [Table 1].

The result of factor analysis showed that three factors had eigenvalue greater than 1, and the total percentage of variance explained was 56.73 [Table 2]. As the items were scattered in three factors and this scatter was not

Table 1: Frequency distribution for participant's gender and age, education level, and NYHA function classification

Characteristics	*n* (%)
Gender	
Male	175 (58.3)
Female	125 (41.6)
Educational level	
Illiterate	38 (12.6)
Below-diploma	119 (39.6)
Diploma	78 (26.0)
Higher	65 (21.6)
NYHA Function classification	
I	17 (5.8)
II	71 (24.4)
III	129 (44.3)
IV	74 (25.4)
Age (Years)	
18-34	40 (13.3)
35-44	54 (18.0)
45-54	59 (19.6)
55-64	65 (21.3)
65-74	56 (18.6)
>74	26 (8.6)

Table 2: Total variance explained before and after Promax rotation

Factor	Initial Eigenvalue			Extraction Sums of Squared Loading			Rotation Sums of Squared Loading
	Total	% of variance	Cumulative %	Total	% of variance	Cumulative %	Total
1	4.921	37.852	37.852	3.910	30.078	30.078	3.920
2	1.333	10.252	48.104	1.158	8.904	38.982	2.764
3	1.121	8.626	56.730	1.110	8.540	47.522	2.763

theoretically justifiable [Table 3], a one-factor scale with 13 items entered the confirmatory factor analysis. The results of confirmatory factor analysis showed that all path coefficients were significant for the mentioned scale in all cases ($P < 0.05$) [Table 4] and the instrument had acceptable goodness-of-fit indices (GFI): incremental fit index (IFI) (0.943), comparative fit index (CFI) (0.943), standardized fit index (NFI) (0.913), goodness-of-fit index (GFI) (0.921), root mean square error of approximation (RMSEA) (0.076), and X^2/df (2.271).[28]

In convergent validity evaluation, Spearman correlation test showed a correlation by fulfilling the abnormal distribution condition between the score obtained by the SDS and the scores of EHFScBS-9 (correlation coefficient: 0.341, $P < 0.0001$).

Discriminant validity using the known-groups comparison method showed that the mean and standard deviation of the Distress Symptom Scale in different NYHA functional classes were I) Mean: 24.9, SD: 3.6), II) Mean: 27.3, SD: 8.4), III) Mean: 32.3, SD: 7.6), and IV) Mean: 35.2, SD: 7.2). The result of the one-way analysis of variance indicated a significant difference between SDS and NYHA functional class for HF patients ($P = 0.001$).

Reliability

The internal consistency of the SDS was calculated as 0.88 by using Cronbach's alpha and was acceptable. The corrected item-total correlation was calculated. The lowest one was related to insomnia (0.448), and the highest one was related to nausea (0.728).

Discussion

Patients experience symptoms as a result of illness or treatment. HF symptom burden is a key element that can potentially affect the quality of life.[29] One of the primary goals of HF management is to reduce the burden of symptoms. To achieve that, it is necessary to systematically assess the burden of symptoms. SDS is a valid tool to assess patients' burden of symptoms by both healthcare providers and researchers. However, SDS was unavailable in the Persian language and thus could not be utilized in Iranian healthcare settings. This study was designed to fill this gap by translation and cultural adaptation and assessment of various psychometric properties of SDS and provide further evidence on the validity of SDS.

Table 3: Pattern matrix

	Factor 1	Factor 2	Factor 3
Nausea (presence)			0.941
Nausea (severity)			0.573
Appetite	0.453		
Insomnia	0.422		
Pain (presence)		0.856	
Pain (severity)		0.867	
Fatigue	0.379		
Bowel	0.608		
Concentration	0.830		
Appearance	0.617		
Breathing	0.570		
Outlook	0.694		
Cough	0.379		

In general, the challenges related to the validity of tools in cross-cultural studies are mainly due to cultural-linguistic adaptation and content validity. Therefore, it is important to follow clear methodological strategies to overcome these challenges, which are mainly due to cultural and linguistic differences between the reference language and the target language.[30,31] Therefore, in this study, we tried to use the best approach to ensure the validity of the content and language of the tool. The results of this step confirmed the construct validity of the scale.

We used Polit criteria recommendations for the content validity of SDS quantitatively and qualitatively.[22] However, the original study did not examine it quantitatively.[16]

The structural validity of the questionnaire was examined using exploratory and confirmatory factor analysis and confirmed based on the fitness of the model. In the original study, exploratory and confirmatory factor analyses were not used to examine the construct validity of the scale. However, the SDS, despite the limitations of psychometric knowledge at the time of the initial development of the instrument, was introduced as a powerful instrument in terms of psychometrics.[16]

Spearman correlation test showed that the HF patient with more distress and more signs and symptoms burden had a lower level of self-care. Studies showed that the burden of symptoms of HF and distress experienced by HF patients interferes with their self-care and prevents them from adhering to a treatment regimen.[5] On the contrary, medication adherence and self-care behaviors

Table 4: Regression path coefficients of the confirmatory factor analysis model SDS

	Path coefficients*	Standard deviation	Standardized Path Coefficients**	*P*
Nausea (presence)	1.000		0.603	<0.001
Nausea (severity)	1.334	0.095	0.720	<0.001
Appetite	1.208	0.130	0.676	<0.001
Insomnia	0.919	0.132	0.467	<0.001
Pain (presence)	1.163	0.127	0.663	<0.001
Pain (severity)	1.171	0.123	0.699	<0.001
Fatigue	0.819	0.110	0.504	<0.001
Bowel	1.162	0.140	0.604	<0.001
Concentration	1.478	0.151	0.727	<0.001
Appearance	1.067	0.136	0.543	<0.001
Breathing	1.091	0.118	0.674	<0.001
Outlook	1.166	0.136	0.609	<0.001
Cough	1.118	0.120	0.675	<0.001

*The path coefficient represents the magnitude of the influence of one variable on another in the path model. **Standardized coefficient determine which independent variable has the greatest direct effect on the dependent variable[28]

are associated with less experience of HF symptoms. Poor medication adherence is one of the most common preventable predictors of worsening HF. Thus, reducing the symptoms of HF can encourage them to improve their medication adherence.[32] The results suggested that the SDS can detect correlations between two instruments that are theoretically related to each other. In other studies, the concurrent and predictive validity of this scale with physical symptom scales and quality of life scale was examined and approved.[15,16]

One-way ANOVA test confirmed that there was a difference between distress scores caused by disease symptoms of HF patients with class I-II and class III-IV. This suggests that the SDS is capable of discriminating between different NYHA functional classification levels. In the original study, known groups were used to examine the construct validity of the scale. The researchers hypothesized that patients with lung cancer differed from patients with myocardial infarction in terms of symptom distress, and the results of the study confirmed the above hypothesis.[16]

SDS reliability assessed using internal consistency was also adequate. Specifically, internal consistency analysis showed that SDS items are interrelated, which is similar to the findings of the original study.[16] The results of a systematic review of studies that used the scale between 1978 and 2013 reported internal consistency in the scale between 0.67 and 0.88. The internal consistency of the instrument in HF patients was 0.79 Cronbach's alpha.[17]

SDS has been used as an explanatory variable as well as a clinical outcome measure variable in different studies and groups of patients and multiple health settings such as home care, nursing home, outpatient, and the hospital. Use of the SDS as a tool for screening patients who may need more careful follow-up and for determining the validity of the SDS in groups who do not have cancer has been recommended. There are various cultural translation versions, including Dutch, French-Canadian, Italian, Spanish, Swedish, and Taiwanese,[16] but no study has been found to examine the psychometric properties using factor analysis techniques. Strengths of the present study are translation and cross-cultural adaptation of the SDS into Persian, investigation of the psychometrics of the instrument by using factor analysis techniques, and the large sample size.

The present study is not without potential limitations. To interpret the results of the study correctly, the following aspects must be considered. First, patients with diastolic HF or normal left ventricular outflow fraction (HFpEF) and moderate left ventricular outflow fraction (HFmrEF) were not included in the study. This implies that the evidence of validity and reliability is mainly not applicable to these patients. Another limitation is related to the lack of determination of the cut-off point for the instrument. The test cut-off point is the point by which one can distinguish some people from others. In some studies in the field of cancer, obtained scores were classified as mild, moderate, and severe, and in some studies as binary (low-high distress),[15] However, these classifications are based on the professional experiences of researchers; therefore, determining the cut-off point of the instrument is necessary.

Conclusion

Based on these findings, the Persian version of SDS can be used as a valid instrument in the community of HF patients due to its desirable psychometric properties. Due to the lack of reliable instruments to measure the distress caused by disease symptoms experienced by HF patients, this scale can be an answer to this urgent need in the field of measurement and assessment. HF management and improving patient outcomes are goals and priorities of health policymakers and require the

development of comprehensive management plans. The first step in this disease management is to identify the patients' experienced symptoms. The SDS can be useful in clinical and research situations to assess treatment and patient care programs. In addition, as a screening instrument is useful for symptoms often experienced by HF patients and can be used as part of a routine clinical monitoring program for HF patients. Further studies are needed to define the cut-off point of mild, moderate, and severe distress.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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SYMPTOM DISTRESS SCALE

Degrees of Distress

Nausea (Presence)

1	2	3	4	5
I seldom if ever have nausea	I have nausea once in a while	I have nausea fairly often	I have nausea half the time at least	I have nausea continually

Nausea (Severity)

1	2	3	4	5
When I do have nausea, it is very mild	When I do have nausea, it is mildly distressing	When I have nausea, I feel pretty sick	When I have nausea, I usually feel very sick	When I have nausea, I am as sick as I could possibly be

Appetite

1	2	3	4	5
I have my normal appetite and enjoy good food	My appetite is usually, but not always, pretty good	I don't really enjoy my food	I have to force myself to eat my food	I cannot stand the thought of food

Insomnia

1	2	3	4	5
I sleep as well as I always have	I occasionally have trouble getting to sleep and staying asleep	I frequently have trouble getting to sleep	I have difficulty getting to sleep and staying asleep almost every night	It is almost impossible for me to get a decent night's sleep

Pain (Presence)

1	2	3	4	5
I almost never have pain	I have pain once in a while	I have pain several times a week	I am usually in some degree of pain	I am in some degree of pain almost constantly

Pain (Severity)

1	2	3	4	5
When I do have pain, it is very mild	When I do have pain, it is mildly distressing	When I do have pain, it is usually fairly intense	The pain I have is very intense	The pain I have is almost unbearable

Fatigue

1	2	3	4	5
I seldom feel tired or fatigued	There are periods when I am rather tired or fatigued	There are periods when I am quite tired and fatigued	I am usually very tired and fatigued	Most of the time, I feel exhausted

Bowel

1	2	3	4	5
I have my normal bowel pattern	My bowel pattern occasionally causes me some discomfort	My present bowel pattern occasionally causes me considerable discomfort	I am usually in considerable discomfort because of my present bowel pattern	I am in almost constant discomfort because of my bowel pattern

Degrees of Distress

Concentration

1	2	3	4	5
I have my normal ability to concentrate	I occasionally have trouble concentrating	I occasionally have considerable trouble concentrating	I usually have considerable difficulty concentrating	I just can't seem to concentrate at all

Appearance

1	2	3	4	5
My appearance has basically not changed	Occasionally I am concerned about the worsening of my physical appearance	I am not often concerned that my appearance is worsening	Most of the time I am concerned that my physical appearance is worsening	The worsening of my physical appearance is a constant, preoccupying concern

Breathing

1	2	3	4	5
I usually breathe normally	I occasionally have trouble breathing	I often have trouble breathing	I can hardly ever breathe as easily as I want	I almost always have severe trouble with my breathing

Outlook

1	2	3	4	5
I am not worried or frightened about the future	I am slightly worried but not frightened about things	I am worried and frightened about things	I am very worried and frightened about things	I am terrified by thoughts of the future

Cough

1	2	3	4	5
I seldom cough	I have an occasional cough	I often cough	I often cough, and occasionally have severe coughing spells	I often have persistent and severe coughing spells