Clinical and Experimental Health Sciences

Development and Psychometric Evaluation of the Symptom Assessment Scale for Turkish Children with Cancer

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ABSTRACT

Objective: The present study was conducted to developed the Symptom Assessment Scale for Children with Cancer (SAS-CC) and assessed its reliability and validity for Turkish children.

Methods: This research was conducted among in 497 children with cancer who were between 7 and 18 years old. The data were collected with a demographic form and SAS-CC. Descriptive statistics, reliability and validity analysis were used to analyze the data.

Results: The mean age of children with cancer was 12.02 ± 3.38 years. The scale consists of 16 items and 3 sub-dimensions. Total factor loads were more than 0.30 in factor analyses. The confirmatory factor analysis revealed all fit indexes as higher than 0.91, and the root mean square error of approximation (RMSEA) was less than 0.080. Cronbach's alpha values of total was 0.96. According to the split-half analysis, α values of the first and second halves were 0.94 and 0.93, respectively.

Conclusions: This study demonstrated that SAS-CC is the first study to develop and test and a valid scale to evaluate symptoms in children with cancer. Effective strategies of coping with symptoms in children with cancer are required to improve prognosis, increase survival, and improve the quality of life. Therefore, assessing symptoms and their frequency in children with cancer is an majority initiative of nurses working in the pediatric oncology clinic.

Keywords: symptom; cancer child; psychometric properties; validity; reliability; SAS-CC

1. INTRODUCTION

Children with cancer suffer several symptoms caused by both cancer and the treatment used. Symptoms here refer to cancer-specific stressors perceived by the patient and those perceived by the patient's parents. Multiple symptoms negatively affect patients' biopsychosocial well-being, decreasing their quality of life. The mean number of multiple symptoms recorded in pediatric oncology patients is 11 to 13 (1).

Although treatment modalities have increased the recovery rates, they can result in adverse side effects such as chemotherapy or radiotherapy as well as symptoms resulting from the illness process itself in the child and the parents (2–4) . Symptoms such as loss of energy, vomiting, oral mucositis, constipation, nutritional problems, and sleep problems are more common than other symptoms (5,6). Children receiving cancer treatment rarely have a single symptom; instead, they experience multiple symptoms and concomitant distress. Multiple symptoms increase the severity of the distress by increasing the effects of each other and resulting in new symptoms (6).The increase in the number and severity of symptoms experienced may put the treatment on hold, reduce the dose of medication, and even discontinue the treatment. Reduced success rates of treatment may decrease the survival of children (7).

Symptom assessment can be used to evaluate symptom relief, compare treatment responses, and increase comfort (8). It is important that nurses carefully evaluate the symptoms experienced by pediatric oncology patients and plan effective interventions (9).This will help to determine the symptom frequency in pediatric oncology patients, identify priorities, and plan appropriate ways to manage symptoms (5,6).Several instruments were created to measure the symptoms of pediatric cancer patients, including the Memorial Symptom Assessment Scale (MSAS), the MD Anderson Symptom Inventory and Checklist for Symptoms in Rotterdam (10,11). As symptoms and distress experienced by pediatric patients with cancer vary significantly from those of adults, there is a need to recognize and describe the several symptoms faced by children in the pediatric oncology community. Extreme symptom discomfort can interrupt designed treatments, the efficacy of chemotherapy protocols, and the processes of recovery (5,6).The MSAS is the only scale available

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for determining the symptoms experienced by pediatric oncology patients in the age of 7-12 years and 10-18 years (12).However, technological and therapeutic developments in recent years and the processes experienced by children with cancer also change. Although treatments are planned so that the side effects are minimal, the use of high-dose drugs in chemotherapy causes children to experience many symptoms. For this reason, measurement tools appropriate for the new situation should be developed by following the changes in treatment and prognosis over time. In addition, it has been reported that other available scales measure the symptoms individually (mucositis, fatigue, etc.) or several symptoms together, with no scale covering all common symptoms (13,14).Therefore, a valid and reliable tool that measures symptoms experienced by children in the other age group of is required. In addition, more valid and reliable tools are required to increase these studies, which are limited in our country.

This study developed the SAS-CC and assessed its validity and reliability in Turkey.

2. METHODS

2.1. Study Design

This methodological, descriptive and correlational study determined the reliability and validity of the SAS-CC scale. The methods used in the study are summarized (Figure 1).

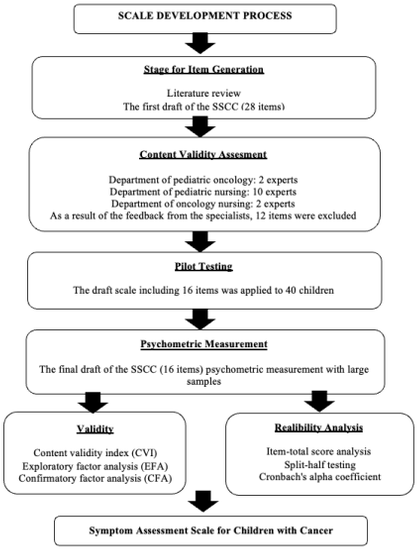

Figure I. *The Development and Validation Process of the SAS-CC*

2.2. Sample Population and Sampling

This study used convenience sampling. According to the literature, a sample size is adequate up to 300 participants and considered excellent up to 1,000 participants for scale development research (15).This study was conducted with children with cancer who were treated at a university hospital in the west of the country. A total of 502 children with cancer who were receiving therapy were interviewed. Five of them did not want to participate in the research. The final group comprised 497 patients with cancer (inpatient *n* = 335, outpatient *n* = 162) who were between 7-12 years (n=284) and 13-18 years (n=213) old, and could read, write, and communicate in Turkish. The patients were recruited from outpatient and inpatient clinics of a hospital in Turkey.

2.3. Ethics Committee Approval

Approval from the Ethics Non-Interventional Study Committee was established at the outset. Institutional permissions were obtained to conduct the study. It received verbal and written approval from children and their parents. Parents and children were also informed about the study before the data were collected. The informed consent form was signed to the parents of the children who agreed to participate.

2.4. Research Stages

Item Generation

The scale items constitute and represent all dimensional aspects of the to be measured variables. Scale items covering all symptoms experienced by children with cancer were created from information obtained from both general and child-specific descriptive and qualitative studies. Because of this literature review, we developed item pools to measure the prevalence of symptoms (5,6,16–21).

Forming Specialist Opinions

At least 10 expert opinions are needed to ensure content validity (17). The content validity of each element was checked in terms of its suitability, importance, and semantic clarification. The panel of experts included those in the field of oncology and child health. First, the 28-item pool was developed. We obtained feedback on the scales from fourteen experts (two professors from the department of pediatric oncology, three professors and seven associate professors from the department of pediatric nursing, and two associate professors from the department of oncological nursing). Experts were asked to rate them between 1 and 4 to determine the compatibility of items on the scale (1 = needs substantial improvement, 4 = very convenient). Twelve items were excluded because they had a validity index of 0.78 for item-based content (I-CVI). Consequently, the last version of the SAS-CC consists of 16 items for three sub-dimensions: general symptoms, gastrointestinal symptoms, and other symptoms.

Preliminary Testing

It is recommended that the scale be administered to a group of 20 or 30 people with similar characteristics, but who are not included in the study sample (18). Twenty children with cancer were invited to evaluate the face validity of the items and rate them for clarity and sentence fluency.

The scale was applied to 40 children who aged 7-12 years (n=20) and 13-18 years (n=20) old and meet the sampling inclusion criteria, but were not involved in the sample. As a result of the preliminary test, the children stated that the items were understandable and clear. In the test, the scale's comprehensibility was calculated to be adequate and then extended to the full sample (7-12 aged and 13-18 aged). The validity and accuracy were evaluated after the application of the scale to a large population.

2.5. Data Measurement Tools

A demographic form and SAS-CC were used for collect of data.

The Demographic Form: This form consisted of four questions, for instance age, sex, diagnosis, treatment place (ambulatory or hospitalized patients).

Symptom Assessment Scale for Children with Cancer (SAS-CC): As previously described, the SAS-CC was developed by researchers depending on the literature to measure the frequency of 16 symptoms experienced (5,6,16).This scale measured the symptoms experienced by children with cancer during the past week. It consisted of three sub-dimensions: general symptoms, gastrointestinal symptoms, and other symptoms. It is a scale of Likert type, with every item in the scale scored from 1 = never, 2=rarely, 3=sometimes, 4 = often. From the scale they received a minimum of 16 and a maximum of 64 points. Higher scores demonstrated more symptoms.

2.6. Statistical Analysis

The data were analyzed using the IBM SPSS Statistics 22.0 (Chicago, IL). Reliability analysis were used to determine the internal consistency of the scale and its sub-dimensions. The content validity index (CVI) and factor analysis were conducted for validity analysis. Using linear structural relations (LISREL), version 10.0 (Scientific Software International, 2019), we carried out a CFA with a complete calculation of the maximum possibility of information. The database was divided into two halves and on the first and second halves, respectively, EFA and CFA analyzes were performed. In addition, Tukey's test and Hotelling's T-square test were used. A margin of error of $p = 0.01$ was used.

3. RESULTS

The mean age of children with cancer in the 7-12 age group was 8.98 ± 1.45, and the mean age of children with cancer in the 13-18 age group was 15.63 + 4.02. Among them, 50.3% ($n = 250$) were girls, and 38.2% ($n = 19$) were diagnosed with acute lymphoblastic or myeloblastic leukemia and 34.2% were diagnosed with central nervous system tumor ($n = 170$), with 67.4% ($n = 335$) receiving treatment in the clinic. Table 1 represents the frequency of symptoms that children suffer in the study.

Table 1. *Symptoms Frequency Experienced by Children with Cancer in the 7-12 age group (n=284) and 13-18 age group (n=213)*

Semptom	Never		Little		Medium		Often	
	n	%	n	%	n	%	n	%
1. Nausea	59	11.9	74	14.9	177	35.6	187	37.6
2. Vomiting	59	11.9	75	15.1	184	37.0	179	36.0
3. Intestinal Changes	56	11.3	77	15.5	183	36.8	181	36.4
4. Change in Taste	53	10.7	82	16.5	183	36.8	179	36.0
5. Difficulty in Swallowing	49	9.9	86	17.3	182	36.6	180	36.2
6. Mucositis	133	26.8	43	8.7	127	25.6	194	39.0
7. Fatigue	47	9.5	103	20.7	145	29.2	202	40.6
8. Energy Loss	55	11.1	105	21.1	139	28.0	198	39.8
9. Weight Loss	76	15.3	126	25.4	135	27.2	160	32.2
10. Loss of Appetite	69	13.9	109	21.9	159	32.0	160	32.2
11. Pain	43	8.7	106	21.3	148	29.8	200	40.2
12. Sweating	298	60.0	39	7.8	115	23.1	45	9.1
13. Dizziness	325	65.4	18	3.6	113	22.7	41	8.2
14. Skin Changes	194	39.0	72	14.5	171	34.4	60	12.1
15. Difficulty in Sleeping	132	26.6	101	20.3	127	25.6	137	27.6
16. Difficulty to Get Attention	268	53.9	63	12.7	63	12.7	103	20.7

3.1. Validity Analyses

Results of content validity analysis; the I-CVIs ranged from 0.80 to 0.98, the scale-level content validity index (S-CVI) was 0.94 and were coherent.

Exploratory factor analysis was used to determine construct validity. Factor analysis revealed the KMO coefficient and Bartlett test X2 value were in Table 2 ($p < .01$). The minimum factor load were be 0.30 and above for the 7-12 aged, 13-18 aged and overall scale (Table 2).

Table 2. *Results of Explanatory Factor Analysis*

Sub-Scale	Items	7-12 aged (n=284)	13-18 aged (n=213)	Overall
First Sub-dimension (Gastrointestinal Symptoms Sub Dimension)	**1**	0.925	0.954	0.941
	2	0.921	0.958	0.944
	3	0.891	0.939	0.927
	4	0.918	0.954	0.937
	5	0.926	0.922	0.927
Second Sub-dimension (General Symptoms Sub-Dimension)	**6**	0.669	0.712	0.747
	7	0.867	0.905	0.910
	8	0.884	0.880	0.899
	9	0.705	0.830	0.737
	10	0.747	0.842	0.758
	11	0.863	0.881	0.893
Third Sub-dimension (Other Symptoms Sub-Dimension)	**12**	0.913	0.880	0.920
	13	0.932	0.895	0.925
	14	0.684	0.709	0.606
	15	0.679	0.702	0.621
	16	0.870	0.865	0.858
Kaiser-Meyer-Olkin		0.907	0.897	0.892
Bartlett's Test of Sphericity		8992.096	6066.388	7086.191

The scale consisted of three sub-dimensions, namely gastrointestinal symptoms, general symptoms, and other symptoms. The total variance for the gastrointestinal symptoms, the general symptoms, the other symptoms and total for 7-12 aged scale accounted for 66.94%, 13.88%, 8.10% and 88.92%, respectively. The total variance for the gastrointestinal symptoms, the general symptoms, the other symptoms and total for 13-18 aged scale accounted for 60.34%, 19.17%, 8.67% and 88.18%, respectively. The total variance for the gastrointestinal symptoms, the general symptoms, the other symptoms and total overall scale accounted for 62.24%, 16.30%, 9.53% and 88.08%, respectively.

Table 3. *Model Fit Indices of the Symptom Assesment Scale for Children with Cancer*

	X^2	DF	X^2/ DF	RMSEA	GFI	CFI	IFI	RFI	NFI	TLI
Three Factor Model	201.04	81	2.481	0.077	0.91	0.99	0.99	0.97	0.98	0.98

The database was divided into two halves and on the first and second halves, respectively, EFA and CFA analyzes were performed. The CFA results showed a three-factor model for SAS-CC items (Figure II). The fit indices and factor loading were presented in Table 3 and Figure II.

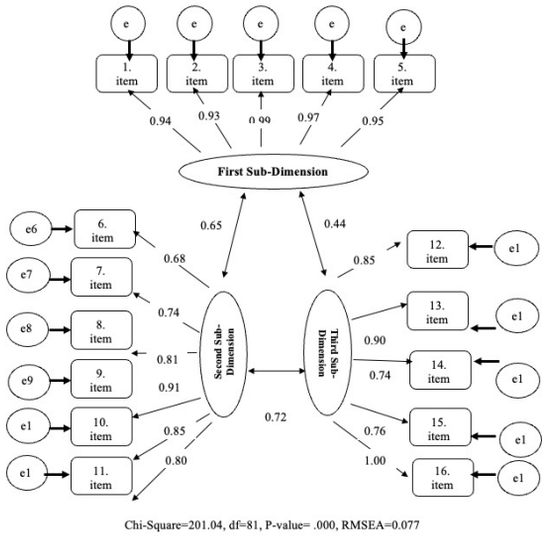

Figure 2. *Confirmatory Factor Analysis of Three Factor Model*

The additivity of the scale was measured using Tukey's additivity test as F = 1.806 and p = .179. The scale was found to be collectable. Hotelling's T-square value was 1117.300 (F = 77.715 and p < .01). No response bias was found in the scale.

Table 4. *Results of the Reliability Analyses of the Scale and Sub-Dimensions (N=497)*

	Overall Cronbach α	7-12 aged Cronbach α	13-18 aged Cronbach α	First half of Cronbach α	Second half of Cronbach α	Spearman-Brown	Guttman split-half	Correlation between two halves	M ± SD (Min-Max)
Scale Total	0.96	0.96	0.95	0.94	0.93	0.86	0.86	0.76	42.55 ± 13.55 (16-64)
First Sub-dimension	0.99	0.98	0.98						14.86 ± 4.93 (5-20)
Second Sub-dimension	0.96	0.96	0.96						17.39 ± 5.83 (6-24)
Third Sub-dimension	0.94	0.94	0.94						10.28 ± 5.08 (5-20)

Table 5. *Correlation of the Item–Total and Item-Sub-Scale Score (N=497)*

Items	Mean + SD	Item-Total Score Correlation *(r)**	Item-Subscale Total Score Correlation (r)*
1. Nausea	2.98 + 1.00	0.74	0.98
2. Vomiting	2.97 + 0.99	0.76	0.99
3. Intestinal Changes	2.96 + 0.99	0.76	0.98
4. Change in Taste	2.96 + 0.99	0.76	0.99
5. Difficulty in Swallowing	2.96 + 0.99	0.75	0.97
6. Mucositis	2.76 + 1.22	0.76	0.77
7. Fatigue	3.01 + 0.99	0.81	0.93
8. Energy Loss	2.97 + 1.02	0.79	0.91
9. Weight Loss	2.77 + 1.06	0.82	0.88
10. Loss of Appetite	2.83 + 1.03	0.84	0.90
11. Pain	3.02 + 0.97	0.81	0.91
12. Sweating	1.81 + 1.07	0.73	0.89
13. Dizziness	1.73 + 1.07	0.71	0.90
14. Skin Changes	2.19 + 1.08	0.78	0.79
15. Difficulty in Sleeping	2.54 + 1.15	0.72	0.75
16. Difficulty to Get Attention	2.00 + 1.22	0.73	0.89

** p<0.001*

3.2. Reliability Analyses

The reliability analyzes results of this study are presented in Table 4.

The correlation value of scale items and item–sub-dimensions with the total scale scores were presented in Table 5.

4. DISCUSSION

We obtained opinions from 14 experts to determine the consistency of items on the scale regarding. Further, we discussed the advices of experts on the phrase and content of items and subsequently excluded certain items from the scale. Minimum values for the number of experts mean the significance of the item. Both I-CVI and S-CVI should be above 0.80, which indicates that the experts agreed (19).Both I-CVI and S-CVI rates were detected above 0.80 in this analysis. The results of I-CVI and S-CVI demonstrated; the scale adequately assessed the subject matter, and the quality of the material was assured.

In this study, a 16-item scale was developed to determine the symptoms experienced by children with cancer. In the literature, it is stated that Memorial Symptom Scale (7-12 years old) has eight items and Memorial Symptom Scale (10-18 years old) has 30 items (12,20).The scale developed in this study has 16 items, which makes it practically feasible and can identify the important symptoms experienced by children with cancer in detail.

In the light of the literature, The Bartlett sphericality test should be statistically relevant and the KMO value should be at least 0.60 for factor analysis (21).Barlett's sphericity test value in this study was $p < 0.05$, and the KMO value was higher than 0.60 for 7-12 aged, 13-18 aged and overall scale. Additionally, the database and sample size is sufficient to evaluate factor (21).

The explained variance in multidimensional scales should be above 40%; higher the overall variance, the greater the validity of the construct. The total variance of 7-12 aged, 13-18 aged and overall scale obtained in this study was above 50%. The tool had a high explained variance. According to this study, the construct validity of the scale is suitable. In general, the minimum factor load should be 0.30 and above and items should be excluded from the scale below this value (21).This result showing that the scale had a strong factor construct in this study.

CFA was used to determine whether the original scale structure was clarified by items and sub-dimensions. CFA evaluates the construction obtained by EFA (22).For the three-factor CFA, factor loadings of the scale were greater than 0.30, the fit indexes were greater than 0.90, and the RMSEA was less than 0.080. We observed a good and significant relation between the tool and its sub-dimensions. In the literature, normal value and acceptable value have been determined for RMSEA, GFI, CFI and NFI. The normal values for these indices are <0.05,> 0.95,> 0.95 and> 0.95, respectively. The acceptable values are <0.08,> 0.90,> 0.90 and> 0.90, respectively. In this analysis, the CFA findings indicated that the data were coherent with the model, the three-factor construct was confirmed, the sub-dimensions were associated with the scale, and the items in each sub-dimensions efficiently defined their factors.

In this analysis, all the factor analysis findings accepted the construct's scale validity, supporting the scale's validity.

α values should be as close to 1. α value between 0.60 and 0.80 indicates a consistent scale. α value between 0.80 and 1.00 indicates that the scale is extremely accurate (23).In this analysis, the alpha values of the α values 7-12 aged, 13-18 aged and overall scale were higher than 0.70, and the α values of the scale and its s sub-dimensions of α values were highly reliable. In addition, The Cronbach's alpha values of the Memorial Symptom Scale (7-12 aged) and Memorial Symptom Scale (10-18 aged) were found to be 0.70 or greater were considered to demonstrate adequate internal consistency. Such results showed that the items measured the subject adequately, the items specific to the subject (23).

α values obtained from the split-half method were more than 0.70. In addition, a clear and important relationship between the halves was established, and the split-half coefficients of both the Spearman-Brown and Guttman were greater than 0.70 (23). These results proved the reliability of the scale.

The T-square test at Hotelling was used to evaluate the scale to assess the presence of bias in response (23). The test revealed that the respondents responded to the items according to their opinions, the participants' responses were different and the scale had no bias in the response, proving the scale was reliable.

Performing an item-total score analysis is a recommended step in the assessment process to determine the extent to which the individual items within the scale accurately measure the targeted variable (21).The correlation coefficients of both the item–total score and the item–sub-scale total scores were positive and greater than 0.20, in this study. Thus, all scale items showed a high correlation with the overall score and the overall score of their sub-dimensions. In our study, the obtained results surpassed the 0.20 threshold, affirming a favorable relationship. The reliability of the scale for the item was high.

4.1. Limitations

Although this study has several strengths, there is three limitation. This analysis used convenience sampling, which can affect the study's generalizability. Another limitation affecting generalizability is single institution. The Parallel Forms Reliability method was not used. In addition, this scale was carried out on the Turkish population. This may limit universal adaptation to locations speaking different languages suggested

5. CONCLUSION

This study demonstrated that SAS-CC is the study to develop and test and a valid scale to evaluate symptoms in children with cancer. This tool can be used in future studies and in pediatric oncology clinics to evaluate symptoms by nurses. Using results obtained from this scale, nurses may improve symptom management practices for children with cancer. Furthermore, it can be used for conducting comparative cross-cultural studies.

Effective strategies of coping with symptoms in children with cancer are required to improve prognosis, increase survival, and improve the quality of life. Therefore, assessing symptoms and their frequency in children with cancer is an majority initiative of nurses working in the pediatric oncology clinic. It is recommended to use this scale in symptom control based drug studies and epidemiological studies. Thus, it will lead the planning of initiatives that will increase the quality of life of children, reduce the burden of caregiving of parents and increase the status of biopsychosocial well-being. They must not only assess symptoms in children with cancer but must evaluate the efficiency of educational and interventional nursing practices providing symptom management using the SAS-CC. In addition, it is recommended that SAS-CC should be used in initiative-based studies to reduce future symptoms, as it helps to clearly demonstrate the symptoms experienced by children with cancer.

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Design of the study: AAK, MB
Acquisition of data for the study: AAK
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