

BMJ Open Symptom screening in paediatrics tool for screening multiple symptoms in Brazilian patients with cancer: a cross-sectional validation study

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ABSTRACT

Objective The objective of this study was to translate, culturally adapt and validate the Symptom Screening in Paediatrics Tool (SSPedi) into the Brazilian Portuguese language to be used by paediatric oncology patients in Brazil.

Design A descriptive, cross-sectional study that follows an established methodology for translation and cultural adaptation, developed in two phases: phase I, linguistic translation and cultural adaptation of the SSPedi scale and phase II, psychometric properties evaluation.

Setting Children's Hospital for Cancer Treatment in Latin America.

Participants Paediatric patients between 7 and 18 years of age and proxies of patients between 2 and 6 years of age, diagnosed with cancer and undergoing chemotherapy treatment. Patients and proxies with significant neuropsychiatric disorders and/or visual impairment that prevented the ability to read were excluded.

Primary outcome measures Construct validation of SSPedi using convergent validity and contrasted groups. Reliability was evaluated using Cronbach's alpha test and assessing the retest using the intraclass correlation coefficient (ICC).

Results The psychometric properties of the symptom screening tool were evaluated using 157 participants, of which 116 were patients and 41 were proxies. Convergent validity and hypothesised correlations (Spearman's $r > 0.4$) were confirmed for both self- and proxy-reported versions of the assessment tool. No significant differences found between the two contrasting groups. Assessment of SSPedi resulted in an internal consistency of reliability of $\alpha = 0.77$ (95% CI 0.70 to 0.82) for the self and $\alpha = 0.81$ (95% CI 0.71 to 0.88) for the proxy and overall reproducibility ICC values of (95% CI), 0.54 (0.15 to 0.77) and 0.77 (0.64 to 0.86).

Conclusion SSPedi was found to be culturally and linguistically adaptable and considered valid and reliable for use by paediatric oncology patients in Brazil. The new translated and adapted version was named SSPedi-BR.

INTRODUCTION

Worldwide, it is estimated that 200 000 children and adolescents are diagnosed with cancer every year.¹ In Brazil alone, paediatric

Strengths and limitations of this study

- Study conducted with the use of previously established systematic and consolidated methodologies based on internationally recommended standards for the translation and cultural adaptation of a symptom screening tool to be used by paediatric oncology patients.
- Validation process used the psychometric properties of reliability (internal consistency and reproducibility) and validity (convergent and contrasting groups).
- Comprehensible adaptation and linguistic equivalence (non-comprehension of scale items) for children ages 7 and 8 years, resulted in unforeseen challenges due to the literacy limitations of the children in this age group.
- A responsive evaluation was not analysed for this study.

cancer accounts for 1%–4% of all cancer cases, and it is estimated that 12 500 new cases will occur by the end of 2018, of these, it is expected that only 64% will survive.²

Over the last decades, the early diagnosis of cancer in paediatric patients and treatment in specialised centres has led to significant progress in cancer treatment and an increase of the survival rate.² Despite these advances in treatment, paediatric patients must endure several symptoms, many of which have been reported to persist for more than 2 weeks.^{3,4}

The amount of time from the diagnosis of cancer and the type of treatment selected are factors that can directly or indirectly influence the symptoms that are experienced by paediatric oncology patients.⁵ In the literature, there is a disagreement over which are the most distressing symptoms, as the frequency and severity may vary depending on different stages and cancer treatment.^{6,7}

Several of the symptoms that are commonly experienced by children and adolescents that undergo chemotherapy include pain,

nausea, vomiting and mucositis.⁸ These symptoms can cause suffering that is often minimised by these patients and attribute them as a consequence of the treatment, subsequently seeking help only after the symptoms have become more severe.⁹

The presence and severity of these symptoms are often reported by the parents or guardian; however, information that is provided directly by the child is extremely important because children are the best sources of information about themselves.^{10 11} In addition, identification and control of symptoms is vital in order to increase the quality of life in paediatric patients and reduce morbidity.¹² Therefore, screening for multiple symptoms is necessary and the most beneficial form of therapeutic management.⁵ To ensure an accurate evaluation of symptoms, there are objective measures that can be used, such as evaluation scales that are capable of quantitatively measuring a variety of symptoms.¹³

The use of scales specifically designed for the use in the paediatric population for symptom assessment has demonstrated to be promising in clinical studies.¹⁴ A systematic review identified eight different symptom tracking scales used in studies: Advanced Symptom Management System (uses five items that evaluate the severity and distress of five different symptoms); Memorial Symptom Assessment Scale (MSAS) 7–12 (uses eight items that evaluate the presence, frequency, severity and distress of eight different symptoms); MSAS 10–18 (analyses the same characteristics of the MSAS 7–12, but uses 30 items and 30 different symptoms in the evaluation); Symptom Distress Scale (13 items that evaluate the distress of 9 different symptoms), Sitaresmi (13 items that evaluate the frequency and severity of 13 different symptoms); Therapy-Related Symptom Checklist for Children (23 criteria items that assess the severity of symptoms), Dupuis (69–71 symptoms) and Rotterdam Symptom Checklist (discusses the discomfort of 39 different symptoms).¹⁵

Although these are important scales used in clinical practice, they are generally long scales and/or used to evaluate isolated symptoms. A brief screening and assessment scale capable of tracking multiple symptoms would be more effective for use in clinical practice,⁹ since it would allow for the early detection of multiple alterations, as well as the implementation of early intervention strategies.^{12 16}

Recently, a group of researchers at the Hospital for Sick Children in Canada have developed and validated the Symptom Screening in Paediatrics Tool (SSPedi). It is a self-report scale that has as its main objective, the screening of symptoms in children and adolescents with cancer from 8 to 18 years of age and proxies (parents or caregivers).¹¹ When compared with other symptom screening scales (Pediatric Quality of Life and Evaluation of Symptoms Technology (PediQUEST), Patient-Reported Outcomes Measurement Information System (PROMIS) and Perceived Symptom Severity (PSS)),

SSPedi stands out to be a tool that is fast, easy to understand and can be used for both proxy and self-applied versions.¹²

It presents 15 items for symptom evaluation by means of a 5-point Likert response scale, ranging from 'not at all bothered' to 'extremely bothered', as well as time reference points such as 'yesterday' and 'today' for tracking of the current symptoms.¹¹

SSPedi is currently being validated in multiple languages, including Spanish and French. It has been developed for use in both paper and electronic format. The validation of the electronic version of SSPedi, for the self-applied version demonstrated to be reliable (internal consistency (alpha 0.86) and test-retest (intraclass correlation coefficient, ICC 0.88) and inter-rater (0.76). For the proxy version, reliability, internal consistency (alpha 0.87) and inter-rater (ICC 0.76), the retest test was not evaluated. Demonstrating that the psychometric properties are reliable and valid for use in clinical practice.^{17 18}

Additionally, Brazil does not have a scale to screen for multiple symptoms, specifically in paediatric cancer patients. Validated scales in the Portuguese language, only evaluate single symptoms for specific age groups.^{19 20} Thus, the objective of this study was to translate, culturally adapt and evaluate the psychometric properties of SSPedi to be used by paediatric oncology patients in Brazil.

METHODS

Study design

It is a descriptive, cross-sectional, study that follows an established methodology for translation and cultural adaptation, which was developed in two phases. The first phase involved the development of an accurate and coherent linguistic translation as well as a cultural adaptation of the original version of SSPedi in English to the Brazilian Portuguese language. The second phase consisted of evaluating the psychometric properties of the newly translated SSPedi scale.

Participants and eligibility criteria

The process of translation and cultural adaptation of phase I took place during the months of January and March of 2017, with the use of 30 participants (24 patients and 6 proxies, stratified by age, two patients per age group).

In phase II, the evaluation of the psychometric properties of SSPedi occurred between the months June 2017 and April 2018, with the use of 157 participants (116 patients, stratified by age, 7 patients per age group and 41 proxies 4 stratified by age, 4 patients per age group) and 78 retests (53 patients and 25 proxies).

The eligibilities of participants for this study were selected using the following criteria; patients 7–18 years of age, male and female, diagnosed with cancer and undergoing chemotherapy, and proxies (parents or guardians) of patients from 2 to 6 years of age. Patients and proxies with significant neuropsychiatric disorders as well as those

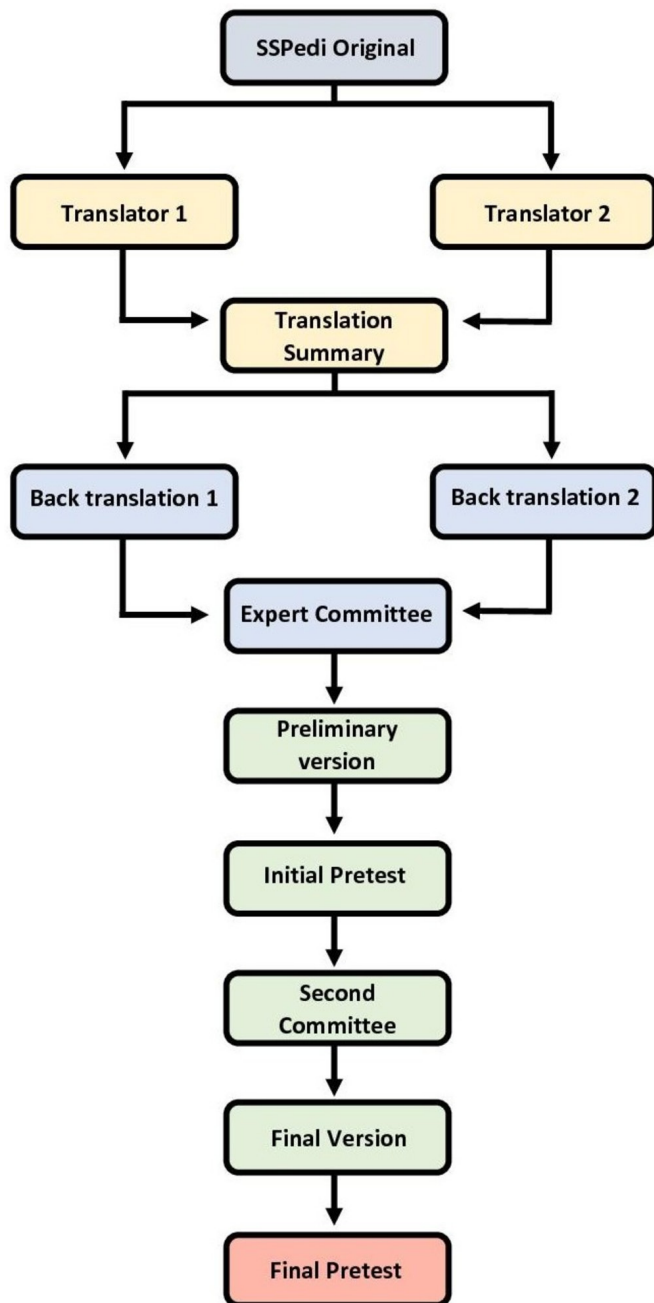


Figure 1 Flow chart—methodological steps, used for translation and cultural adaptation of the Symptom Screening Paediatrics Tool (SSPedi).

with some type of visual impairment that prevented them from visualising the evaluation instruments, documented in the patient's chart were excluded.

Study site

The research was conducted at Hospital Infantojuvenil—Barretos Cancer Hospital, located in the city of Barretos (SP). Patient and proxy interviews were conducted taking into consideration the individual and appropriate place free of interruptions.

Patient and public involvement statement

Patients and/or public were not involved in the design or planning of the study.

All participants and primary caregivers were informed in regard to the nature of this study. Authorisation for participation was obtained in the form of signed consent forms from the primary caregivers and signed assent forms from the patients. The entire validation process was carried out following the authorisation of one of the authors of the original SSPedi.¹¹

Calculation of sample size

Sample calculation for the first phase, the process of translation and cultural adaptation, followed the methodology described by Beaton *et al*, which advocates the participation of 10–40 participants in order to evaluate the difficulties and to gain an understanding of the items.²¹ The sample size selected for validation was estimated based on validation studies of other health instruments, which take into consideration between 3 and 20 times the number per research items.²²

SSpedi validation process

The process of transcultural translation, adaptation and validation of a scale for use in other cultures, languages and countries, requires cautious planning as well as a rigorous and well-established methodological approach.²³

Phase I: translation and cultural adaptation

The process for cross-cultural adaptation was conducted following the guidelines set forth by Beaton and Sousa,^{21 23} which began with the initial translation, synthesis of the translation, a back-translation, followed by an expert committee review, concluding with pretesting of the instrument (figure 1).

The first step consisted of the translation of the instrument from the English language into Brazilian Portuguese, which was carried out by two independent translators, both, native in the language of the desired instrument. None of the translators had knowledge of the translated instrument (SSPedi). This generated a translated version of the scale called T1 and T2.

The second step was to create a synthesis of the translation. The translated versions were compared with the original instrument by the researchers of this study knowledgeable in the construct of the instrument. An analysis and evaluation of the format of items and responses, sentence structure, similarity, meaning and relevance, was conducted. Based on the evaluation of the research group, a synthesis version (T12) was generated.

The third step, back translation (BT), consisted of translating the instrument from the Brazilian Portuguese language back to the original English language, in order to analyse any conceptual errors or inconsistencies in the translation process. Two other independent translators were used, North American, fluent in Portuguese, in order to perform the (BT1 and BT2). Both translators

were unaware of the construct or knowledge of the scale in its original version.

For the fourth step, an evaluation of all the previous processes was carried out by a committee of experts of five specialists, an oncologist with experience in translation and adaptation, an oncologist, a paediatric oncologist, a pedagogue and a professional with experience in translations and linguistic adaptations. Their function was to consolidate all the translated versions and to develop a preliminary version of the scale that was adapted culturally and suitable for the accomplishment of a pretest. This phase was fundamental, since it allowed for the identification and clarification of inappropriate expressions and concepts of the translation.^{21 23}

The members of the expert committee received a specific document with the material of versions T12 and B12 and were instructed to evaluate each item of the scale according to the semantic, cultural and conceptual equivalences. The analysis of the data was performed both qualitatively and by an analysis of the scores of the specialists' answers. To evaluate the representativeness of each item, we used a Likert scale with scores between 1 and 4. This index was calculated considering the sum of the equivalences divided by the total number of items. The items were considered equivalent when the mean Cultural Validity Index (CVI) was greater than 0.8.

The fifth step was the pretest, the final process of the cultural adaptation stage. It consisted of evaluating the instructions, the format of the answers and the scale items to ensure that they were clear and comprehensible. Each of the participants evaluated for content, clarity and their understanding of the scale items. This step was further used to support the cultural, semantic and conceptual, content equivalence of the translated scale, it also contributed to improving the sentence structure used in the instructions and items of the instrument so that it could be easily understood by the target population before the psychometric tests.²³ During the pretest, it became apparent that it would be necessary to make some adjustments to some of the items. It was found that a lack of literacy development in some of the paediatric test subjects made it difficult for them to understand the questions. This resulted in the need of a reanalysis by a new committee that identified the need to add synonyms to the words not understood. Thereafter a secondary pretest or 'final pretest' was initiated.

Phase II: evaluation of psychometric properties

The eligibility criteria for inclusion and exclusion of participants at this phase were the same as in phase I.

Reliability

The internal consistency of items of the instrument were calculated using Cronbach's α coefficient, where values vary between 0 and 1, with zero (0) representing no consistency between the evaluated items and 1 representing a perfect correlation. Reproducibility was assessed using the ICC, with an analysis performed 48–72 hours after

the first evaluation, the time of evaluation was defined as a function of the test–retest of the original scale and discussed with one of the original SSPedi authors.

Convergent validity

The following items of the SSPedi scale were hypothesised correlations with items from other scale instruments that were used in the validation process: the item 'Throwing up or feeling like you may throw up' with Paediatric Nausea Assessment Tool (PeNAT), the items 'Mouth sores', Hurt or pain (other than headache) 'Changes in taste' with Children's International Mucositis Evaluation Scale (ChIMES), the items 'Headache', 'Hurt or pain (other than headache)' with Faces Pain Scale-Revised (FPS-R) and Feeling disappointed or sad, Feeling scared or worried, Feeling cranky or angry, Problems with thinking or remembering things, Changes in how your body or face look, Feeling tired, Hurt or pain (other than headache), Tingly or numb hands or feet, Feeling more or less hungry than you usually do, Constipation (Hard to poop) with Paediatric Quality of Life Inventory V.4.0 (PedsQL).

Contrasted groups validity

Prior differences were defined in outpatient versus inpatient scores and metastatic versus non-metastatic patient scores.

Instruments for data collection

Participants completed the SSPedi,¹¹ PeNAT,²⁴ ChIMES,^{25 26} (FPS-R^{27 28} and PedsQL).^{19 29}

Paediatric Nausea Assessment Tool

Developed and validated in 2006, Developed, it is a reliable and valid scale that measures the severity of nausea in children ages 4–18 years who are undergoing chemotherapy, allowing for effective intervention control of symptoms.²⁴

Children's International Mucositis Evaluation Scale

The original version was developed and validated in 2009.²⁶ It presents a total of seven items, related to mouth or throat pain, pain with swallowing, food related pains, pain related to fluid intake, use of pain medication, use of medication for pain in the mouth or throat and the presence of ulcerated lesions.²⁵ The Brazilian version of self-applied and proxy ChIMES was considered culturally valid and reliable for paediatric patients and renamed CHIMES-BR.³⁰

Faces Pain Scale-Revised

FPS-R is an instrument consisting of six faces and can be scored on a scale from 0 to 10, used to measure pain intensity,³¹ for children between 4 and 18 years of age.²⁸ Translated and adapted for the Brazilian population, it is a valid and reliable, it is the preferred method for self-reporting pain measurement.²⁷

PedsQL V.4.0 Generic Core Scales

Developed to be a modular approach for assessing the quality of life related to paediatric health (five items), and School Functioning (five items). It is composed of parallel forms use for the self-evaluation of children and questionnaires for parents or guardians.^{19 29}

Patient characterisation questionnaire

Sociodemographic information regarding the patient and clinical information were obtained from patient records.

Statistical analysis

A descriptive analysis was used to report on the demographic and clinical information that was obtained. The internal consistency of the SSPedi scale was verified through the use of the Cronbach's alpha coefficients, were the values between (0.70 and 0.90) and consistent. The correlations between the scores on the SSPedi versus ChIMES, SSPedi versus PeNAT, SSPedi versus FPS-R and SSPedi versus PedsQL were tested using Spearman's rank correlation coefficient, with correlations above 0.4 were considered adequate. The reproducibility was verified through the use of the ICC values above 0.7 and were considered reproducible. Comparisons of the SSPedi scores between the metastasis groups (no vs yes) and treatment sites (inpatient unit vs outpatient infusion centre) were performed using the Mann-Whitney U test. Analyses were then performed by taking into consideration only the proxy-reported version, followed by the consideration of only the self-reported version and ending with a consideration of both the proxy-reported and self-reported versions in unison. Overall in all of the analyses, a significance level

of 0.05 was considered. The data were then tabulated using Research Electronic Data Capture Platform and analysed using IBM SPSS V.21.

RESULTS

Translation and cultural adaptation

Throughout the process of linguistic translation and cultural adaptation, the most frequent discrepancies found between the different translated versions were in regard to semantic equivalence.

Regarding the CVI, all items showed adequate results (CVI ≥ 0.8). Of all the items assessed, four of the items obtained CVI=0.80. The description of equivalences is shown in [table 1](#).

In the initial pretest, 32 participants were recruited, of which 30 participants (24 patients and six proxies, stratified by age 2 patients per age group) accepted to participate in the study and 2 refused. The proxies did not have any question or doubts about the scale items during the pretest; however, in the self reporting version, paediatric patients between the ages of 7 and 12 had doubts regarding the meaning of some of the words (semantic equivalence) used in the scale. Based on the difficulties that were encountered by the participants (understanding of the words), a new committee of experts (specialists in the validation process) identified the need to create a second pretest called the final pretest (online supplementary table).

The Brazilian Portuguese version of SSPedi was renamed SSPedi-BR ([table 2](#)).

Table 1 Cultural Validity Index (CVI)

Items SSPedi	CVI		
	Semantics/ idiomatic	Cultural	Conceptual
Original	Feeling cranky or angry		
Translation	Sentindo-se mal-humorado ou bravo		
Committee	Sentindo-me mal-humorado ou raiva	1.00	1.00
Original	Problems with thinking or remembering things		
Translation	Dificuldade em pensar ou lembrar as coisas		
Committee	Dificuldade em pensar ou lembrar das coisas	0.80	0.80
Original	Constipation (hard to poop)		
Translation	Constipação (difícil para fazer cocô)		
Committee	Constipação (dificuldade para fazer cocô)	1.00	0.80
Original	Please tell us about any other things that have bothered you lately by writing about them here		
Translation	Por favor, se tiver alguma outra coisa que tem te incomodado ultimamente, escreva aqui.		
Committee	Por favor, se alguma outra coisa tem te incomodado ultimamente, escreva aqui	1.00	0.80

SSPedi, Symptom Screening in Paediatrics Tool.

Table 2 Symptom screening in paediatrics

	Not all bothered	A little	Medium	A lot	Extremely bothered
1-Feeling disappointed or sad	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2-Feeling scared or worried (reflective)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3-Feeling cranky or angry (don't feel like smiling)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4-Problems with thinking or remembering things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5-Changes in how your body (visually) or face look	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6-Feeling tired	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7-Mouth sores	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8-Headache	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9-Pain (other than headache)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10-Tingly (small shocks) or numb hands or feet (no feeling in the hands or feet)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11-Vomiting or feeling like vomiting	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12-Feeling more or less hungry (change in appetite) than you usually do	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13-Changes in taste (taste of the food)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14-Constipation (hard to poop)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15-Diarrhoea (watery, runny poop)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please tell us how much each of these things bothered you yesterday or today by ticking the circle that best describes the amount it bothered you. Please write down any other things that have bothered you lately.

Evaluation of psychometric properties

Between June 2017 and April 2018, 164 participants were recruited, of which 157 accepted to participate in the study, with 7 participants refusing to participate because they were not feeling well at the time of the interview.

Of the 157 participants, 116 patients and 41 proxies were used for the study. Retests were then performed on 53 patients and 25 proxies for a total of 78 participants. Children ages 7 and 8 years (children in the literacy phase) needed help with reading the items. The

sociodemographic and clinical characteristics of the participants are as described in the [table 3](#).

Reliability

The internal consistency was verified using Cronbach's alpha test, with values of $\alpha=0.77$ (95% CI 0.70 to 0.82) for the self-reported version, $\alpha=0.81$ (95% CI 0.71 to 0.88) for the proxy-reported version. Values >0.70 were considered acceptable ([table 4](#)).

Table 3 Sociodemographic and clinical characteristics of participants

Characteristics		Self-reported version		Proxy-reported version	
		Frequency		Frequency	
		N	%	N	%
Sex	Male	72	62.1	6	14.6
	Female	44	37.9	35	85.4
Race	White	60	52.6	13	31.7
	Black	10	8.8	6	14.6
	Mixed	42	36.8	22	53.7
	Asian	2	1.8	0	0.0
Educational level	Incomplete basic	66	56.8	–	–
	Complete basic	8	7.0	–	–
	Incomplete primary	36	31.1	2	4.9
	Complete primary	4	3.5	6	14.6
	Incomplete secondary	1	0.9	3	7.3
	Complete secondary	–	–	18	43.9
	Incomplete higher education	–	–	4	9.8
	Complete higher education	–	–	6	14.6
Region of origin	Graduate education	–	–	2	4.9
	North	37	31.8	10	24.4
	Northeast	6	5.2	14	34.1
	Central West	16	13.8	2	4.9
	Southeast	51	44	14	34.1
Primary tumour	South	6	5.2	1	2.4
	Solid	65	58.0	20	48.7
	Hematologic	43	38.4	17	41.4
	Central nervous system	4	3.6	2	4.8
	Without defined diagnosis	–	–	2	4.8
Distant metastasis	No	87	75.0	31	75.6
	Yes	29	25.0	10	24.4
Treatment performed	Chemotherapy	113	97.4	41	100
	Radiotherapy	14	12.1	1	2.4
	Surgery	32	27.6	14	34.1
Amputation	Yes	7	6.2	1	2.4
	No	106	93.8	40	97.6
Cancer diagnosis to date collection months	Mean (SD)	5.5 (8.3)	–	6.4 (8.4)	–

Reproducibility test–retest

Reproducibility was assessed by the ICC. There were a total of 53 patients in the self-reported version and 25 patients in the proxy-reported version that participated in the retest. The ICC (95% CI) values were 0.77 (0.64 to 0.86) for the self-reported version, 0.54 (0.15 to 0.77) for the proxy-reported version.

Convergent validity

The correlations between the total SSPedi scores for the self- and proxy-reported versions are described in [table 5](#). The correlations hypothesised a priori were confirmed for the self-reported and proxy-reported versions: the

items ‘Feeling tired’ x PedsQL (school dimension) (0.502); ‘Hurt or pain’ (other than headache) x FPS-R; (0.528) Throwing up or feeling like you may throw up x PeNAT (0.706); Changes in taste (taste of the food) x ChIMES (0.602).

Contrasted groups

Previously, differences between the groups inpatients versus outpatients and metastatic versus non-metastatic patients were hypothesised, but there were no significant differences between groups in the inpatient versus outpatient ($p=0.64$) or metastasis versus non-metastasis ($p=0.29$) versions, or in the proxy-reported inpatients

Table 4 Internal consistency analysis by means of Cronbach's alpha

SSPedi item	Cronbach's alpha (95% CI) Self-report	Alpha if item deleted	Cronbach's alpha (95% CI) Proxy	Alpha if item deleted
	0.77 (0.70 to 0.83)		0.81 (0.72 to 0.89)	
Feeling disappointed or sad		0.753		0.798
Feeling scared or worried (reflective)		0.752		0.777
Feeling cranky or angry (Don't feel like smiling)		0.754		0.785
Problems with thinking or remembering things		0.753		0.818
Changes in how your body (visually) or face look		0.774		0.810
Feeling tired		0.742		0.790
Mouth sores		0.768		0.815
Headache		0.760		0.815
Hurt or pain (other than headache)		0.758		0.808
Tingly (small shocks) or numb hands or feet (no feeling in the hands or feet)		0.766		0.817
Throwing up or feeling like you may throw up		0.749		0.809
Feeling more or less hungry (change in appetite) than you usually do		0.755		0.791
Changes in taste (taste of the food)		0.766		0.792
Constipation (hard to poop)		0.757		0.808
Diarrhoea (watery, runny poop)		0.772		0.808

SSPedi, Symptom Screening in Paediatrics Tool.

versus outpatients ($p=0.65$) or metastasis versus non-metastasis ($p=0.80$) versions (table 6).

DISCUSSION

The present study carried out the processes of linguistic translation, cultural adaptation and evaluation of the psychometric properties of SSPedi for use by the Brazilian paediatric oncology population. It used a systematic methodology and an already consolidated methodology, which

was based on internationally recommended standards, this was an important process to assure the quality of methodological research involving instrument validation.^{21 32}

The validation process of an instrument is completed to ensure that the measuring capabilities of the tool, function as it was designed to do so.³³ The results indicated that it is a reliable and valid scale for the screening of symptoms in paediatric cancer patients in the Brazilian population. The reliability of the SSPedi was assessed using Cronbach's alpha

Table 5 Correlation coefficients between the SSPedi and the PedsQL, FPS-R, PeNAT and ChIMES (convergent validity)

Self-reported version items		Proxy-reported version items	
Feeling disappointed or sad xPedsQL (emotional dimension)	0.449	Feeling cranky or angry (don't feel like smiling) x PedsQL (school dimension)	0.443
Feeling scared or worried xPedsQL (emotional dimension)	0.464	Problems with thinking or remembering things xPedsQL (school dimension)	0.484
Feeling cranky or angry xPedsQL (emotional dimension)	0.502	Changes in how your body (visually) or face look xPedsQL (school dimension)	0.651
Feeling tired xPedsQL (school dimension)	0.424	Mouth sores xPedsQL (school dimension)	0.466
Hurt or pain (other than headache) xFPS-R	0.528	Headache xFPS-R	0.405
Throwing up or feeling like you may throw up xPeNAT	0.706	Throwing up or feeling like you may throw up xPeNAT	0.519
		Changes in taste (flavour of the food) xChIMES	0.602
		Constipation (hard to poop) xPedsQL (school dimension)	0.624

ChIMES, Children's International Mucositis Evaluation Scale FPS-R, Faces Pain Scale-Revised; SSPedi, Symptom Screening in Paediatrics Tool; PedsQL, Paediatric Quality of Life Inventory; PeNAT, Paediatric Nausea Assessment Tool;

Table 6 Self-reported and proxy-reported versions comparison measured using the SSPedi among patient groups (contrasted groups analysis)

Version	Contrasted groups	N	Mean	Median	P value
Self	Inpatient unit	14	10.5 (9.1)	8.5 (1–34)	0.64
	Infusion centre	99	8.63 (6.05)	8.0 (0–27)	
	Non-metastatic	85	9.07 (6.34)	8.0 (0–34)	0.29
	Metastatic	26	7.77 (6.32)	5.5 (0–27)	
Proxy	Inpatient unit	5	9.00 (2.35)	10.0 (6–11)	0.66
	Infusion centre	36	9.94 (8.36)	6.50 (0–30)	0.80
	Non-metastatic	31	9.84 (7.63)	9.0 (0–30)	
	Metastatic	10	9.80 (8.97)	6.0 (0–25)	

SSPedi, Symptom Screening in Paediatrics Tool.

test, considering values >0.7 as acceptable. In the present study, the values were satisfactory for the self-reported and proxy-reported versions with values of $\alpha=0.77$ and $\alpha=0.81$, respectively, thus confirming the values of the original study of $\alpha=0.86$ and $\alpha=0.87$ for the self-reported and proxy-reported versions, respectively. The reproducibility also obtained good results. However, the test–retest for the proxy-reported version was low. This will need to be further evaluated in a subsequent future study. A time interval of 48–72 hours after the first evaluation was found to be a period considered suitable for symptom validation studies.³⁴ Each evaluated item had its self-reported and proxy-reported version compared. Objective items such as ‘Changes in taste’ (taste of the food), ‘Constipation’ (hard to poop) and ‘Changes in how your body (visually) or face look’ showed a high ICC in the proxy-reported version, and subjective items such as ‘Feeling disappointed or sad’ and ‘Problems with thinking or remembering things’ presented a low ICC. Reaching a similar conclusion to that of the original validation study of the SSPedi proxy version, in which some of these items did not recognise the children’s perceptions. Thus, the importance of the children’s perception, that is, of their self-reporting, is emphasised, considering that the best evaluators of symptoms or of other constructs that one intends to measure, are the patients themselves. Proxies, for the most part, may underestimate or overestimate the children’s symptoms.¹⁴

The construct validity of the SSPedi was tested according to the convergent validity and contrasted groups validity. The correlation values of the coefficients found between the SSPedi and the other scales proposed for this study were considered good ($r \geq 0.4$).³⁵

The difficulty found in the study was in the initial pretest phase, regarding the semantic equivalence, that is, the non-comprehension of some items of the SSPedi scale. The children who participated in the initial pretest had doubts regarding some of items. These were children identified to be in the age group of 7–8 years of age, who were in the process of literacy. A regional validation study conducted in Brazil, with children ages 8–12, identified this group as having less stable responses. These findings were similar

to those found in the present study in which the children between the ages of 8 and 9 years also demonstrated similar results having significant differences in the test and retest.³⁶ It is important to note that in Brazil, many children in this age group are in the process of literacy, that is, learning to read and write. As noted in this study, it was necessary for the researchers to read the scales for these patients, which was considered a normal procedure, taking into account the literacy phase in which these children were in. Therefore, it was fundamentally important to perform a careful translation and adaptation process, as executed in this study, in order to minimise the difficulties of understanding within the children of this age group.

The present study was epidemiologically correct and adequate to attend the validation process. However, no significant differences were observed in relation to the scores between the contrasted groups, hypothesised a priori (inpatients vs outpatients) and (metastatic vs non-metastatic). This hypothesis was not carried out in the original article of validation auto version and proxy, in these studies, the significant differences were between groups of less and more symptoms, not done in this study.¹⁷

The process of validating an existing assessment instrument produces results that can be compared internationally. Thus, it becomes more feasible to carry out the processes of cultural adaptation and validation in comparison to existing evaluation instruments than to develop a new tool, since development would have been important only if the construct to be measured did not have an already existing instrument for such.³⁷ As in the original study, the validation of the SSPedi presented satisfactory psychometric properties, being a scale that can be applied quickly and is easy to use, as well as very useful in clinical practice,¹⁷ making it possible to institute prophylactic approaches and treatment in a timely manner, resulting in improving the quality of life of paediatric cancer patients.⁵ The findings in the Brazilian Portuguese version of SSPedi are consistent with the validation of the original scale. Our data demonstrate that the validated version had a correlation with the original and that it was considered adequate, as it presented similar values in the psychometric properties that were

evaluated. Reliability (Cronbach alpha 0.86 original and 0.77, translated version, test-retest 0.88 and 0.77, respectively). These findings support the feasibility and reliability of the instrument.^{17 18}

We conclude that the self and proxy versions of SSPedi were considered to be culturally adaptable for Brazilian paediatric patients. The psychometric properties evaluation process of the translated version of SSPedi into Brazilian Portuguese has proven that it is a valid and reliable scale for tracking symptoms in paediatric oncology patients and their proxies, and may be considered a vital tool for clinical practice thusly renaming it SSPedi-BR.

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