



Translation, Cultural Adaptation, Reliability, and Validity Evidence of the Feeding/Swallowing Impact Survey (FS–IS) to Brazilian Portuguese

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Abstract

The purpose of this study was to translate and adapt the Feeding/Swallowing Impact Survey (FS–IS) into Brazilian Portuguese and provide a validated instrument for caregivers of children with feeding/swallowing disorders. This cross-cultural study involved initial translation, synthesis of translations, back-translation, Committee of Experts, and pre-test. The sample consisted of 95 primary caregivers of children with feeding/swallowing disorders classified by Pediatric Dysphagia Evaluation Protocol (PDEP) in mild ($n=9$), moderate–severe ($n=40$), or profound ($n=46$) dysphagia. Reliability and evidence of validity based on test content, response processes, internal structure and the relations to other variables were investigated. Internal consistency, test–retest, exploratory and confirmatory factor analysis were performed, in addition to the correlation with PedsQL™ Family Impact Module (PedsQL™FIM). The pre-test participants did not report any difficulties in understanding the translated version. The Brazilian Portuguese version of FS–IS (Pt–Br–FS–IS) presented Cronbach's Alpha of 0.83, Exploratory Factor Analysis verified that the instrument would not be unifactorial ($KMO=0.74$ and Bartlett's sphericity test $p < 0.001$) and Confirmatory Factor Analysis confirmed the original model in three subscales with $\chi^2/df=1.23$, $CFI=0.92$, $TLI=0.90$, $RMSEA$ (90% CI) 0.049 (0.011–0.073) adjustment indexes and the ICC was excellent in all subscales and total score. The correlation with PedsQL™FIM was significant in the total score and subscales. This study successfully translated and cross-culturally adapted the FS–IS instrument to the Brazilian Portuguese language and the investigation of its reliability and validity evidence suggests that the Pt–Br–FS–IS is a reliable and valid tool to measure the impact of feeding/swallowing disorders on the quality of life of caregivers of affected children.

Keywords Swallowing disorders · Caregivers · Child · Health-related quality of life · Validation · Adaptation

Introduction

The estimated prevalence of feeding/swallowing disorders in the pediatric population ranges from 25 to 45% in typically developing children and from 33 to 80% in children with developmental disorders [1]. Its increasing incidence has been attributed to the improved survival of children with histories of prematurity, low birth weight, and complex clinical conditions [1–5]. Feeding and swallowing are intrinsically linked processes in early childhood and are essential for child growth and development. Feeding disorders may threaten the adequacy of nutrition or respiratory health and result in cumulative problems throughout lifetime [5–10]. Importantly, all children with swallowing problems have feeding disorders; however, not all children with feeding disorders have swallowing problems [11].

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In addition to the potential impact of feeding disorders on general health and development of affected children, their influence the child-caregiver relationships, can cause emotional distress in caregivers and affect their well-being [11, 12]. Parents and caregivers may feel unprepared for the demands of caring for children who need feeding strategies, or some may feel responsible for the feeding problems. These types of response may have profound effects on their self-esteem, self-efficacy, and confidence in parenting [12–15] and can lead to burden, stress and isolation, affecting their daily life [16, 17].

FS-IS is the first validated instrument designed to measure the impact of children's feeding/swallowing problems their caregivers [18]. To date, it has been validated as a quality of life (QOL) instrument for caregivers of children with cerebral palsy [18, 19], laryngeal clefts [20], eosinophilic esophagitis [21], and esophageal atresia and tracheoesophageal fistula [22]. In addition, it has been translated from English into Turkish and validated for children with cerebral palsy [19]. It has been shown to be sensitive to detecting changes in caregiver responses related to interventions for laryngeal clefts [20].

There is no comparable dysphagia-specific instrument to assess the QOL of caregivers of children with feeding/swallowing difficulties or the impact of interventions in Brazil. Therefore, the aim of this study is to translate, culturally adapt, and evaluate the reliability and validity evidence of FS-IS in its Brazilian Portuguese version.

Methods

This cross-sectional study included the translation and cultural adaptation of the FS-IS and investigated its validity evidence. The study protocol was approved by the HCPA Ethics Committee (85654118.0.0000.5327). Authorization for use of the FS-IS was provided by the primary author and owner of the FS-IS copyright, Maureen A. Lefton-Greif.

Translation and Cultural Adaptation

We adhered to the guidelines for cross-cultural adaptation of self-report measures, developed by Beaton et al. [23]. The FS-IS was translated into Brazilian Portuguese by two native speakers of Brazilian Portuguese. One translator was a speech-language pathologist who specializes in dysphagia and was aware of the objectives and concepts of the investigation. The other was an independent translator who was blinded to the objectives of the study. Using a process of consensus, the two translations were synthesized into a single version. Next, two back-translations were carried out by native English-speaking translators, who were blinded to the objectives the study. By consensus, a new synthesis

(back-translation) was created. All versions were compared and analyzed by a committee of experts (nutritionists, speech-language pathologists, pediatricians, and translators), which determined that the items of the translated instrument were comparable to the original FS-IS. The final version of the Feeding/Swallowing Impact Survey for Brazilian Portuguese (Pt-Br-FS-IS) was then completed. This version was sent to the primary author of the FS-IS for analysis and approval to continue the adaptation process. To verify comprehension of the meaning and wording of test items, the final version was administered to 30 caregivers [23].

Instruments

Feeding/Swallowing Impact Survey (FS-IS)

FS-IS is a self-report instrument comprised of 18 items, distributed across three main subscales of quality of life: Daily Activities (five items), Worry (seven items), and Feeding Difficulties (six items). Responses vary on a Likert scale with a score of 1 = "Never" to a score of 5 = "Almost Always". The score for each subscale is calculated by adding the Likert scores for items in that subscale and dividing them by the number of items answered in that subscale. It is also possible to obtain a total score of the instrument, adding the 18 items and dividing by 18. The higher the score, the greater the impact on quality of life [18].

PedsQL™ Family Impact Module (PedsQL™ FIM)

The PedQL™ FIM is a multidimensional validated instrument used to assess the family's QOL. We used the validated Brazilian Portuguese version to confirm validity and replicate the methodology used during the development of the FS-IS [24]. PedQL™ FIM measures the impact of chronic medical conditions on the QOL-related to the health of parents and family functioning. However, it is not specific for populations with dysphagia. It has 36 items with 6 domains that measure the self-reported functioning of parents. The instrument has 5 Likert scale responses ranging from 0 = "never" to 4 = "almost always". The total score is calculated by adding the 36 items divided by the number of items answered. There is also a parental score (20 items) and a family score (16 items). Higher scores indicate better functioning, therefore, less negative impact [25].

Pediatric Dysphagia Evaluation Protocol (PDEP)

PDEP is a Brazilian standardized assessment protocol for clinical evaluation of pediatric dysphagia [26]. It is designed to identify changes in the physiology of swallowing, assess the impact of dysphagia on the patient's feeding, verify the

Table 1 Summary of Pediatric Dysphagia Evaluation Protocol (PDEP): stages of clinical swallowing evaluation and classification of pediatric dysphagia

PDEP: stages of clinical swallowing evaluation		
Stage		Summary of procedures
1	Clinical aspects	Registration of the patient's feeding route and respiratory condition
2	Vital signs	Verification of vital signs such as respiratory rate, cardiac frequency, and oxygen saturation levels
3	Structural and functional exam	Observation of posture, muscle tone and mobility of orofacial structures during rest, and performance of stomatognathic functions Observation of vocal quality, non-nutritive sucking (for infants aged 1 to 4 months), and swallowing of saliva
4	Clinical swallowing evaluation	Observation of the child's typical way of feeding (e.g., breastfeeding, bottle-feeding, spoon-feeding) with the child's typical liquids and foods Observations of prehension, swallowing frequency, suck-swallow-breath coordination, oral transit time, feeding time, food refusal, other clinically relevant aspects of feeding
PDEP: Classification of Pediatric Dysphagia		
Level		Definition
No dysphagia		No signs or symptoms of swallowing disorder
Mild dysphagia		Presence of clinical swallowing problems during administration of PDEP Problems appear to be resolved with postural, utensils, and/or flow adjustments
Moderate–Severe dysphagia		Observations consistent with suspicion of pharyngeal phase or oral phase problems with potential impact on adequate nutrition and hydration Requires restriction of consistencies and/or alternative complementary feeding
Profound dysphagia		Observations consistent with high risk of aspiration that precluded oral feeding Requires an alternative exclusive feeding route and may require measures to control saliva aspiration

Source Flabiano-Almeida et al. [26]

need for an alternative feeding, and assist in decision-making for feeding outcomes and rehabilitation [26–28]. The PDEP protocol is divided into four stages for clinical swallowing evaluation shown in Table 1. The PDEP uses a binary rating system to indicate whether clinical variables are adequate/inadequate, altered/non-altered, or present/absent. After the evaluation of the swallowing, the speech-language pathologist will classify the patient with the level that matches their performance in the evaluation [26–28]. The dysphagia classification levels used in the PDEP protocol are shown in Table 1 [26].

Participants

Participants included primary caregivers of children seen at the Pediatric Dysphagia Outpatient Clinic or admitted to the Pediatric Infirmary of the Hospital de Clínicas de Porto Alegre (HCPA), which serves the entire state of Rio Grande do Sul, in Brazil, from November 2018 to December 2019. The primary caregiver was defined as the individual most responsible for feeding. Inclusion criteria included primary caregivers of all children younger than 18 years of age, presenting with signs of or complications associated with feeding/swallowing disorders (e.g., coughing, gagging during mealtimes, history of recurrent pneumonia, difficulty in weight gain.). Exclusion criteria included caregivers younger

than 18 years of age and those with children who had transient feeding/swallowing disorders (e.g., secondary to an intercurrent illness or airway intervention such as intubation), or institutionalized children.

Procedures

Data collection was performed by a speech-language pathologist, nutritionist, and nutrition academic trained for task. The caregiver was interviewed for sociodemographic and demographic information and the patient's feeding/swallowing history (e.g., number of hospitalizations of the patient, time of the onset of difficulty with food/liquids, signs of feeding/swallowing disorder). Electronic medical records were used to complement the feeding and swallowing history. After the interview, the caregiver filled out the Pt–Br–FS–IS, and PedsQL™ Family Impact Module (FIM) instruments. Patients were classified according to the PDEP protocol [26].

Evidence of Validity

The validity was investigated following the guidelines for *Standards for Educational and Psychological Testing—SEPT (2014)* [29]. During the process of translation and cultural adaptation, evidence based on test content was

validated through the analysis and consensus provided by the committee of experts and in conjunction with responses on the pre-test (pilot).

Internal validity analysis was performed through internal consistency and test–retest as reliability measures. Exploratory Factor Analysis (EFA) was performed, and the Kaiser–Meyer–Olkin (KMO) test was used to verify the proportion of data variance that can be considered common to all variables and the Bartlett’s test of sphericity to check if the matrix is factorable. In addition, Confirmatory Factor Analysis (CFA) was performed to confirm the original model in three subscales.

Finally, evidence based on the relation to other variables was obtained, first verified by the correlation between Pt–Br–FS–IS and PedsQL™ FIM (convergent validity). Also, the discriminant validity was performed by dividing the sample into two groups: Group 1—caregivers of children with mild and moderate–severe dysphagia (i.e., oral feeding—or supplemented by alternative feeding) and Group 2—caregivers of children with profound dysphagia (i.e., only alternative feeding) and comparing the distribution of scores of Pt–Br–IS–FS.

Associations between the scores of the total and subscales of the Pt–Br–FS–IS were also made with sociodemographic clinical variables of patients and their caregivers.

Data Analysis

For the calculation of the sample size, the recommendation of 5 to 10 participants per item of the instrument to be translated was considered [30], making up the minimum number of 90 individuals.

Quantitative variables were described as mean and standard deviation or median and interquartile range, according to their distribution, and qualitative variables in absolute and relative frequencies.

Evidence Based on Internal Structure

To analyze internal consistency, Cronbach’s Alpha coefficient analysis was performed. Values above 0.70 are considered satisfactory [31] and for test–retest Intraclass Correlation Coefficient (ICC) value with 95% confidence intervals (two-way mixed-effects model) was used. An ICC value between 0.60 and 0.80 was considered good correlation and greater than 0.80 excellent correlation [32]. The Pt–Br–FS–IS was administered twice to 20 caregivers of the study, with a 15 days interval between applications. For the Exploratory Factor Analysis, the Promax rotation method of extraction was used and the following values were considered for the KMO: less than 0.5 unacceptable; between 0.5 and 0.7 mediocre; between 0.7 and 0.8 good; and greater than 0.8 and 0.9, great and excellent, respectively, and for

the Bartlett’s test the significance level $p < 0.05$ to indicate that the matrix is factorable [33]. In the Confirmatory Factor Analysis, the adjustment indices considered were as follows: RMSEA (*Root Mean Square Error of Approximation*), whose values must be less than 0.08 with a 90% confidence interval (less than 0.10), CFI (*Comparative Fit Index*), and TLI (*Tucker–Lewis Index*), where both values must be greater than 0.90, in addition to the ratio between chi-square (χ^2) and degrees of freedom (df), whose values must be between 1 and 3 [30, 34].

Evidence Based on the Relation to Other Variables

The convergent validity has been verified by Spearman’s correlation coefficient between the Pt–Br–FS–IS and PedsQL™ FIM being considered the following values: < 0.30 —weak correlation, between 0.30 and 0.70—moderate correlation, and > 0.70 —strong correlation [35]. The discriminant validity was verified by comparing the two groups using the Mann–Whitney U test. To assess differences between the patient’s sociodemographic and clinical characteristics, we used the Kruskal–Wallis or Mann–Whitney U tests. The results for all analysis were considered statistically significant when $p < 0.05$. Statistical analysis was performed using the *Statistical Package for the Social Sciences* (SPSS) version 22.0. Confirmatory Factor Analysis was performed using the SPSS AMOS version 18.

Results

Evidence Based on Test Content and Response Processes

The translation process obtained idiomatic, semantic, experimental, and conceptual equivalences to the original version of FS–IS, which provided the evidence based on test content. The version translated into Brazilian Portuguese did not present any difficulties in understanding by the caregivers who participated in the pre-test, and did not change, obtaining evidence based on response processes. The version of the Feeding/Swallowing Impact Survey for Brazilian Portuguese (Pt–Br–FS–IS) is shown in Table 2.

Participants

Ninety-five caregivers and patients with feeding/swallowing disorders were included (30 participants from the pilot study). Of the total caregivers, 89 (93.7%) were mothers, 4 (4.2%) were fathers, and 2 (2.1%) were other family members (maternal grandmother and aunt). The characteristics of the caregivers and patients are shown in Table 3.

Table 2 Feeding/Swallowing Impact Survey Brazilian Portuguese version (Pesquisa de Impacto da Alimentação/Deglutição - Pt-Br-FS-IS)

	Nunca	Quase Nunca	Metade do Tempo	Muito Fre-quente	Quase Sempre
No ÚLTIMO mês, com relação aos problemas de alimentação/deglutição de seu(sua) filho(a), com que frequência você teve problemas para realizar suas atividades diárias?					
É difícil para mim, fazer meu trabalho, ir à escola/ faculdade ou trabalhar em casa	1	2	3	4	5
É difícil para mim, conseguir ajuda dos outros porque eles têm medo de alimentar ou de cuidar do(a) meu(minha) filho(a)	1	2	3	4	5
É difícil para mim, deixar meu(minha) filho(a) porque eu tenho medo de que outras pessoas alimentem ou cuidem dele(a)	1	2	3	4	5
É difícil para a minha família fazer planos ou sair para comer	1	2	3	4	5
Estou muito cansado(a) para fazer as coisas que quero ou preciso fazer	1	2	3	4	5
No ÚLTIMO mês, com relação aos problemas de alimentação/deglutição de seu(sua) filho(a), com que frequência você teve problemas se preocupando?					
Eu me preocupo com a saúde geral do(a) meu(minha) filho(a)	1	2	3	4	5
Eu me preocupo que meu(minha) filho(a) não coma ou beba o suficiente	1	2	3	4	5
Eu me preocupo com a forma que os outros irão reagir aos problemas de alimentação/deglutição do(a) meu(minha) filho(a)	1	2	3	4	5
Eu me preocupo com como o(a) meu(minha) filho(a) respira quando se alimenta e se ele(a) vai se engasgar	1	2	3	4	5
Eu me preocupo que meu(minha) filho(a) nunca vá comer ou beber como as outras crianças	1	2	3	4	5
Eu me preocupo se estou fazendo o suficiente para ajudar nos problemas de alimentação/deglutição do(a) meu(minha) filho(a)	1	2	3	4	5
Eu me preocupo sobre quanto os problemas de alimentação/deglutição do(a) meu(minha) filho(a) afetam outros na minha família	1	2	3	4	5
No ÚLTIMO mês, com relação aos problemas de alimentação/deglutição de seu(sua) filho(a), com que frequência você teve problemas para alimentá-lo(a)?					
É difícil alimentar meu(minha) filho(a) porque demora muito tempo para preparar líquidos e alimentos do jeito correto	1	2	3	4	5
É difícil alimentar meu(minha) filho(a) porque eu não sei como preparar líquidos e alimentos	1	2	3	4	5
É difícil alimentar meu(minha) filho(a) porque outras pessoas dão líquidos e alimentos que não são permitidos	1	2	3	4	5
É difícil alimentar meu(minha) filho(a) porque eu não sei quanto tempo esses problemas vão durar	1	2	3	4	5
É difícil alimentar meu(minha) filho(a) porque membros da família ou profissionais têm opiniões diferentes sobre como cuidar dos problemas de alimentação/ deglutição dele(a)	1	2	3	4	5
É difícil alimentar meu(minha) filho(a) porque eu não recebo informações suficientes sobre como fazê-lo(a) comer e beber como as outras crianças	1	2	3	4	5

The medians and interquartile ranges of the Pt-Br-FS-IS scores presented by the caregivers of patients from the outpatient clinic and hospitalization (Table 3) were associated with the dysphagia classification. A significant association was found in the subscale Feeding Difficulties among caregivers of patients with moderate-severe dysphagia from the outpatient clinic ($p = 0.008$).

Comparisons were made between Pt-Br-FS-IS scores and sociodemographic and clinical variables (Table 4). Statistically significant inverse correlation was found, from weak to moderate, with years of study and family income in the Total

Score and subscales of the Pt-Br-FS-IS. There were a weak positive correlations between the number of hospitalizations of the patient in the Daily Activities subscale and the Total Score, and between the time of difficulty with food/liquids in the Feeding Difficulty subscale and Total Score. There was no significant difference in relation to the other variables.

Table 3 Sociodemographic characteristics and Pt–Br–FS–IS scores of caregivers and sociodemographic and clinical characteristics of patients

Caregivers	Total	Daily activities Median [IQQ ^b]	Worry Median [IQQ ^b]	Feeding difficulties Median [IQQ ^b]	Total score Median [IQQ ^b]
Gender, female, <i>n</i> (%)	91 (95.8)				
Age (years), mean (SD ^a)	31.99 (8.11)				
Settings, <i>n</i> (%)					
Outpatient Clinic	45 (47.4)	4.0 [2.7–4.4]	3.86 [3.6–4.6]	2 [1.3–2.9]	3.3 [2.8–4]
Hospitalization	50 (52.6)	3.3 [2.6–4.2]	3.71 [3.1–4.3]	1.6 [1.1–2.3]	3 [2.4–3.5]
		PDEP: Classification of Pediatric Dysphagia ^c			
Patients	Total	Mild	Moderate–Severe	Profound	
Gender, <i>n</i> (%)					
Male	62 (65.3)	6 (9.7)	26 (41.9)	30 (48.4)	
Female	33 (34.7)	3 (9.1)	14 (42.4)	16 (48.5)	
Age (months), median [IQQ ^b]	30 [11–76]	60 [25–150.5]	53.5 [18.3–81.8]	15 [6–43.3]	
Race/Ethnicity, <i>n</i> (%)					
Whites	73 (76.8)	7 (9.6)	29 (39.7)	37 (50.7)	
Non-whites	22 (23.2)	2 (9.1)	11 (50.5)	9 (40.9)	
Main Diagnosis, <i>n</i> (%)					
Neurological disorders	34 (35.8)	2 (5.9)	12 (35.3)	20 (58.8)	
Genetic syndromes	25 (26.3)	2 (8)	13 (52)	10 (40)	
Others	36 (37.9)	5 (13.9)	15 (41.7)	16 (44.4)	
Settings, <i>n</i> (%)					
Outpatient clinic	45 (47.4)	8 (17.8)	23 (51.1)	14 (31.1)	
Hospitalization	50 (52.6)	1 (2)	16 (32)	33 (66)	

^aStandard deviation^bInterquartile range^cAccording to the PDEP Protocol (Flabiano-Almeida et al. 2014)

Evidence Based on Internal Structure

Reliability (Internal Consistency and Test–Retest)

The Pt–Br–FS–IS obtained a Cronbach's alpha value of 0.83 in the Total Score, showing satisfactory internal consistency in the subscales Daily Activities, Worry, and Feeding Difficulties, the alpha values were, respectively, 0.67, 0.61, and 0.79. None of the Cronbach's alpha values of the subscales increased if any item of the instrument was excluded (data are not shown), confirming the instrument in 18 items. The ICC values for the subscales of Pt–Br–FS–IS were 0.95, 0.89 and 0.87 and 0.91 for total score.

Exploratory and Confirmatory Factor Analysis

The Exploratory Factor Analysis (KMO = 0.74 and Bartlett's sphericity test $p < 0.001$) confirmed the adequacy of the data, demonstrating that the Brazilian Portuguese version is not unifactorial. The results of Confirmatory Factor Analysis showed satisfactory fit in the Brazilian version,

suggesting the plausibility of the original model proposed (Table 5). The graphical expression of the path diagram (Fig. 1) allowed to visualize the factorial loads as well as covariance between the factors and the variances of the items.

Evidence Based on the Relation to Other Variables

Convergent Validity

A significant correlation was observed between Pt–Br–IS–FS with the PedsQL™ FIM in the reverse direction, as expected, both in the total score, and in subscales, with values ranging from –0.23 to –0.58 (Table 6).

Discriminant Validity

A significant difference was found in the Total Score and in the Feeding Difficulties subscale, between the group of caregivers of children with mild and moderate–severe dysphagia and the group with profound dysphagia (Table 7).

Table 4 Sociodemographic variables of caregivers and clinical variables of patients and correlation with the Feeding/Swallowing Impact Survey Brazilian Portuguese version (Pt-Br-FS-IS)

	Total	Daily activities	Worry	Feeding difficulties	Total score
Sociodemographic variables of caregivers¹					
Years of study, mean (SD) ^a	9.48 (2.83)	-0.236*	-0.282**	-0.445**	-0.397**
Formal work, <i>n</i> (%)	75 (78.9)				
No					
Family income, median [IQQ] ^b	R\$ 1500.00 [0.0-1500]	-0.290**		-0.409**	-0.356**
Clinical variables of patients¹					
Number of Clinical Complications, mean (SD) ^a	3.62 (1.63)				
Number of hospitalizations, median [IQQ] ^b	4 [2-9]	0.206*			0.247*
Time of difficulty with food/ liquids, in months, median [IQQ] ^b	22 [5-54]			0.209*	0.205*
Signs of feeding/swallowing disorder, median [IQQ] ^b	4 [3-6]	0.230*			0.258*

¹Correlation of Spearman^aStandard deviation^bInterquartile range**p* < 0.05****p* < 0.01

Table 5 Confirmatory factor analysis results of the Brazilian version of the Feeding/Swallowing Impact Survey (Pt-Br-FS-IS)

Measure	Results
χ^2 /Degrees of freedom	1.23
Root mean square error of approximation (RMSEA)	0.049
90% CI	0.011–0.073
Comparative Fit Index (CFI)	0.92
Tucker–Lewis Index (TLI)	0.90

Discussion

The present study translated and cross-culturally adapted the Feeding/Swallowing Impact Survey (FS-IS) to the Brazilian Portuguese language, following all the steps proposed by the guidelines prepared by Beaton and collaborators [23]. The final version of the process proved to be adequate and easy to understand, providing evidence of validity based on test content and based on response processes. In addition, the analysis of internal consistency, as well as the exploratory and confirmatory factor analyses were satisfactory. This analysis verify that the instrument has convergent and discriminant validity, providing validity evidence based on internal structure, and based on relation to other variables. In addition to the reliability of the instrument in caregivers of children with feeding/swallowing disorders. These findings allowed to develop the first valid instrument able to measure the impact on the quality of life of this population in Brazil.

Our internal consistency analysis for total instrument score was satisfactory and comparable to findings for the FS-IS (Cronbach's alpha values 0.83, 0.89, respectively). Our findings for the subscales (Daily Activities, Worry, and Feeding Difficulties) were lower than those reported for the FS-IS [18], which may be explained by differences in demographic characteristics of caregivers and children. Differences in Cronbach's alpha values are known to vary according to the sample [29, 31]. Additionally, Cronbach's alpha value is influenced by the number of items evaluated and, therefore, factors with few items tend to have lower alpha values [29, 31, 33]. The test–retest analysis of reliability was excellent in all subscales and total score.

Assessment of the factorial structure of an instrument is an essential step in the process of validating an adapted instrument because it is needed to confirm the underlying theoretical basis of the instrument [36, 37]. Therefore, the Exploratory Factor Analysis was performed to confirm that the instrument adapted for Brazil had the same subscale structure as the FSIS. This analysis demonstrated that the Brazilian Portuguese version of FS-IS is not explained by a single factor. Hence, the Confirmatory Factor Analysis was continued, and showed satisfactory adjustment rates,

confirming the acceptability of the original model proposed in three factors [33, 34].

Convergent construct validity was investigated to assess the correlation between the Pt-Br-FS-IS and PedQL™ FIM, which has a similar construct. There was an inverse correlation with significant results observed in almost all subscales except for Daily Activities versus Worry and Worry versus Family Relationships. The inverse correlation was consistent with our expectations because *higher* Pt-Br-FS-IS scores and *lower* PedsQL™ FIM scores represent worse QOL. Most of the correlations found were moderate, as well as in the original version of the instrument, which also used PedsQL™ FIM for this validity [18]. It was also found that the correlations were higher with the PedsQL™ FIM Parental score than with the Family Score, possibly because this score reflects more the individual daily impact on the primary caregiver, as well as the Pt-Br-FS-IS. These data corroborate a study by Mishra et al. (2015), who investigated the QoL of parents of children with nephrotic syndrome and also found a greater impact on the Parental Score of the PedsQL™ FIM in relation to the Family Score [38]. Studies have shown that the caregiver can be strongly influenced by the demand for care, which, combined with the increase in concerns and responsibilities, can generate burden, isolation and stress, changing the daily life of caregiver [16, 17]. Murphy et al. (2007) reported that families of children with disabilities experienced stress in caregiving, a negative impact on caregiver health, the need to share the burden of care with others, concerns about the future, and the value of caregiver coping strategies [39, 40].

For discriminant validity the sample was divided into two groups: Group 1—caregivers of children with mild and moderate–severe dysphagia (i.e., oral feeding—supplemented by alternative feeding) and Group 2—caregivers of children with profound dysphagia (i.e., only alternative feeding). The Pt-Br-FS-IS was able to discriminate between the caregivers of children with and without oral feeding, with groups in Total Score and Feeding Difficulties subscale. The group with oral feeding (group 1) had higher scores, indicating worse QOL, than the group that does not orally feed (group 2), which corroborates studies that demonstrate the difficulties of caregivers in relation to the mealtime (as preparation and offer of adapted food and liquids, the increase on time of eating and pressure of providing enough food) [41–45]. These findings are similar to those reported for the translation of the FS-IS into the Turkish language [19], which found higher scores in the group of children who aspirated than in the group of those who did not, suggesting that the greatest impact on QOL was represented by the group with the greatest difficulties in swallowing. We found a significant association between the classification of moderate–severe dysphagia with the subscale Feeding Difficulty in Pt-Br-FS-IS for patients in the

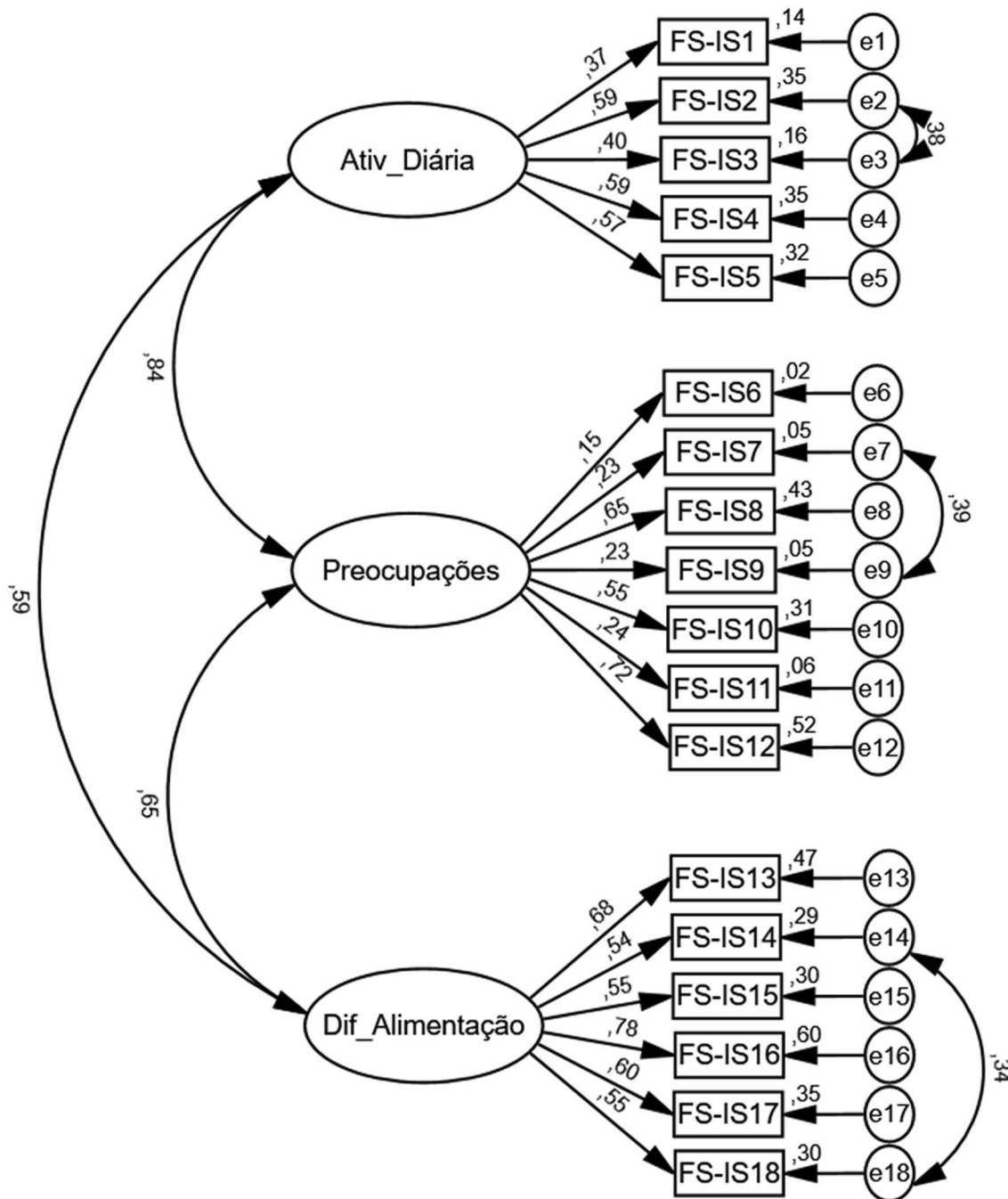


Fig. 1 Path diagram of the confirmatory analysis results concerning the adapted version of Feeding/Swallowing Impact Survey (Pt-Br-FS-IS)

outpatient clinic. Patients with moderate–severe dysphagia typically require close monitoring and management for their oral intake. Given that our outpatient clinic serves patients from distant locations, from hospital reaches 281.000 square km), it is difficult to provide frequent follow-up and monitor the subsequent impact on caregivers. [46]. There was a significant inverse relationship between Pt-Br-FS-IS scores with education and family income, which is comparable to

other studies, reporting a greater impact on quality of life when caregivers had less education and among families with lower incomes. [47, 48]. Regarding the lower impact on the QOL for caregivers of children classified as having profound dysphagia, it is possible the use of gastrostomy may have improved nutritional status and facilitated the administration of medications and food and improved the caregivers' perception of the child's health status [49, 50].

Table 6 Correlation between the scores of the Pt-Br-FS-IS and PedsQL™ FIM (Convergent Validity) scores of caregivers of patients with feeding/swallowing disorders

	Pt-Br-FS-IS			
	Daily activities	Worry	Feeding difficulties	Total
PedsQL™ FIM total	-0.48**	-0.40**	-0.52**	-0.58**
Physical capacity	-0.39**	-0.36**	-0.44**	-0.49**
Emotional aspect	-0.38**	-0.38**	-0.43**	-0.49**
Social aspect	-0.40**	-0.26*	-0.42**	-0.46**
Mental ability	-0.31**	-0.28**	-0.28**	-0.36**
Caregiver score	-0.47**	-0.40**	-0.50**	-0.57**
Communication	-0.46**	-0.36**	-0.51**	-0.56**
Worry	-0.16	-0.37**	-0.23*	-0.35**
Daily activities	-0.32**	-0.27**	-0.38**	-0.41**
Family relationships	-0.24*	-0.17	-0.31**	-0.27**
Family score	-0.29**	-0.23*	-0.37**	-0.36**

Spearman Correlation *r* values**p* < 0.005***p* < 0.001**Table 7** Association of Pt-Br-FS-IS scores of caregivers of children with and without oral feeding (Discriminant validity) at a tertiary hospital in southern Brazil

	Average Total (SD)	GROUP 1 Mean (SD)	GROUP 2 Mean (SD)	<i>p</i> -value*
Pt-Br-FS-IS	n = 95	n = 49	n = 46	
Daily activities	3.41 (1.1)	3.56 (1.1)	3.28 (1.0)	0.196
Worry	3.82 (0.8)	3.89 (0.7)	3.77 (0.8)	0.410
Feeding difficulties	2.05 (1.0)	2.33 (1.0)	1.79 (0.8)	0.007*
Total	3.12 (0.7)	3.28 (0.7)	2.97 (0.7)	0.043*

Group 1 = Mild and Moderate-severe dysphagia

Group 2 = Profound dysphagia

**p* < 0.05 (*p*-value for the Mann-Whitney *U* test)

We found greater impact on the QOL of caregivers, evidenced by the subscales and total Pt-Br-FS-IS scores, than reported in the original article and some FS-IS validation studies that studied children with specific conditions [19, 24]. Differences in the ages of the children and the timing of the administration of the survey may account for these discrepancies in findings. Our study focused on caregivers of older children (median 30 months), while the original study reported primarily on younger children (median age of 14 months) [18]. In the current investigation, we included patients at the time of their first evaluations and during follow-up. Whereas the original study was limited to the first outpatient consultation. Interestingly, the correlation between the variable time of difficulty with food/liquids and the Total Pt-Br-FS-IS Score and the Feeding Difficulty subscale, showed that the longer the duration of the difficulty, the greater the impact in the caregiver's quality of life.

We recognize that the lack of instrumentals assessment of swallowing is a limitation of this study. Unfortunately, many patients do not have access to these assessment modalities and rely upon clinical diagnosis and management. Nonetheless, Pt-Br-FS-IS fills a significant gap, by being the first

instrument in Brazil capable of assessing the impact on the QOL of the caregivers of children with feeding and swallowing problems. To achieve this goal, we used well-established and validated methodologies in the process of translation and cultural adaptation, and current methodologies of modern psychometry, seeking to innovate research in this area [29, 36]. Understanding the unique challenges experienced by these caregivers of children with feeding/swallowing disorders is critical to the attainment of optimal outcomes.

Conclusion

This study translated and culturally adapted the FS-IS instrument to Brazilian Portuguese, applied it to a sample of caregivers of children with feeding/swallowing disorders, both in and outpatient settings. This investigation demonstrates that the Pt-Br-FS-IS is a reliable and valid instrument for measuring the impact of feeding/swallowing disorders on the QOL of caregivers. Future clinical research will focus on using the Pt-Br-FS-IS to help caregivers/

family members to adapt to challenges of caring for children with these problems.

Declarations

Conflict of interest The authors have no conflicts of interest to disclose.

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