


RESEARCH REPORT

Cross-cultural adaptation and validation of the Italian version of the Montreal Children's Hospital Feeding Scale in a special healthcare needs population

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Abstract

Background: The Montreal Children's Hospital Feeding Scale (MCH-FS) allows paediatricians and other health care professionals to identify feeding difficulties among children.

Aim: To translate and adapt the MCH-FS into Italian, and to evaluate the validity and reliability of this Italian version of the Montreal Children's Hospital Feeding Scale (I-MCH-FS).

Methods & Procedures: A total of 150 children with special healthcare needs were admitted to the Rare Disease Unit of the Paediatrics Department at the Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy, between March 2021 and March 2022 (74 males; mean age = 3.85 ± 1.96 years; median age = 4 years; age range = 6 months–6 years and 11 months) and 150 healthy participants (83 males; mean age = 3.5 ± 1.98 years; median age = 3 years; age range = 6 months–6 years and 11 months) were included in the study, which was approved by the local ethics committee. The original version of the MCH-FS was translated and cross-cultural adapted through five stages: (1) initial translation, (2) synthesis of the translations, (3) back translation, (4) expert committee and (5) test of the prefinal version. Test–retest reliability and internal consistency were assessed using Pearson *r*, Spearman *r* and Cronbach's alpha, respectively. Construct validity was established by comparing data obtained from patients with those of healthy participants using the Mann–Whitney *U*-test.

Outcomes & Results: A Pearson *r* of 0.98, a Spearman *r* of 0.95 and Cronbach's alpha value of 0.86 were obtained. In the clinical group, 40.6% children were classified as having feeding disorders ($n = 61$), while in the normative group 4.7%

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were diagnosed with feeding problems ($n = 7$). Mean total score of the clinical group was significantly different from the normative's.

Conclusions & Implications: The I-MCH-FS is a valid and reliable one-page, quick screening tool used to identify feeding disorders among children with special needs in outpatient paediatric setting.

KEYWORDS

disability, feeding disorders, personalized medicine, rare genetic syndromes, scale, validation

WHAT THIS PAPER ADDS

What is already known on the subject

The MCH-FS is a valid and reliable parent-report measure aimed at discriminating between children presenting or not feeding disorders.

What this paper adds to existing knowledge

This paper presents the translation and cross-cultural adaptation of the scale into the Italian language.

What are the potential or actual clinical implications of this work?

The Italian version of the MCH-FS can be used in the special healthcare needs population.

INTRODUCTION

Paediatric feeding disorders (PFDs) encompass a wide range of activities observable during a child's meal. In 2019, Goday et al. published a consensus definition of PFDs, which was defined as 'impaired oral intake that is not age-appropriate and is associated with medical, nutritional, feeding skill and/or psychosocial dysfunction' (Goday et al., 2019 p. 125). Children with regular neurodevelopment and growth rarely face serious feeding disorders resulting in nutritional deficiencies (Borowitz & Borowitz, 2018), and, if present, they commonly resolve with time (Field et al., 2003; Kerzner et al., 2015; Manikam & Perman, 2000; Rommel et al., 2003; Rybak, 2015). Contrarily, in children with a recognized medical aetiology, the rate of feeding disorders is higher (40–70%) (Sharp et al., 2017), the disorders are more severe (Borowitz & Borowitz, 2018), and might be associated with swallowing difficulties and oral motor dysfunction (Conforti et al., 2015). Feeding disorders are multidimensional in nature. The evaluation approach must include the investigation of health conditions and personal and environmental factors (Goday et al., 2019).

Since this topic is drawing increasing research and clinical attention (Sanchez et al., 2015), multiple proxy-reported outcomes (PxROs) have been designed in the last decades, but only a few have tested psychometric properties.

The Montreal Children's Hospital Feeding Scale (MCH-FS) was intended as a parent-reported screening tool to identify PFDs in orally fed children from 6 months to 6 years and 11 months of age (Ramsay et al., 2011). It has shown good psychometric qualities with good sensitivity and specificity. Its 14 items were generated according to the biopsychosocial model of feeding disorders (Ramsay et al., 2011) and cover seven feeding domains: oral motor, oral sensory, appetite, maternal concerns about feeding, mealtime behaviours, maternal strategies used and family reactions to their child's feeding. Each answer is scored on a seven-point Likert scale. On the scoring page, the total raw score, as per the original scale, is converted into the *T*-score, which allows discrimination between mild, moderate or severe feeding disorders.

The MCH-FS was initially validated in Canada in English and French (Ramsay et al., 2011). So far it has already been validated in other languages—e.g., Brazilian Portuguese (Diniz et al., 2021), Polish (Bąbik et al., 2019) and Thai (Benjasuwantep et al., 2015)—but still need to be validated for the Italian-speaking population.

Therefore, the purpose of the present study was to translate and culturally adapt the MCH-FS into Italian by including a population composed of children with special healthcare needs, and to examine its internal consistency, reliability and construct validity.

POPULATION AND METHODS

Participants

The study was carried out in compliance with the principles of the Declaration of Helsinki and was approved by the local ethics committee as part of a larger protocol evaluating disability and nutritional aspects in patients with rare diseases.

All patients between 6 months and 83 months of age who were consecutively admitted to the Rare Disease Unit of the Paediatrics Department at the Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy, between March 2021 and March 2022 were deemed eligible for inclusion in the study as components of the clinical group. Exclusion criteria were the absence of proficiency in the Italian language by the primary caregivers (defined as the parent 'most responsible' for the child's feeding activities) and the presence of total artificial enteral nutrition for the child, in line with the original study criteria by Ramsay et al. (2011). Children with total enteral nutrition were excluded to ensure that all seven domains of the scale were assessable, including appetite, whose regulation is affected in G-tube-fed children.

For the normative group, healthy siblings (aged between 6 and 83 months) of enrolled patients whose parents agreed to participate in the study were included. Children with no medical history were also recruited through authors' networking after obtaining their caregiver's informed written consent.

The demographic characteristics of all children (age, sex, clinical diagnosis) were assessed and recorded to make data generalizable and comparable with those from previously reported cohorts (Bąbik et al., 2019; Benjasuwantep et al., 2015; Diniz et al., 2021; Ramsay et al., 2011). All included participants were categorized into two main age groups (6–24 and 25–83 months) for further exploratory analysis.

MCH-FS translation process

The cross-cultural adaptation process of the MCH-FS was carried out in adherence to the Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures described by Beaton et al. (2000).

The process consisted of five different stages: initial translation (stage 1); synthesis of the translations (stage 2); back translation (stage 3); expert committee (stage 4); and test of the prefinal version (stage 5):

Stage 1: Initial translation. After obtaining permission from the original author of the scale (Dr M. Ramsay) via

e-mail, the MCH-FS was first translated from English into Italian by a bilingual speech–language pathologist experienced in feeding disorders and a bilingual naïve translator with no medical or clinical background. The two translators produced two independent versions accompanied by a written report. At this stage, cultural translation was preferred over literal one.

Stage 2: Synthesis of the translations. Starting from the two translated copies, the authors synthesized a common questionnaire after the resolution of any disagreements. Slang or dialect terms or complex unfamiliar terminology were avoided.

Stage 3: Back translation. The resulting Italian version of the questionnaire was later given to two native English translators unaware of the original version, who translated the scale back into the original language. Therefore, they ensured a consistent translation between the Italian version and the original source version.

Stage 4: Expert committee. Subsequently, the translators involved in the forward and back translations and the developer of the original English version, along with a multidisciplinary panel composed of paediatricians, met to evaluate the content validation of the pre-final Italian version of the MCH-FS (I-MCH-FS). Finally, the readability of the I-MCH-FS was checked among hospital workers with at least secondary education.

Stage 5: Test of the prefinal version. A total of 30 caregivers of children (15 male; mean age = 4.15 years; age range = 1–6 years) admitted to the Rare Disease Unit of the Paediatrics Department were enrolled in the pilot study for the pretesting stage of I-MCH-FS. Each caregiver completed the questionnaire and the interpretation of terms was analysed for possible suggestions with the speech–language pathologist. Specifically, the clinician interviewed the caregivers to explore what they thought was meant by each questionnaire item. Responders were asked to rephrase the scale in order to verify their understanding. Subsequently, minor changes were made, and the final version was used for validation.

The Italian version of the MCH-FS was also tested for internal consistency and reliability analysis. Normative data were generated, and validity analysis was performed following the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist (Mokkink et al., 2019).

Internal consistency and test–retest reliability analyses of the I-MCH-FS

Missing scores were handled with a single imputation method, precisely item median substitution (Jadhav

et al., 2019). Cronbach's α was calculated to measure the internal consistency of the I-MCH-FS administered in the clinical group. A positive rating was attributed to the correlation between items of the scale if $\alpha > 0.7$ (Terwee et al., 2007).

Pearson r and Spearman r were calculated to measure test-retest reliability. In this case, the same participants were asked to fill the I-MCH-FS twice, with the same type of administration (in presence), 2 weeks apart, expecting the children to remain stable during this interval, that clinical changes would not occur and recall of previous answers could be prevented. The stability over time of the scale was considered acceptable with a Pearson r and Spearman r of at least 0.7 (Terwee et al., 2007).

Construct validity

For construct validity analysis, the I-MCH-FS scores previously obtained by the clinical group were compared with the ones obtained by the normative group, considering the background hypothesis that the I-MCH-FS mean total score of the clinical group would have been higher than the one of the normative samples. Each of the 14 items' scores were compared among the normative and clinical samples using the Mann-Whitney test, two-tailed, with a significance level of 0.05 ($p = 0.05$), as the normality test using the Anderson-Darling test revealed no normal distribution between samples. Cohen d for the t -test was used to calculate the effect size and it was determined by calculating the mean difference between the two groups divided by the pooled standard deviation (SD).

Data analysis was performed using GraphPad Prism version 9.1.2.

RESULTS

Translation of the questionnaire advanced without significant difficulties. During the third stage, no gross inconsistencies and conceptual errors with the original version were highlighted.

During the fourth stage, the professionals discussed and evaluated each item from their viewpoints. The wording of Italian questions was considered not to influence the participants' responses, but relevant and applicable in the Italian linguistic context. The panel deemed questions as comprehensible and easily interpretable. Moreover, incongruent terms and conceptual equivalents were verified, and the expert committee decided to translate the term 'to gag' into Italian as 'avere conati di vomito' rather than 'soffocare'. All the included hospital workers responders had a minimum of lower secondary school education level

and considered the I-MCH-FS items straightforward to understand.

Internal consistency and test-retest reliability of the I-MCH-FS

Demographic and clinical data were obtained from 150 patients (74 males; mean age = 3.85 years, SD = ± 1.96 ; median age = 4 years; age range = 6 months–6 years and 11 months), different from the ones included in the pre-testing stage. All patients were diagnosed with rare congenital syndromes, including Noonan syndrome ($n = 9$), Smith-Magenis syndrome ($n = 8$), CHARGE syndrome ($n = 5$), VACTERL association ($n = 3$), cardiofaciocutaneous syndrome ($n = 2$) and other disabilities (e.g., 17 children with positive genetics for trisomy 21) reported in Tables 1 and 3.

Among the most represented conditions in our population, Pallister Killian syndrome obtained the higher mean score (68.7) on the scale (Table 2). Additionally, feeding disorders were observed in one-third of patients with a diagnosis of RASopathy ($n = 14$) with a high prevalence of food refusal and gag episodes with certain types of food.

Three responders missed one answer each of items 4, 3 and 6, respectively, handled through the item median substitution method. The study results showed that Cronbach's α was 0.86, displaying high coherence in internal consistency.

Test-retest reliability was calculated in 50 children (32 participants from the clinical group and 18 from the normative group). The scale showed adequate stability over time, with a Pearson r of 0.98 at $p 0.001$ (two-tailed) and a Spearman r of 0.95 at $p 0.001$ (two-tailed) for the recruited participants ($n = 50$).

All the participants completed the questionnaire in less than 10 min.

Construct validity

Demographic details of the normative group were obtained from all 150 healthy participants (83 males; mean age = 3.5 years, SD = ± 1.98 ; median age = 3 years; age range = 6 months–6 years and 11 months) (Table 3). Most of them were recruited through the author's networking, as just a minority of included patients had siblings. This limited the potential influence of confounding environmental factors shared by siblings. The mean total score of I-MCH-FS scores was 42.76 ± 7.86 (single-item means in Table 4); among the two age groups 6–24 months ($n = 51$) and 25–83 months ($n = 99$) mean of the total score were 41.6 ± 6.4 and 43.3 ± 8 , respectively (Table 5).

TABLE 1 Diagnoses from the clinical sample ($n = 150$)

		<i>n</i>
Genetic disease	RASopathies	14
	Smith–Magenis s.	8
	CHARGE s.	5
	ASD associated s.	5
	PRS associated s.	2
	Rubinstein Taybi s.	1
	Wolf–Hirschhorn s.	1
	Joubert s.	1
	Meckel s.	1
	Under definition	40
Chromosomal disorder	Others	40
	Trisomy 21 (Down s.)	17
	Tetrasomy 12p (Pallister–Killian s.)	3
	Trisomy 8	1
Others	Others	2
	Preterm	5
	Cerebral palsy	4

Note: ASD, autism spectrum disorder; PRS, Pierre Robin sequence; s, syndrome.

TABLE 2 Mean scores and prevalence of score above the cut-off in the most represented conditions of the population

Conditions	Mean \pm SD	Prevalence (%)
Trisomy 21 (Down s.)	50.1 \pm 8.9	3/17 (18%)
RASopathies	54.8 \pm 15.6	5/14 (36%)
Smith–Magenis s.	52.8 \pm 8.5	1/8 (12.5%)
CHARGE s.	55.0 \pm 10.1	2/5 (40%)
ASD associated s.	48.0 \pm 13.7	3/5 (60%)
Preterm	61.8 \pm 14.3	2/5 (40%)
Cerebral palsy	61.3 \pm 8.1	2/4 (50%)
Tetrasomy 12p (Pallister–Killian s.)	68.7 \pm 17.5	2/3 (67%)

Note: ASD, autism spectrum disorder; PRS, Pierre Robin sequence; s, syndrome; SD, standard deviation.

There were significant differences ($p < 0.0001$) between the means of the total equivalent score of the clinical sample and the normative sample (55.56 ± 14.18 and 42.76 ± 7.86 , respectively).

Children in the control group obtained significantly lower mean scores ($p < 0.01$) compared with the clinical medical group (Table 3), with a large-to-medium effect size for most of the items.

A higher frequency of children considered as having difficulties was found within the clinical medical group (40.6%) (Table 6).

DISCUSSION

In the present study we translated and adapted into Italian the MCH-FS, a parent-report screening tool to detect feeding disorders in children from 6 months to 6 years and 11 months of age (Ramsay et al., 2011).

The original source, developed for French and English speakers, had previously been translated into Brazilian Portuguese (Diniz et al., 2021) following the International Test Commission (ITC) Guidelines for Translating and Adapting Tests, into Polish (Bąbik et al., 2019) following the Sousa et al. guideline (Sforza et al., 2022) and into Thai (Benjasuwantep et al., 2015) though translation guidelines were not referenced.

In this study we followed the translation and cross-cultural adaptation guideline by Beaton et al. (2000) translating into Italian the MCH-FS and adapting it within the Italian cultural context. Our Paediatric Department benefits from a large catchment area with families arriving from all over the country. Therefore, as the target population was composed of caregivers with a wide variability of both demographics and cultural backgrounds, we emphasized reaching an adequate level of readability of the questionnaire. Moreover, as suggested by Beaton et al., to maintain the content validity of the questionnaire, we put our utmost effort into attaining semantic and conceptual equivalence between the original and the Italian version.

As for psychometric measures, the I-MCH-FS shows an adequate internal consistency (Cronbach's $\alpha = 0.86$), in

**TABLE 3** Demographic information of clinical ($n = 150$) and normative ($n = 150$) participants and their caregivers

		N (%)	
		Clinical	Normative
Participant gender	Female	76 (50.7)	112 (74.7)
	Male	74 (49.3)	38 (25.3)
Participant age	Mean	3.85 ± 1.96 years	3.5 ± 1.98 years
	Median	4 years	3 years
	Range	6–83 months	6–83 months
	6–24 months	39 (26)	51 (34)
	25–83 months	111 (74)	99 (66)
Ethnic origin	European	145 (96.7)	149 (99.3)
	African	1 (0.7)	0
	South American	2 (1.3)	0
	Asian	2 (1.3)	1 (0.7)
Participant's living situation	With family	149 (99.3)	150 (100)
	Assisted living facility	1 (0.7)	0
Caregiver completing study	Biological mother	130 (86.7)	120 (80)
	Biological father	16 (10.7)	29 (1.9)
	Adoptive mother	3 (2)	1 (18.1)
	Other family member	1 (0.6)	0

accordance with those reported in the original study and translated versions. Specifically, in the article by Ramsay et al., the correlations between the individual items and this one-component model ranged from 0.48 to 0.87 (Ramsay et al., 2011); Cronbach's alpha for internal consistency was 0.79 in the Brazilian-Portuguese version (Diniz et al., 2021), 0.83 in the Thai version (Benjasuwantep et al., 2015), reaching 0.93 in the Polish version (Bąbik et al., 2019).

Additionally, test-retest reliability analysis showed robust temporal stability (Pearson $r = 0.98$; Spearman $r = 0.95$) computed by measuring at two different times, similar to the original scale (normative Pearson $r = 0.845$; clinical Pearson $r = 0.92$) (Ramsay et al., 2011) and the translated versions (Pearson $r = 0.92$; $p < 0.001$ (Diniz et al., 2021); intraclass correlation coefficient (ICC) = 0.98 (Bąbik et al., 2019).

The mean scores of our normative population (43.1) are consistent with those previously reported by other studies, ranging from 43 (Bąbik et al., 2019) to 50 (Ramsay et al., 2011). The significant differences in the total score mean values between the control group and the case group demonstrate the efficiency of I-MCH-FS in differentiating children presenting with or without feeding disorders.

The cases obtained a significantly higher mean total score than controls, in accordance with Manikam's observation, namely that although feeding disorders may occur across the general paediatric population, their inci-

dence is higher in children with special healthcare needs (Manikam & Perman, 2000). Moreover, patients obtained a higher percentage of moderate-to-severe feeding disorders scores, confirming that feeding issues are generally not severe in otherwise healthy children with regular development and growth (Borowitz & Borowitz, 2018).

Higher scores indicating mild to severe disorders were found in 40% of our clinical population with different medical conditions, thus highlighting the greater extent of the issue in children with multiple disabilities.

The statistically significant difference between the two groups concerning all questions confirms the construct validity of I-MCH-FS.

In the comparison by age group (≤ 24 and > 24 months), mean scores were similar in both clinical and normative groups, in accordance with the findings of Ramsay et al. (2011). Results differ from the Brazilian (Diniz et al., 2021) study, where in the clinical medical cases older children had higher mean scores than younger ones, suggesting no decrease in feeding disorders with increasing age.

To date, there is neither a 'gold standard' nor a validated Italian instrument for criterion validity testing.

Results showed that I-MCH-FS is a reliable caregiver-administered questionnaire suitable for children diagnosed with a genetic disease or chromosomal disorders commonly presenting feeding disorders often associated

TABLE 4 Differences in I-MCH-FS-equivalent scores between clinical and control groups

Individual item	Clinical (<i>n</i> = 150)		Normative (<i>n</i> = 150)		<i>p</i> -value ^a	Cohen's <i>d</i>
	Mean ± SD	Median	Mean ± SD	Median		
1 How do you find mealtimes with your child?	3.37 ± 1.94	4	1.75 ± 1.18	1	< 0.0001	1.00
2 How worried are you about your child's eating?	3.71 ± 2.38	4	1.99 ± 1.62	1	< 0.0001	0.84
3 How much appetite (hunger) does your child have?	2.69 ± 2.11	1	1.69 ± 1.23	1	< 0.0001	0.57
4 When does your child start refusing to eat during mealtimes?	2.80 ± 2.41	1	1.67 ± 1.36	1	< 0.0001	0.57
5 How long do mealtimes take for your child (in minutes)?	3.34 ± 1.76	3	2.11 ± 1.00	2	< 0.0001	0.85
6 How does your child behave during mealtimes?	2.85 ± 2.07	2	2.21 ± 1.68	1	0.0059	0.33
7 Does your child gag or spit or vomit with certain types of food?	2.45 ± 2.23	1	1.45 ± 1.04	1	< 0.0001	0.57
8 Does your child hold food in his/her mouth without swallowing it?	2.40 ± 2.07	1	1.34 ± 0.98	1	< 0.0001	0.65
9 Do you have to follow your child around or use distractions (toys, TV) so that your child will eat?	3.67 ± 2.55	3	2.21 ± 1.80	1	< 0.0001	0.66
10 Do you have to force your child to eat or drink?	2.65 ± 2.10	1	1.74 ± 1.51	1	< 0.0001	0.50
11 How are your child's chewing (or sucking) abilities?	3.79 ± 2.43	4	1.54 ± 1.33	1	< 0.0001	1.14
12 How do you find your child's growth?	2.98 ± 2.33	1	1.37 ± 0.95	1	< 0.0001	0.90
13 How does your child's feeding influence your relationship with him/her?	1.85 ± 1.69	1	1.25 ± 0.67	1	0.0025	0.46
14 How does your child's feeding influence your family relationships?	1.75 ± 1.54	1	1.31 ± 0.78	1	0.0213	0.36
Total	55.56 ± 14.18	54	42.76 ± 7.86	40	< 0.0001	1.11

Notes: SD, standard deviation.

^aData were compared using the Mann-Whitney *U*-test.

TABLE 5 Comparison of total equivalent scores between clinical and normative groups stratified by age

Age (months)	Clinical		Normative		<i>p</i> -value
	<i>n</i>	Mean ± SD	<i>n</i>	Mean ± SD	
6–24	39	54.71 ± 15.81	51	42.03 ± 6.88	< 0.0001
25–83	111	55.23 ± 14.60	99	43.51 ± 8.45	< 0.0001

Note: SD, standard deviation.

with oral-motor dysfunctions (Ferrantini et al., 2022; Leoni et al., 2016; Sforza et al., 2022).

Thus, the questionnaire can be understood by the target audience being able to achieve the objectives described

in the original scale and has appropriate psychometric measures for identifying feeding disorders in Italian children from 6 months to 6 years and 11 months of age.

TABLE 6 Levels of feeding difficulties measured through the I-MCH-FS in the clinical and normative samples

Levels	Clinical ($n = 150$) n (%)	Normative sample ($n = 150$) n (%)
No difficulties	89 (59.3)	143 (95.3)
Mild difficulties	25 (16.6)	7 (4.7)
Moderate difficulties	11 (7.3)	0 (0)
Severe difficulties	25 (16.6)	0 (0)
	Total of children presenting difficulties^a	
	61 (40.6)	7 (4.7)

Note: ^aFrom mild to severe.

Limitations and strengths

Some limitations should also be noted. As to date there is neither a 'gold standard' nor a validated Italian instrument, criterion validity testing was not evaluable. However, Ramsay et al.'s (2011) data resemble those reported in larger scale studies (Archer et al., 1991; Crist & Napier-Phillips, 2001). Thus, in terms of construct validity, MCH-FS compares favourably with previously validated behavioural feeding scales. Moreover, although responsiveness analysis is an important parameter in determining the sensitivity to clinical changes in the questionnaire, we did not perform the responsiveness analysis of the scale. Another limitation is not having extensively included other populations at high risk of feeding disorders, for example, autism spectrum disorder. The major downside of our convenience normative sampling was selection bias. A strength of this study is the use of well-established methodologies in translation and cultural adaptation, with proper statistical methods.

Conclusions and Implications

Current evidence for PFDs recommends using an interdisciplinary team approach for conducting comprehensive assessments in consideration of the multidimensional nature of the problem. At the same time, physicians need assessment tools that guide objective and consistent evaluation, independently of who is completing it. The promising results obtained from cultural and psychometric testing of the Italian version of the MCH-FS enhance the applicability of this scale for clinical and research purposes. The original scale and the I-MCH-FS, along with scoring forms are available in Appendices 1 and 2 in the additional supporting information. The I-MCH-FS provides rapid, cost-free, reliable screening for detecting feeding disorders in children with special needs. The valuable clinical content of the questionnaire may direct paediatricians to clarifying symptoms, conducting periodic follow-ups, or even referring patients to dedicated multidisciplinary teams. Therefore, this tool

is intended to reduce the negative effects of distress brought by feeding disorders upon children and their families. Further studies are needed to test the measurement properties of I-MCH-FS across other paediatric populations.

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CONFLICTS OF INTEREST

The authors have no competing interests to declare that are relevant to the content of this article.

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DATA AVAILABILITY STATEMENT

The datasets generated during the current study are available from the corresponding author upon reasonable request.

INFORMED CONSENT STATEMENT

Written informed consent was obtained from all participants.

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SUPPORTING INFORMATION

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