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Expanded Protocol of Orofacial Myofunctional Evaluation with Scores for Nursing Infants (6-24 months) (OMES-E Infants)

Protocolo de Avaliação Miofuncional Orofacial com Escores Expandido: AMIOFE-E LACTENTES (6-24 MESES)

ABSTRACT

Purpose: Adapt and validate the content and appearance of the Expanded Protocol of Orofacial Myofunctional Evaluation with Scores (OMES-E) for nursing infants aged 6 to 24 months. **Methods:** This is a validation study. The parameters were based on the literature on orofacial motor development, the authors' experience, and on a committee of ten members. Data analysis was performed using descriptive statistics, content validity index, and agreement among experts. **Results:** The protocol was organized into functional blocks after maintenance, exclusion, modification, and addition of items, and was adapted according to the age group. A high level of agreement between experts was obtained for 90% of the items. The final version of the protocol includes new items such as history of feeding, orofacial parafunctional habits, facial mobility, dentition, oral breathing mode, swallowing of pasty food, and details specific for the age group. An operational manual and a table for recording the scores were also included. **Conclusions:** The OMES-E Infants protocol was validated for its content and appearance, and may contribute to orofacial myofunctional diagnosis in the 6 to 24-month age group.

RESUMO

Objetivo: Adaptar e validar conteúdo e aparência do Protocolo de Avaliação Miofuncional Orofacial com Escores Expandido (AMIOFE-E) para lactentes de 6 a 24 meses de idade. **Método:** Estudo de validação. Os parâmetros foram baseados em literatura sobre desenvolvimento motor orofacial, experiência dos autores e painel de 10 especialistas. Os dados foram analisados por estatística descritiva, Índice de Validade de Conteúdo e concordância entre especialistas. **Resultados:** O protocolo foi organizado em blocos funcionais após manutenção, exclusão, modificação e acréscimo de itens, adaptando-se à faixa etária. Obteve-se alto nível de concordância em 90% dos itens. Na versão final foram acrescentados: histórico de alimentação e hábitos parafuncionais orofaciais, mobilidade facial, dentição, modo oral de respiração, deglutição de pastoso e detalhamentos específicos para a faixa etária. Acrescentou-se um manual operacional e uma tabela para registro de escores. **Conclusão:** O Protocolo AMIOFE-E Lactentes e respectivo manual operacional foram validados quanto ao conteúdo e aparência, e poderá contribuir no diagnóstico miofuncional orofacial na faixa etária de 6 a 24 meses de idade.

Study conducted at Universidade Federal de Sergipe – UFS – São Cristóvão (SE), Brasil.

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INTRODUCTION

In Speech-language Pathology (SLP), structured assessment instruments that allow the determination of deviations and changes in Orofacial Motricity (OM) are very important to guide the therapeutic program to be implemented. Thus, it is possible to establish the baseline at the beginning of the therapeutic process and make comparisons to analyze the case evolution⁽¹⁾.

The preparation or adaptation of protocols by specialists is the first step towards the definition of a method. Subsequently, this protocol (or method) must go through the appraisal of other specialists and validity analyses to test and evidence the capacity of the measure to capture or reveal a certain phenomenon, including its format, content, and scales⁽²⁾. The validation process is important so that the interpretation of the results obtained with the instrument can be valid, reliable, accurate, and equitable⁽³⁾.

Protocols for assessing neonates (0-28 days of life)^(4,6) and children aged ≥ 6 years^(7,8) have been validated in the area of OM. However, there is no instrument for the specific assessment of OM in early childhood, especially for the nursing infant population (6-24 months old). The existing validated instruments address feeding, and the data are mainly obtained from surveys with parents^(9,10).

However, the craniofacial and oral structures are influenced by sex, ethnicity, age, and genetic, epigenetic and environmental factors⁽¹¹⁾, which are not always positive. Therefore, the combination of a family survey with an assessment of orofacial structures and functions of nursing infants would be useful to define preventive goals and promote craniofacial growth and development.

The Orofacial Myofunctional Evaluation with Scores (OMES)⁽⁷⁾ was the first protocol validated in Brazil for the assessment of OM for the 6 to 12-year age group. The OMES has numerical scales that represent orofacial characteristics and behaviors, allowing measurement from direct observation by speech-language therapists and diagnosis of orofacial myofunctional disorders (OMD). Later, an expanded version in terms of number of items and numerical scale amplitude was developed and validated: the Expanded Protocol of Orofacial Myofunctional Evaluation with Scores (OMES-E), which is the basis for this study.

This study aims to present the OMES-E Infants (nursing infants aged 6-24 months) protocol and describe the validation process of its content and appearance.

METHOD

This validation study is part of a larger project entitled Orofacial Motricity in Infants and Preschoolers approved by the Human Research Ethics Committee of Federal University of Sergipe (CEP-UFS), Brazil, under protocol no. 12529419.6.0000.5546.

Participants

Ten speech-language therapists from the five regions of Brazil, selected from the Lattes Curriculum platform of the National Council for Scientific and Technological Development (CNPq), agreed to participate as evaluators of the instrument (OMES-E

Infants). Having a title of expert in OM and experience with nursing infants were the inclusion criteria. Unavailability to participate or respond to the electronic form within the time established to complete the research was the exclusion criterion. All participants signed an Informed Consent Form (ICF) prior to responding to the electronic form received.

Development of the instrument

The OMES-E protocol⁽⁸⁾ can be applied without the need of sophisticated and/or invasive equipment in a reasonably brief time. It was adopted as the basis to develop the Expanded Protocol of Orofacial Myofunctional Evaluation with Scores for Nursing Infants (OMES-E Infants). The authors of the original protocol issued a favorable opinion for its adaptation and validation for nursing infants. Subsequently, the following recommended strategies were adopted⁽³⁾: theoretical study, experience of researchers with the outcome of interest, and submission to a committee of expert evaluators in the area.

The literature considered addressed orofacial motor development between 6 and 24 months of age⁽¹¹⁻¹⁵⁾. The numerical scales of the current protocol were defined based on psychophysics, as performed in the OMES and OMES-E protocols. According to Stevens⁽¹⁶⁾, measuring consists of assigning numbers to objects or events according to certain determined rules, which establish a correspondence between certain properties of numbers and certain properties of things and clinical or social attributes⁽¹⁶⁾. Therefore, it was defined that the relationship between the numbers should be ordinal (ordinal level of measurement), which allows the establishment of an order (rank) of clinical conditions and does not require that the intervals between the numbers on the scale be equidistant.

Expert assessment

The material produced was submitted to experts for content and appearance analysis. As recommended for validation studies⁽³⁾, the following steps were performed:

Step I: Instrument Analysis - First round. The experts were contacted individually via instant messaging application and email. After consent, the evaluators received an electronic form by e-mail for analysis of the instrument's content. An initial questionnaire was used to collect data on the demographic characteristics and professional experience of the experts. After that, the evaluators visualized the OMES-E Infants and answered the evaluation form prepared by the researchers on the relevance of each item in the protocol. Participants answered whether or not they agreed on the sufficiency and suitability of each item for the intended assessment. The answers were dichotomous (yes/no) and followed by areas for justification.

In this step, the Delphi technique⁽¹⁷⁾ was used to obtain the evaluators' judgments aiming to validate the content, update the nomenclature, and verify the capacity of the instrument to perform a myofunctional assessment in the intended age group. However, only the authors had access to the responses of the different evaluators and worked on them to establish a consensus. Upon obtaining the answers, the Content Validity Index (CVI)⁽¹⁸⁾ and the agreement between the experts were

calculated. The minimum response agreement limit adopted in this stage for the maintenance of an item was 70%, considering that a new evaluation would be carried out after adjustments.

Step II: Adequacy of the protocol. The evaluators' responses were recorded and analyzed in a Microsoft Word 2016® document. The necessary reformulations were carried out considering the level of agreement.

Step III: Reassessment of the instrument's content and appearance validity - Second round. The redesigned protocol was resubmitted to the evaluators' analysis. The evaluators expressed their opinions on the pertinence and suitability of the various parts that comprise the OMES-E Infants, as well as on their appearance, through a 5-point scale as follows: totally agree (score 1), agree (score 2), indifferent (score 3), disagree (score 4), and totally disagree (score 5). In this step, to be considered valid, the level of agreement between the evaluators in the answers "totally agree" and "agree" should be greater than 80% (>0.8)⁽¹⁹⁾. The items with values lower than the established should be reformulated or excluded after analysis. Appraisal of the operational manual (Appendix 1), which had been previously requested by the evaluators, was included in this step. The manual aims to facilitate the application of the instrument in the clinical context, through definitions, conceptualize what is intended to be evaluated in certain items.

RESULTS

The OMES-E Infants protocol presented here was divided into functional blocks of related structures, and most items present points/score on an ordinal level scale. It was established that numbers 4, 3, 2, 1 would correspond to terms familiar to the clinician, such as normal and mild, moderate and severe changes, respectively. Only in some items of the protocol, the scale of four was not followed, such as in "efficiency of swallowing" and "elevation of the jaw" in mastication, for which a scale three points was used. Additionally, the items "other behaviors and change signs" during swallowing and chewing have dichotomous scales [present (1) and absent (2)], and the results should be added to the other scores attributed to these functions. The protocol has descriptions that assists with assigning the scores. No score should be assigned if certain aspects could not be determined in the development phase.

The application parameters of the original instrument continued to be used, with video and photo image records for further analysis. Aiming at standardisation of the results, guidance on the infant's posture during the evaluation and information about food texture were added.

The expert committee was composed only of women. In addition to a title of expert in OM and experience with infants, most of them had a doctorate degree, were SLP teachers, and had worked with OM for over 15 years. Specifically, regarding the performance with infants, there is a uniform distribution concerning time, as shown in Table 1.

According to the experts' analysis in the first round, the researchers made some changes in the protocol and submitted a revised version of the instrument for further evaluation, together with the operational manual. In the second assessment round, the

final version of the instrument, in terms of content and scores, obtained a high level of agreement between the evaluators. Table 2 shows the results of the first and second assessment rounds. The experts also agreed on the appearance and distribution of the protocol (100%) and on the clarity of its items (90%) (Table 3).

The content adaptation and development of the OMES-E Infants, initially carried out only by the authors and, later, considering the analyses and suggestions of the experts, involved the following conducts: 1. Maintenance, 2. Exclusion, 3. Modification, and 4. Addition of items.

1. Maintenance: The protocol is still divided into categories. The following items remain the same as those of the OMES-E protocol in terms of content: facial symmetry, volume of the cheeks, lips, and tongue, width and height of the hard palate, some behaviors of the lips and tongue during the swallowing function, swallowing efficiency, bite regarding the teeth involved, and behaviors suggestive of changes during mastication.
2. Exclusion: items incompatible with assigning scores due to age, such as proportion between thirds of the face, vertical and anteroposterior mandible/maxilla relationship, nasolabial groove, labial commissure, mentalis muscle, tongue postural relationship with occlusion, in addition to the category isolated mobility of the stomatognathic system components, which would depend on the imitation or execution of direct orders provided by the examiner.
3. Modification: Descriptions of changes in maxilla/mandible morphology in the face block were included. Lip condition

Table 1. Sociodemographic and academic characterization of experts.

Characteristics (N=10)	N	%
Age group	31-40 years	5 50%
	41-50 years	5 50%
Region of the country	North	1 10%
	Northeast	3 30%
	Mid-west	2 20%
	Southeast	2 20%
	South	2 20%
Title	Specialist	1 10%
	Master's degree	2 20%
	Doctorate degree	6 60%
	Post doctorate degree	1 10%
Teaching experience	Not a teacher	2 20%
	5-10 years	4 40%
	10-15 years	1 10%
	15-20 years	3 30%
Experience in OM	<5 years	1 10%
	5-10 years	1 10%
	15-20 years	8 80%
Experience in OM with nursing infants	<5 years	2 20%
	5-10 years	3 30%
	10-15 years	1 10%
	15-20 years	3 30%
	20-25 years	1 10%

N: number of participants; %: percentage of participants.

Table 2. Agreement between evaluators in the content analysis of the adapted OMES-E Infants protocol.

Item	First round		Second round	
	Agreement	CVI	Agreement	CVI
	%		%	
Identification and clinical data	20%	0.2	100%	1.0
Feeding mode: Breastfeeding	-	-	100%	1.0
Feeding mode: Food in general	90%	0.9	90%	0.9
Diet texture	-	-	90%	0.9
Difficulties and/or adaptations during feeding	-	-	100%	1.0
Orofacial parafunctional habits	90%	0.9	100%	1.0
Face	90%	0.9	100%	1.0
Cheeks	90%	0.9	100%	1.0
Lips	90%	0.9	100%	1.0
Tongue	90%	0.9	100%	1.0
Hard palate	100%	1.0	100%	1.0
Soft palate/uvula	90%	0.9	100%	1.0
Breathing	90%	0.9	100%	1.0
Feeding mode	90%	0.9	100%	1.0
Deglutition (liquid/pasty): Lips behavior	80%	0.8	100%	1.0
Deglutition (liquid/pasty): Tongue behavior	90%	0.9	100%	1.0
Deglutition (liquid/pasty): Other behaviors and change signs	90%	0.9	100%	1.0
Deglutition (liquid/pasty): Efficiency	70%	0.7	100%	1.0
Deglutition (solid): Lips behavior †	-	-	100%	1.0
Deglutition (solid): Tongue behavior †	-	-	100%	1.0
Deglutition (solid): Other behaviors and change signs †	-	-	100%	1.0
Deglutition (solid): Efficiency	90%	0.9	100%	1.0
Mastication (solid): Bite	100%	1.0	100%	1.0
Mastication: Type	100%	1.0	100%	1.0
Mastication: Other behaviors and change signs	100%	1.0	100%	1.0

N, number of participants; %, percentage of agreement between experts; CVI, Content Validity Index; †: items included in the second round.

Table 3. Agreement between evaluators regarding the appearance of the final version of the OMES-E Infants protocol.

Item	Totally agree		Agree		Indifferent	
	N	%	N	%	N	%
Instrument appearance	7	70	3	30%	-	-
Distribution of items	8	80%	2	20%	-	-
Clarity of items	6	60%	3	30%	1	10%

N: number of participants; %: percentage of agreement between experts.

at rest and positioning of the tongue in the position/appearance category and swallowing function were also modified, in the case of the tongue, due to the impossibility of verifying the association of the tongue position with the dental relationships in the focused age group. Aspects related to the mastication of solids were also modified, giving priority to mandibular movements and observation of trituration.

4. Addition: Five topics were added to obtain data, namely, feeding mode - breastfeeding; feeding mode - food in general; diet texture; difficulties and/or adaptations during feeding; orofacial parafunctional habits. In this version of the protocol, subitems and descriptions appropriate to the age group were also included. They were related to the appearance/position and morphology of the lips, tongue (including the frenulum), cheeks and hard palate, in addition to behaviors suggestive of changes (cough and residues in the oral cavity), as well

as information on whether there was choking and coughing during or after the function, and oral breathing mode. The following items were included: “facial mobility”, whose data can be obtained from the observation of spontaneous situations during the evaluation, “soft palate/uvula”, and “swallowing of pasty food” as of 6 months of age. For the evaluation of mastication and swallowing of solid food, a minimum age of 12 months was established. In addition, the type of utensil used in feeding and an illustration for recording the dental elements present in the deciduous dentition were included with respective numerical representation. No scores are attributed to history, dentition, and utensil used in feeding, which are useful in interpretation, but do not interfere with the final score.

Finally, a scaled table to record the score obtained by the individual in the assessment was prepared. It contained, for reference, the maximum score for each item and the total score,

by age group, according to the following chronology: from 6 to 11 months and 29 days and from 12 to 24 months. Appendix 2 shows the OMES-E Infants protocol containing the table for recording the results.

DISCUSSION

This study presents the development process and final version of the OMES-E Infants protocol, which aims to be an orofacial myofunctional evaluation tool.

The profile of the evaluators who participated in the study evidences great expertise in the area, which is important to attest the validity of the contents covered by the instrument. Moreover, all regions of Brazil were represented, which is relevant for future applications of the OMES-E Infants protocol.

For application of the instrument, initial reading of the operational manual is recommended. This manual was developed from the need to inform how the protocol should be used and the understanding of its items and sub-items. This manual facilitates the protocol application in clinical practice.

The adaptations made to the OMES-E Infants protocol considered the OM development parameters expected for this age group based both on the rescue of specific concepts in the literature of the area^(11-15,19,20) and on the considerations of the authors and the expert committee, as recommended⁽³⁾.

Data from the guardians' reports on the history of feeding and orofacial parafunctional habits of the nursing infants, as in other studies at early ages^(9,10), were included to favor interpretation of the clinical evaluation results. Feeding mode - Breastfeeding refers to how liquid is offered to the child at every two months of life, based on the parameters of breastfeeding⁽²⁰⁾.

The indication of the International Dysphagia Diet Standardisation Initiative (IDDSI) framework scale⁽²¹⁾ was the option found to define the diet texture addressed in the OMES-E Infants protocol and the consequent standardisation of results, in the absence of specific material. The IDDSI researchers aimed to provide standardized terminologies and definitions regarding foods and liquids applicable to cases of dysphagia.

Feeding mode - Food in general considers the utensil used and whether the infant's feeding is assisted or independent, which is related to motor development⁽¹²⁾, as recommended in studies involving maternal reports⁽¹³⁾ on the infant's ability to drink from a cup (with and without a lid) and on the child's autonomy to use utensils.

As for the difficulties and/or adaptations during feeding, the record of the beginning and duration of the event was considered, including the importance of early detection of symptoms of eating problems⁽¹⁰⁾. The frequency and duration of orofacial parafunctional habits must be determined, because it is widely accepted that these variables have an influence on the orofacial muscles and occlusion⁽¹¹⁾.

In general, it is expected that, in the first six months of life, the infant will present oral behaviors related mainly to readiness for feeding, which enables coordinated deglutition of the liquid bolus. From that age, exploratory movements of the tongue are observed in terms of shape and textures, together with

movements of the upper lip to remove food from a spoon. Then the possibility of offering pasty consistencies is observed⁽¹³⁾.

At approximately nine months of age, the infant can eat foods containing small soft pieces without choking and, with eruption of the teeth, can chew most of the foods brought to the mouth, increasing the ability and efficiency with harder consistencies with advancing age⁽¹³⁾.

Exclusion of the items that depended on isolated execution according to the examiner's order was based on the impossibility of obtaining accurate data, since before the second year of age, the ability of motor execution from the child's understanding of verbal language, or by imitation, would not be guaranteed⁽²²⁾. Also, items such as direct anthropometric orofacial measurements⁽¹⁴⁾ and classification of malocclusions were excluded because the first deciduous molars erupt at 6 years old on average⁽¹⁹⁾.

On the other hand, registration of dental elements was considered important⁽¹¹⁾, because the occlusion of the 20 deciduous teeth is established until the age of three on average⁽¹³⁾, and there is a close relationship between the development of dentition and muscle activity. To this end, a double-digit registry was used for the deciduous teeth, according to the internationally adopted nomenclature⁽¹⁹⁾.

Items related to the position/appearance of the tongue were added to the protocol because the infant may present certain postures and characteristics, such as cracks in the tongue or even apparent macroglossia⁽¹⁵⁾, which may be relevant for the diagnosis of bone mineral density (BMD).

Since the characteristics of the uvula and conditions such as palatal abnormalities are often assessed in studies addressing the risks for sleep disorders^(23,24), they were included in the protocol. Thus, the elongated soft palate was classified as different from the normal pattern because of the risk of obstructive sleep apnea (OSA), which can occur since the neonatal period, although the prevalence increases as of 2 years of age⁽²⁵⁾. The reason that the elongated soft palate may be a risk factor for OSA in the first year of life is that contact with the epiglottis, which has an elevated (more cranial) position at this stage, facilitates pharyngeal obstruction⁽²⁶⁾. In contrast, velopalatal insufficiency often results in hypernasal speech and dysphagia⁽²⁷⁾, which is difficult to treat especially when accompanied by a short palate⁽²⁸⁾. It should be clarified that, although the scores define the change severity, they are not exclusive to a single problem. Therefore, some scores are repeated and the possible changes are listed to facilitate marking for the evaluator.

The OMES-E Infants protocol is not exhaustive. Therefore, some aspects such as changes in the tongue frenulum, hard and soft palate, and detection of signs of dysphagia were included, so that at the end of the evaluation it is possible to have an overview of the case. The infant may not have been assessed previously, and relevant problems may be present. Therefore, it is suggested that, when detecting any of these problems, the professional should use specific protocols or refer the patient to specialized teams.

The OMES-E Infants protocol aims at enabling the evaluation and identification of changes in stomatognathic components and functions. In addition, the use of a numerical scale in the orofacial myofunctional clinical evaluation can contribute

to drawing a profile of the individual, allowing comparisons between them and the monitoring of the results obtained with the treatment⁽⁸⁾.

The use of numerical scales does not solve all difficulties and entails problems. Subjectivity is inherent in clinical evaluation regardless of the use of numerical scales, because it depends on the professional's ability to observe, perceive and judge, which are skills that result from their education and training. However, considering that an instrument that specifies what should be evaluated and standardizes the documentation, at least improves communication and consistency between clinicians⁽²⁹⁾.

It should be contextualized that the need to adapt the OMES-E Infants protocol became evident from the birth of individuals affected by microcephaly resulting from the Zika virus outbreak that occurred in the northeast region of Brazil⁽³⁰⁾. Despite the need to register the orofacial characteristics of affected infants, there were no specific instruments validated in the OM area aimed at this age group.

The OMES-E Infants protocol presented here fills a gap in the OM area, as it may be a useful tool for detecting deviations and disorders in the population up to 24 months of age. This may contribute to adopt strategies that favor the growth and development of the stomatognathic system and health promotion.

Further studies are needed to establish the construct and criterion validity of the OMES-E Infants protocol, as well as its accuracy, sensitivity and specificity values and the cutoff points between normality and orofacial myofunctional disorder.

CONCLUSION

The OMES-E Infants protocol (6-24 months old) was developed and its content and appearance were validated with a high level of agreement among experts. Future studies should verify the instrument's ability to discriminate between infants with and without BMD, as well as its psychometric properties, contributing to both clinical practice and research in the field of OM.

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Authors' contributions

AMCM: conception and design of the study, guidance of the adapted version of the protocol and its validation, and writing, review, and approval of the final version of the manuscript; GRDN: adaptation of the protocol, analysis and interpretation of the data, and writing of the manuscript; IDCB: analysis and interpretation of the data and English version of the manuscript; EMSJ: conceptual adaptation and validation of the protocol. GAP: preparation of the adapted and validated version of the protocol and review and approval of the final version of the manuscript; ALSM and SCSN: validation of the content and appearance of the protocol. CMF: preparation of the adapted and validated version of the protocol and writing, review, and approval the final version of the manuscript. All authors read and approved the final version of this article.

APPENDIX 1. OPERATIONAL MANUAL –OMES-E INFANTS

EXPANDED PROTOCOL OF OROFACIAL MYOFUNCTIONAL EVALUATION WITH SCORES FOR NURSING INFANTS (6-24 months)

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This operational manual is included in the Expanded Protocol of Orofacial Myofunctional Evaluation with Scores for Nursing Infants (6-24 months old): OMES-E Infants and presents information and instructions for its application.

The OMES-E Infants protocol was developed from the Expanded Protocol of Orofacial Myofunctional Evaluation with Scores (OMES-E) (Felício et al., 2010)⁽⁸⁾ to allow the assessment of OM of the population aged 6 to 24 months.

The clinical evaluation, as proposed in the OMES-E Infants, is subjective and depends on the professional's ability to observe, perceive, and judge, which are skills that result from their education and training. The fact that it allows expression of the results in scores (numerical scales) does not make it objective, but it allows systematization and monitoring of the data of each patient according to their clinical evolution.

The OMES-E Infants protocol is not exhaustive. Therefore, the professional will be able to complement the investigation with other assessments and protocols when there is need for a more comprehensive analysis on some aspect found altered or with suspicion of change.

The OMES-E Infant is divided as follows:

The initial pages of the protocol include identification information, clinical data, and the history of feeding and orofacial parafunctional habits. The information to be filled out should be obtained through an interview with the legal guardian of the infant. In this initial part, scores are not assigned, but the information will be essential for interpretation of the assessment data and diagnosis of the orofacial myofunctional condition.

FOOD HISTORY AND OROFACIAL PARAFUNCTIONAL HABITS:

In the tables related to the **feeding history**, the speech-language therapist must mark the periods (in months) of occurrence, for each offering mode (method). The “never” option should be checked if the offering mode has not been used at any time in life to feed the infant.

1. Feeding mode: Breastfeeding

It refers to the breastfeeding situation, which may involve both exclusive breast milk (offered on the breast, bottle, cup, or tube), and the use of artificial milk (milk formulas prescribed by a physician); or even both forms (mixed breastfeeding).

The description of a mixed diet and/or use of a tube and the complementary information, which may reveal difficulties encountered during feeding, should be written in the area indicated below the table.

2. Feeding mode: Food in general

It refers to the situation of feeding that includes the use of various utensils. The feeding skills that involve the motor control of nursing infants can provide important information about their orofacial myofunctional development.

3. Texture of the diet

To specify and standardize the texture (consistency) of foods, the classification of the International Dysphagia Diet Standardisation Initiative (IDDSI) was adopted (Cichero et al. 2017)⁽²¹⁾, whose latest version was published as Complete IDDSI Framework - Detailed definitions - 2.0 | 2019 (available at <https://iddsi.org/framework/>).

The proposal of the IDDSI researchers provides standardized terminologies and definitions regarding foods and liquids applicable to cases of dysphagia. Despite this, in the absence of such a clear classification, the OMES-E Infants was adopted because of the constant difficulty experienced by professionals, including speech-language therapists, with the nomenclature related to the diet.

The two tables indicate the months in which the infant received the food, according to the feeding mode and texture of the diet, and we could mark whether the feeding was done in an assisted or independent way, choosing the letters “A” or “I”, respectively.

4. Difficulties during and/or adaptations in feeding:

In this item, the period (beginning, duration) in months in which each difficulty and/or adaptation occurred can be recorded, including the investigation of food refusal and hospitalization.

The professional needs to describe the difficulty/adaptation found/performed to guide the clinical reasoning of the etiology of any changes that may be observed in the clinical examination to be performed.

5. Parafunctional orofacial habits:

In this item, the time of occurrence (in months) of each oral habit (pacifier, finger sucking, and others) can be registered. In case of other types of habits, describe it in field provided.

It is also recommended to note the daily frequency of the habit in hours, as this survey can give indications of the impact of this habit on the orofacial structures, depending on its frequency, intensity, and duration.

CLINICAL EXAMINATION

The individual clinical evaluation of OM should be performed with the individual standing vertically, keeping the spine supported (infant car seat, chair, or guardian’s lap), facing the evaluator. The protocol was adapted considering that the foods offered must be registered, with attention to the possibilities inherent in the age and the nursing infant’s usual dietary pattern.

Appearance and postural condition/position:

Visual observation of orofacial structures and components is recommended to evaluate this item. Some support can be used by the speech-language therapist if they consider that this facilitates the analysis. For example, when evaluating face symmetry, dental floss can be used, holding it in the midline of the face to compare the right and left sides.

Although Morphology/Volume, Function at rest, Tension, and Mobility are recorded separately in the items Cheeks, Lips and Tongue, the speech-language therapist should relate them to the behaviors in the orofacial functions at the end of the evaluation.

Regarding dentition, the speech-language therapist should only mark the teeth that have erupted completely. Subsequently, consulting the literature on the chronology of deciduous dental eruption will help define whether the development of dentition follows normal patterns or not, and specific referral to a dental professional is required.

As for the palate, it should be considered as altered when there are changes involving both the hard and soft/uvula palate. Oral malformations associated with palate/uvula problems are considered to aggravate the condition and should receive lower scores.

Mobility:

Facial mobility should be assessed based on the observation of spontaneous movements of the nursing infant during the interaction with the speech-language therapist and/or guardian. It should be observed from the first moment, in the situation of the initial interview with the guardian.

FUNCTIONS

Breathing: To classify the breathing mode, speech-language therapists may consider if the nursing infant remains with the lips occluded whenever at rest, which indicates exclusively nasal breathing (normal). They can base their classification on the frequency at which mixed breathing is used, and classify it as light (few times) or moderate (most times) oronasal breathing. If breathing is performed only through the oral cavity, a classification of severe dysfunction should be assigned. A millimeter mirror can be used as an auxiliary method to verify whether there is expiration through the nostrils and whether flow out of both nostrils is symmetrical or not.

Deglutition: Observation of this function should consider the pattern according to the infant's age range and the feeding mode and food consistency.

The following utensils are considered in the feeding modes: spoon and cup. If another utensil is used, such as a fork, it should be described in the area for "Other".

Breastfeeding and bottle feeding were not considered in the clinical evaluation of this protocol. When liquid is offered via breast or bottle, it is recommended that the evaluation be carried out using a specific feeding assessment instrument.

A common cup with a lid and/or a valve can be used to evaluate liquid feeding.

Although the terms liquid, pasty and solid have been maintained in this protocol because they are common in the area, the food texture thought for each of these terms considered the classification of the IDDSI (Cichero et al. 2017)⁽²¹⁾. As a result, Table 3 of the protocol shows the texture levels so that the speech-language therapist can consult the document, which has easy and free access.

Evaluation of deglutition of liquid and pasty food is conducted in nursing infants aged >6 months, whereas deglutition of solids is conducted from 12 months of age, following the same age range for observation of the mastication function.

We should consider the postural behaviors of the tongue and lips, and others, during the performance of the function. In the event of any occurrence feeding with liquid consistency, we should consider whether it is expected (physiological standard) for the corresponding age group. When the observed behavior is expected for the age group, the assigned score must be normal.

Mastication: For analysis of this function, solid food should be offered, which is considered everyday food of the same consistency as that of the family, and all types of utensils should be used during feeding. Therefore, the nursing infant will be subjected to mastication assessment according to their chronological age and individual development.

All aspects evaluated contain spaces for recording partial scores, even during the examination situation. At the end of the protocol, the partial and total scores should also be recorded in the "Results" table, thus obtaining the total score of the infant.

The values shown in the results table are the maximum possible scores to be registered in the protocol for each item evaluated, according to the age group. However, at the moment, it cannot be stated that children with normal orofacial myofunctional conditions would always reach all maximum scores.

There is intention to establish cutoff points from the use of the OMES-E Infants protocol in the future. It is worth mentioning, however, that the scores obtained in the orofacial myofunctional evaluation are a record/photograph of the infant's current moment, presenting an important value in the longitudinal and individual monitoring of the infant's OM profile.

APPENDIX 2. OMES-E INFANTS

EXPANDED PROTOCOL OF OROFACIAL MYOFUNCTIONAL EVALUATION WITH SCORES FOR NURSING INFANTS

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IDENTIFICATION AND CLINICAL DATA

Date of application ___/___/___ Identification number: _____

Child's name: _____

Address: _____

Legal guardian: _____

Degree of relationship of the guardian: _____

Telephone: (____) _____

Medical diagnosis: _____ Referral: _____

Birth day ___/___/___ Current age: ___ years and ___ months Corrected age: ___ years and ___ months

Gestational age: _____ weeks APGAR: 1st min: _____ 5th min: _____

Weight at birth: _____ Kg Current weight: _____ Kg Current height: _____ cm

FOOD HISTORY AND OROFACIAL PARAOFUNCTIONAL HABITS

1. Feeding mode: Breastfeeding

Indicate the months in which the infant was breastfed (liquid*) according to the feeding mode.

For those not used, check the “Never” column in the corresponding line.

Mode	Never	Age in months								
		1-2	3-4	5-6	7-9	10-12	13-15	16-18	19-21	22-24
Breastfeeding										
Bottle feeding										
Cup										
Mixed										
Tube										

* Zero levels of liquid thickness according to the International Dysphagia Diet Standardisation Initiative (IDDSI) framework. Available at <https://iddsi.org/framework/>.

If you checked Mixed, describe it: _____

If you checked Tube (nasogastric tube), describe it: _____

Additional information (e.g., nipple type, nipple orifice size, difficulties, and others): _____

2. Feeding mode: Food in general

Indicate the months in which the infant received food according to the feeding mode. In each of the periods, you should mark “A” if assisted or “I” if independent.

Mode	Never	Age in months													
		4-6		7-9		10-12		13-15		16-18		19-21		22-24	
Cup with valve/lid		A	I	A	I	A	I	A	I	A	I	A	I	A	I
Common cup		A	I	A	I	A	I	A	I	A	I	A	I	A	I
Spoon		A	I	A	I	A	I	A	I	A	I	A	I	A	I
Hands to hold the food and bring it to the mouth to bite		A	I	A	I	A	I	A	I	A	I	A	I	A	I
Fork		A	I	A	I	A	I	A	I	A	I	A	I	A	I

3. Diet texture

Indicate the months in which the infant received food according to texture. In each of the Periods, you should mark “A” if assisted or “I” if independent.

Textures*	1-3		4-6		7-9		10-12		13-15		16-18		19-21		22-24	
Thin liquid ⁰	A	I	A	I	A	I	A	I	A	I	A	I	A	I	A	I
Moderately thick liquid 3 (first baby's food)	A	I	A	I	A	I	A	I	A	I	A	I	A	I	A	I
Pasty (Pureed) ⁴	A	I	A	I	A	I	A	I	A	I	A	I	A	I	A	I
Chopped (or ground) and moist	A	I	A	I	A	I	A	I	A	I	A	I	A	I	A	I
Requiring minimal chewing																
Soft food ⁶	A	I	A	I	A	I	A	I	A	I	A	I	A	I	A	I
Requiring mastication																
Solid (Regular) ⁷	A	I	A	I	A	I	A	I	A	I	A	I	A	I	A	I
Requiring mastication																

*Source: International Dysphagia Diet Standardisation Initiative (IDDSI) framework. Adopted to define food textures. Available at <https://iddsi.org/framework/>.
⁰ Liquid thickness level 0 (zero); ³ Liquid thickness level 3; ⁴ Liquid thickness level 4 or Food texture level 4; ⁵ Food texture level 5; ⁶ Food texture level 6; ⁷ Food texture level 7.

4. Difficulties and/or adaptations during feeding

Record the period in months of each difficulty and/or adaptation.

Difficulty/adaptation	No	Yes	Start (age in months)	Duration (age in months)	Which?
Bottle nipple adaptation					
Adaptation to utensil (spoon)					
Use of alternative feeding route					
Diagnosis of food restriction					
Food refusal					
Hospitalization					

5. Orofacial parafunctional habits

Check all periods (months) that the infant performed each habit. If the infant has not had one or more habits, check the “Never” column in the corresponding line.

	Never	Age in months														
		1-2	3-4	5-6	7-9	10-12	13-15	16-18	19-21	22-24						
Pacifier																
Finger sucking																
Others																

If you checked others, describe it: _____

Inform the daily frequency of the habits (e.g., number of hours) _____

CLINICAL EXAMINATION

APPEARANCE AND POSTURAL CONDITION/POSITION

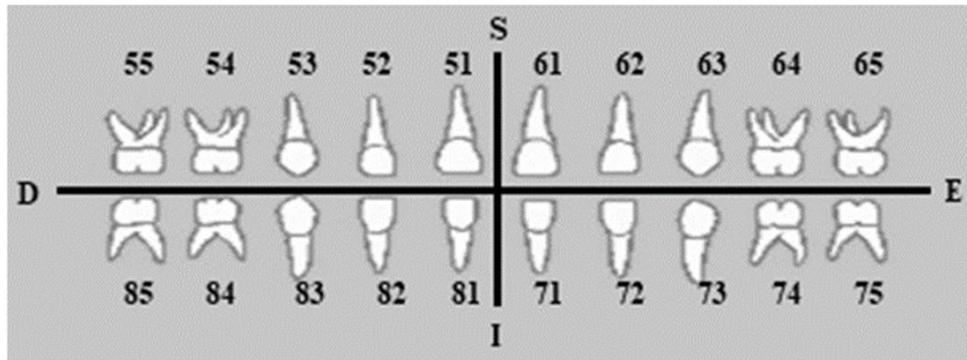
Face		Scores
Symmetry between right and left sides	Normal	(4)
Asymmetry	Light dysfunction	(3)
	Moderate dysfunction	(2)
	Severe dysfunction	(1)
Decreased side (mark the side)	Right	Left
Maxilla/Mandible		
Morphology	Normal	(3)
Altered	Micrognathia	(2)
	Maxilla and mandible hypoplasia	(1)
Decreased side (mark the side)	Right	Left
Relationship with the midline	Normal	(4)
Altered (lateral deviation)	Light dysfunction	(3)
	Moderate dysfunction	(2)
	Severe dysfunction	(1)
Side with deviation	Right	Left
Result of the evaluated individual =		
Maximum score = 11		

Cheeks			Scores	
Volume	Normal		(4)	
Altered volume	Light dysfunction		(3)	
	Moderate dysfunction		(2)	
	Severe dysfunction		(1)	
Increased	Decreased	Right	Left	Both
Tension	Normal		(4)	
Increased	Light dysfunction		(3)	
	Moderate dysfunction		(2)	
	Severe dysfunction		(1)	
Flaccid/drooping	Light dysfunction		(3)	
	Moderate dysfunction		(2)	
	Severe dysfunction		(1)	
Result of the evaluated individual =				
Maximum score = 08				

Teeth

Mark the dental elements present.

Lips		Scores
Morphology	Normal	(4)
Altered morphology	Dry/Cracks	(3)
	Operated (cheiloplasty)	(2)
	Uncorrected cleft lip	(1)
Volume	Normal	(4)



Lips		Scores
Altered Volume	Light dysfunction	(3)
	Moderate dysfunction	(2)
	Severe dysfunction	(1)
Increased	Decreased	
Lips function at rest		Occluded: normally fulfill the function
		(4)
Lips closure	Light dysfunction (half-open)	(3)
	Moderate dysfunction	(2)
	Severe dysfunction	(1)
Result of the evaluated individual =		
Maximum score = 12		

Tongue		Scores
Position/Appearance	Normal (the infant remains with the mouth closed and there is no exposure of the tongue)	(4)
Altered	Light dysfunction (the infant remains the mouth open with the tongue on the floor of the mouth)	(3)
	Moderate dysfunction (the infant remains with the mouth open with the tongue interposed to lips)	(2)
	Severe dysfunction (the infant remains with the open with the tongue exceeding the lips)	(1)
Morphology	Normal (size and shape)	(4)
Altered morphology	Light dysfunction	(3)
() Microglossia () Macroglossia	Moderate dysfunction	(2)
	Severe dysfunction (with impaired breathing)	(1)
Volume		
Volume compatible with the oral cavity	Normal	(4)
Increased and/or widened volume (check the relationship with the oral cavity space)	Light dysfunction	(3)
	Moderate dysfunction	(2)
	Severe dysfunction	(1)
Tongue Frenulum*		
	Normal (extension, fixation, and thickness)	(4)
Altered in:	Light dysfunction	(3)
() Thickness	Moderate dysfunction	(2)
() Fixation	Severe dysfunction	(1)
() Extension		
Result of the evaluated individual =		
Maximum score = 16		

*Note: In the event of frenulum change, application of a specific protocol is recommended.

Hard palate		Scores
Morphology	Normal	(4)
Altered	Operated (Palatoplasty)	(3)
	Moderate changes (other)	(2)
	Uncorrected cleft palate	(1)
Width	Normal	(4)
Decreased width (narrow)	Light dysfunction	(3)
	Moderate dysfunction	(2)
	Severe dysfunction	(1)
Height	Normal dysfunction	(4)
Increased height (deep)	Light dysfunction	(3)
	Moderate dysfunction	(2)
	Severe dysfunction	(1)
Result of the evaluated individual =		
Maximum score = 12		

Soft Palate/Uvula		Scores
Morphology	Normal	(4)
Altered palatine veil	Long	(3)
	Short	(3)
	Short associated with another oral malformation	(2)
	Bifid uvula associated with another oral malformation	(2)
	Absent uvula associated with another oral malformation	(1)
	Uncorrected cleft palate	(1)
	Other changes	(1)
Result of the evaluated individual =		
Maximum score = 04		

Observations: _____

MOBILITY

Facial mobility		Scores
Appropriate facial expression	Normal	(4)
Reduced or altered facial expression	Little facial expression	(3)
	Asymmetry when performing facial expressions	(2)
	Absent - no facial expression	(1)
Result of the evaluated individual =		
Maximum score = 04		

FUNCTIONS

Breathing		Scores
Mode		
Nasal breathing	Normal	(4)
Oronasal breathing	Light dysfunction	(3)
	Moderate dysfunction	(2)
Mouth breathing	Severe dysfunction	(1)
Result of the evaluated individual =		
Maximum score = 04		

If the millimeter mirror was used to analyze the expiratory flow, write the result: _____

Deglutition (liquid/pasty)

Utensil used during feeding: () Spoon () ; Cup: common with lid with valve.

Other: _____

EVALUATE AS OF 6 MONTHS OF AGE

Deglutition: Lips behavior		Scores
Lips closure	Without apparent effort	(4)
Partial closure (when expected for the age group)		
Lips closure but with inadequate contraction for the age group	Sharp contraction	(3)
	Reduced contraction	(2)
Lips do not close the oral cavity	Does not fulfill the function	(1)
Food used in the evaluation:		
Result of the evaluated individual =		
Maximum score = 04		

EVALUATE AS OF 6 MONTHS OF AGE

Deglutition: Tongue behavior		Scores
Contained in the oral cavity	Normal	(4)
Slightly interposed (when expected for age group)		
Not contained in the oral cavity - interposition		
Interposed with teeth or gingival arches (atypically)	Light dysfunction	(3)
Remaining in contact with the upper and lower lips	Moderate dysfunction	(2)
Excessively surpassing gingival arches/teeth	Severe dysfunction	(1)
Result of the evaluated individual =		
Maximum score = 04		

EVALUATE AS OF 6 MONTHS OF AGE

Deglutition: other behaviors and change signs			Scores		
			Present	Absent	Present (when expected for the age group)
Movements of the head or other parts of the body			(1)	(2)	(2)
Mandible sliding			(1)	(2)	(2)
Facial muscle tension			(1)	(2)	(2)
Food Escape			(1)	(2)	(2)
Choking	During deglutition	After deglutition	(1)	(2)	
Cough	During deglutition	After deglutition	(1)	(2)	
Noise			(1)	(2)	(2)
Residue in the oral cavity			(1)	(2)	(2)
Result of the evaluated individual =					
Maximum score = 16					

EVALUATE AS OF 6 MONTHS OF AGE

Deglutition Efficiency		Scores
Liquid bolus		
Does not repeat the deglutition of the same bolus		(3)
Two repetitions		(2)
Multiple deglutition (three or more repetitions)		(1)
Result of the evaluated individual =		
Maximum score = 03		

Deglutition(solids) EVALUATE AS OF 12 MONTHS OF AGE

Deglutition: Lips behavior		Scores
Lips closure	Without apparent effort	(4)
Lips closure but with inadequate contraction for the age group	Sharp contraction	(3)
	Reduced contraction	(2)
Lips do not close the oral cavity	Does not fulfill the function	(1)
Food used in the evaluation:		
Feeding mode:		
Result of the evaluated individual =		
Maximum score = 04		

Deglutition: Tongue behavior		Scores
Contained in the oral cavity	Normal	(4)
Not contained in the oral cavity - interposition		
Interposed with teeth or gingival arches	Light dysfunction	(3)
Remaining in contact with the upper and lower lips	Moderate dysfunction	(2)
Excessively surpassing gingival arches/teeth	Severe dysfunction	(1)
Result of the evaluated individual =		
Maximum score = 04		

EVALUATE AS OF 12 MONTHS OF AGE

Deglutition: other behaviors and change signs			Scores	
			Present	Absent
Movements of the head or other parts of the body			(1)	(2)
Mandible sliding			(1)	(2)
Facial muscle tension			(1)	(2)
Food escape			(1)	(2)
Choking	During deglutition	After deglutition	(1)	(2)
Cough	During deglutition	After deglutition	(1)	(2)
Noise			(1)	(2)
Residue in the oral cavity			(1)	(2)
Result of the evaluated individual =				
Maximum score = 16				

Deglutition Efficiency		Scores
Solid bolus		
Does not repeat deglutition of the same bolus		(3)
Two repetitions		(2)
Multiple deglutition (three or more repetitions)		(1)
Result of the evaluated individual =		
Maximum score = 03		

Mastication (solids) EVALUATE AS OF 12 MONTHS OF AGE

Bite		Scores
Incisors	Normal	(4)
Canines-premolars		(3)
Molar		(2)
Does not bite		(1)
Result of the evaluated individual =		
Maximum score = 04		

Mastication		Scores
Jaw depression	Adequate, allowing to introduce food in the oral cavity	(4)
	Partial, with difficulty introducing food into the oral cavity	(3)
	Insufficient to introduce food into the oral cavity	(2)
	None (mandibular locking)	(1)
Jaw elevation	Adequate, occludes the mouth and keeps it closed during most of the mastication cycle	(3)
	It rises but does not keep the mouth closed during most of the mastication cycle	(2)
	It does not rise to fulfill the mastication function	(1)
Mandibular movements	Rhythmic and organized	(3)
	Not rhythmic, disorganized, and/or with tremors	(2)
	Absent	(1)
	For the movements present, indicate how they occur most of the time:	
	<input type="checkbox"/> Rotational movement of the mandible throughout most of the mastication cycle	
	<input type="checkbox"/> Vertical throughout most of the mastication cycle (without rotation)	
	<input type="checkbox"/> Both (lateral and vertical)	
Trituration	Thorough trituration of the food	(4)
	Very slow trituration of the food	(3)
	Very slow and partial trituration of the food	(2)
	Does not perform the function despite the age	(1)
Result of the evaluated individual =		
Maximum score = 14		

Mastication: other behaviors and change signs	Scores	
	Present	Absent
Movements of the head or other parts of the body	(1)	(2)
Altered posture (head or other body parts)	(1)	(2)
Food escape	(1)	(2)
Result of the evaluated individual =		
Maximum score = 06		

RESULTS

Functional Blocks	Age in months (m) and days (d)		Total Score
	06m-11m29d	12-24m	
Items			
Face	11	11	
Cheeks	08	08	
Lips	12	12	
Tongue	16	16	
Hard palate	12	12	
Soft palate/uvula	04	04	
Mobility	04	04	
Breathing	04	04	
Liquid/pasty deglutition: lips behavior	04	04	
Liquid/pasty deglutition: tongue behavior	04	04	
Liquid/pasty deglutition: other behaviors and change signs	16	16	
Deglutition efficiency (liquid/pasty)	03	03	
Solid deglutition: lips behavior	---	04	
Solid deglutition: tongue behavior	---	04	
Solid deglutition: other behaviors and change signs	---	16	
Deglutition efficiency (solid bolus)	---	03	
Bite	---	04	
Mastication	---	14	
Mastication: other behaviors and change signs	---	06	
Total score	100	149	