ORIGINAL ARTICLE

Translation and Validation of the Drooling Infants and Preschoolers Scale (DRIPS) into Malay Language

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ABSTRACT

Introduction: Sialorrhea or drooling is common among children with developmental disabilities, such as Cerebral Palsy and Global Developmental Delay. To date, no translation and validation study has been conducted on the Drooling Infants and Preschoolers Scale (DRIPS) in the Malay language. This study aimed to translate and validate the Drooling Infants and Preschoolers Scale (DRIPS) into its Malay version. **Methods:** This cross-sectional study was conducted among primary caregivers of children with developmental disabilities. An iterative forward-backward translation of the DRIPS was performed by four independent certified translators. The study involved 31 parents of children aged 2 to 7 years, diagnosed with Cerebral Palsy (CP), Autism Spectrum Disorder (ASD), and Global Developmental Delay (GDD), who exhibited drooling symptoms. Participants were recruited from private centers in Klang Valley and completed the M-DRIPS. The content validity, face validity, internal consistency, and test-retest reliability of the M-DRIPS items were examined. **Results:** An assessment with 20 M-DRIPS items was successfully translated and validated into Malay. All items demonstrated excellent content validity (CVI = 1.00 for all items, S-CVI/Ave = 1.0, S-CVI/UA = 1.0), strong face validity (I-FVI range 0.9 to 1.0), good internal consistency (Cronbach's $\alpha = 0.82$), and excellent test-retest reliability (Pearson correlation coefficient $r = 0.99$, Spearman's rank correlation coefficient $rs = 0.95$ to 0.96). **Conclusion:** The findings indicated that the M-DRIPS was successfully translated and validated into Malay, demonstrating strong psychometric properties. This instrument can be used as a drooling assessment tool for Malaysian children with disabilities experiencing drooling.
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Keywords: Drooling, Drooling frequency, Drooling severity, Sialorrhea, Drooling assessment tools

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INTRODUCTION

Sialorrhea or drooling is common in children and is defined as the release or spillage of saliva due to excessive production of saliva or decreased frequency of swallowing, regarded as primary and secondary sialorrhea, respectively (1-2). Normal development intensifies at 18 months of age and disappears as the oral sensorimotor function matures (3). It is considered atypical among children aged 4 years and above, potentially leading to health and social issues (4-5). Drooling can be further categorized into two groups: anterior drooling and posterior drooling. According to Lawrence and Bateman (6), anterior drooling occurs when saliva leaves the oral cavity, while posterior drooling results from secretions pooling in the hypopharynx, increasing the risk of aspiration pneumonia. Additionally, issues in comprehensive somatic and sensory function may result in drooling problems, such as poor oral motor function, sensory processing disorders, and poor coordination in recognizing and swallowing saliva (7).

Furthermore, according to Van Hulst (8), the international prevalence of dysphagia in neurodevelopmental disabilities is estimated to be between 27% and 99%, indicating a high prevalence. Van Den Engel-Hoek et al. (9) stated that oropharyngeal dysphagia emerges as a significant risk factor for morbidity and mortality in this population. Unfortunately, most assessments that measure drooling only focus on its general severity and frequency without assessing the degree of drooling in various situations, which may differ depending on time and activity participation. Examples include the Drooling Severity and Frequency Scale (DSFS) (10), Drooling Quotient (DQ) (11), and Drooling Impact

Scale (DIS) (12), making current assessments insufficient for measuring drooling comprehensively (3).

To address this issue, a parent-reported subjective assessment to measure drooling was established by Van Hulst et al. (7) called the Drooling Infants and Preschoolers Scale (DRIPS) for children below 4 years old. It assesses drooling severity and frequency in various situations, including the effects of tooth eruption or colds on drooling. In addition, DRIPS has been translated into Korean due to the significant role of occupational therapy in Korea in managing drooling (13). A similar scenario can also be observed in Malaysia, where occupational therapists play a significant role in the early stages of drooling management and feeding therapy. However, to date, no drooling assessment, including the DRIPS, is available in Malay. Therefore, translating the DRIPS assessment is necessary to improve treatment delivery, as Malay is the national language in Malaysia. Hence, the objective of this study is to translate and validate the DRIPS into the Malay language version.

MATERIALS AND METHODS

Overview of the Procedure

This research was conducted in five stages: translation (stage 1), content validity (stage 2), face validity (stage 3), internal consistency (stage 4), and test-retest reliability (stage 5). In the translation stage, this study did not undergo the process of cultural validation as the items within the assessment did not contain any elements deemed inappropriate in relation to Malaysia's cultural practices. Additionally, research approval was requested from the ethics committee, and permission to translate the DRIPS was obtained from the original author. The stages involved in this research are described in **Figure 1** below.

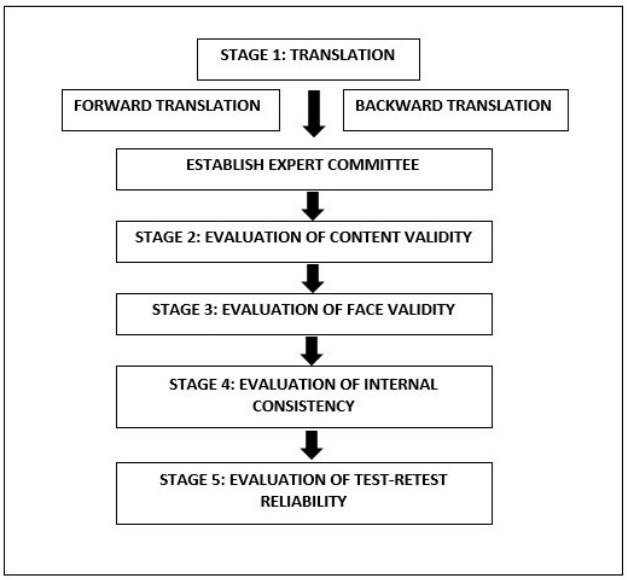

Fig.1: Selected study stages adapted from Tsang et al. (2017)

Stage 1: Translation process

Permission was secured from the original author, Van Hulst et al. (7), before the translation took place. The translation process consisted of forward and backward translation, as outlined by Tsang et al. (14), and involved six experts. The first part of the translation involved forward translation from the original language, which is English, into the target Malay language. Two translators (T1 and T2) separately translated the assessment items and synthesized their work. The first translator was aware of the questionnaire's concept and its intended measurement, while the second translator was unaware of the objective of the questionnaire to allow for precise detection of any differences. Both translators had certificates in Teaching English as a Second Language (TESL). The second part of the translation involved backward translation, which refers to translating from the target language back into the original language to ensure translation accuracy. This task was performed by two independent translators who translated into their mother tongue and were unaware of the intended concepts measured by the questionnaire. Both translators also held certifications in TESL. Lastly, the third part of the translation process was a review by an expert committee, which evaluated the questionnaire items and produced the pre-final translated version of the DRIPS.

Stage 2: Evaluation of content validity

The evaluation of content validity was conducted with the participation of six experts who had experience and familiarity with children with developmental disabilities experiencing drooling. This evaluation involved the use of a rating scale that included four criteria: relevance, clarity, simplicity, and ambiguity, each rated on a 4-point scale. To ascertain content validity, systematic methods such as expert reviews and item analysis were employed to validate the relevance, representativeness, and comprehensiveness of the instrument items. The Content Validity Ratio (CVR) and Content Validity Index (CVI) were computed, with panellists assessing the essentiality of each item for measuring the construct. Items receiving higher ratings were considered more essential, contributing to the overall content validity. A higher CVI indicates stronger content validity, signifying that the items effectively capture the intended construct.

Stage 3: Evaluation of face validity

Face validity is a type of validity assessment that involves a subjective judgment of whether a test or assessment appears, on the surface, to measure what it is intended to measure. Feedback was gathered from 10 individuals who were representative of the target audience—carers of children with developmental disabilities experiencing drooling—who had a good understanding of the construct. The rating was based on the clarity and comprehensibility of items in each domain, using a four-point scale. Participants provided ratings for all items to determine the face validity of the assessment. The face validity index (FVI) was determined in two distinct forms:

item-level FVI (I-FVI) and scale-level FVI (S-FVI). I-FVI was calculated by dividing the number of items rated as 3 or 4 (agreed items) by the total number of raters. Meanwhile, S-FVI/Ave was determined by averaging the I-FVI scores for all items across all raters, yielding values that could range from 0 to 1.

Stage 4: Evaluation of internal consistency

Thirty carers who were looking after children with developmental disabilities experiencing drooling participated in this stage and were asked to complete the questionnaires. The internal consistency was determined by calculating Cronbach's alpha value through reliability analysis in SPSS version 25. A Cronbach's alpha value of 0.70 indicates adequate internal consistency of the questionnaire items (14).

Stage 5: Evaluation of test-retest reliability

For the retest measurement, thirty carers who were looking after children with developmental disabilities experiencing drooling were asked to complete the same questionnaire two weeks after the initial date. To assess the test-retest reliability of the M-DRIPS, the Pearson correlation coefficient test and Spearman's rank correlation coefficient test were used to measure the correlation between responses at two different points.

Study Setting

This study involved carers who look after children with developmental disabilities experiencing drooling in Klang Valley.

Instrument

The original English version of the Drooling Infants and Preschoolers Scale (DRIPS) by Van Hulst et al. (7) is an instrument used to measure the ability of typically developing children aged 0-4 years to control drooling and acts as a drooling assessment tool to recognize drooling development milestones in children under four years old. The items of the DRIPS were generated based on knowledge about drooling, children's psychomotor development, and the development of saliva control from the carers' viewpoint. In addition, there were no validity and reliability evaluations reported on this assessment, except for its internal consistency. The DRIPS assessment showed high reliability, with good internal consistency (Cronbach's alpha value >0.82), and Pearson's correlation coefficients between the factors were significant, though moderate to weak (7). It is an observational, parent-rated questionnaire comprising 20 items divided into 3 sections: 1) basic information and health status, 2) drooling severity and frequency in various situations such as eating and drinking, and 3) the effects of teeth eruption and cold on drooling. When elevated values are observed across all contributing factors, it suggests that an overarching developmental delay may be at the root of the drooling issue (7). The score is compared to eight sex-specific reference charts based on the four factors derived from typically developing children aged 0-4 years old, acting as a norm-referenced tool (7). DRIPS incorporates four factors: First, drooling during activity (when in the prone position, assisted sitting, participating in gross and fine motor activities, and babbling/talking—items (8-11). Second, drooling during feeding (item 12). Third, drooling during non-nutritive sucking (items 13 and 14), and fourth, drooling when sleeping in various positions (item 15).

Ethical Clearance

Ethical approval was obtained from the Faculty Ethics Research Committee (FERC), Universiti Teknologi MARA (UiTM) prior to data collection. The reference number is FERC/FSK/MR/2023/00132.

RESULTS

Stage 1: Translation Process

Initially, two certified TESL translators independently translated the instructions and questions, resulting in two distinct Malay versions of DRIPS. These versions were then harmonized through collaboration between the translators and the researcher, leading to a unified version of DRIPS. Throughout the translation process, certain terms posed challenges. For example, the term 'drooling' in Malay could be expressed as 'air liuh meleleh' or 'pengeluaran air liur.' To ensure clarity, 'pelelehan air liur' was chosen for its familiarity in the Malay language (15). Similarly, the term 'tummy position' was deliberated and resolved as 'meniarap' after thorough discussion, referencing Dewan Bahasa dan Pustaka (15). After the initial harmonized Malay version was crafted, two additional certified TESL translators took on the task of backward translation, translating the assessment back into English. Factors such as format, wording, grammatical structure, and overall meaning and relevance were carefully scrutinized. Upon completion of both forward and backward translations, collaboration with an expert committee took place, consisting of both forward and backward translators alongside researchers. The expert committee reached a consensus on the instructions, questions, wording, and overall assessment, leading to the development of the pre-final version of the translated DRIPS.

Stage 2: Content Validity

A total of six expert panels actively participated in assessing the content validity, and the process involved a review by experts of the 16 questions related to drooling frequency and severity in the M-DRIPS. The assessment criteria included evaluating each question's relevance, clarity, simplicity, and ambiguity. All questions scored an I-CVI value of 1.0 for relevance, indicating unanimous agreement among experts that each question effectively captured the concept of drooling frequency and severity from the caregiver's perspective. The S-CVI/Ave and S-CVI/UA values for clarity and simplicity also met the acceptable criteria,

further validating the robustness of the instrument. Table I provides the evaluation of the content validity of the M-DRIPS, focusing on item relevance. The kappa value (k*) for each question showcased an impressive value of 1.0, indicating excellent agreement among experts regarding the relevance of each item. All 16 questions in the M-DRIPS demonstrated excellent content validity, meeting the criteria of (I-CVI ≥1.0 and k*≥1.0). This implies unanimous consensus among experts that each item is not only relevant but also essential in capturing the intricacies of drooling frequency and severity from the caregiver's perspective.

Stage 3: Face Validity

Based on Table II, the values for clarity and comprehension are predominantly excellent, with an I-FVI of 1.0 for most questions. However, exceptions are noted in items 4, 14, and 16, where the I-FVI values are 0.9 each. These slightly lower values still indicate a high level of appropriateness, as acknowledged by DeVon et al. (5). The S-FVI values further support the overall robustness of the instrument, with an S-FVI/AVE of 0.98 and an S-FVI/UA of 0.81.

Stage 4: Internal Consistency

The study involved 31 parents of children aged 2 to 7 years, all diagnosed with one of the following conditions: Cerebral Palsy (CP), Autism Spectrum Disorder (ASD), or Global Developmental Delay (GDD). All participants were Malay, with ages ranging from 25 to 40 years old. The parents were recruited from private centres within the Klang Valley, Malaysia. The demographic characteristics of their children are presented in Table III. The analysis revealed strong overall internal consistency for the 16 items of the M-DRIPS, as indicated by a Cronbach's alpha coefficient of 0.82, based on these

Table I: Evaluation of the Content Validity of the M-DRIPS (n=6)

Question	Number of experts	The number giving a rating of 3 or 4	CVR	I-CVI	Pc	k*	Evaluation
Item 1 (Q8)	6	6	1.0	1.0	0.016	1.0	Excellent
Item 2 (Q9)	6	6	1.0	1.0	0.016	1.0	Excellent
Item 3 (Q10)	6	6	1.0	1.0	0.016	1.0	Excellent
Item 4 (Q11)	6	6	1.0	1.0	0.016	1.0	excellent
Item 5 (Q12)	6	6	1.0	1.0	0.016	1.0	Excellent
Item 6 (Q13)	6	6	1.0	1.0	0.016	1.0	Excellent
Item 7 (Q14)	6	6	1.0	1.0	0.016	1.0	Excellent
Item 8 (Q15)	6	6	1.0	1.0	0.016	1.0	Excellent
Item 9 (Q15 a))	6	6	1.0	1.0	0.016	1.0	Excellent
Item 10 (Q15 b))	6	6	1.0	1.0	0.016	1.0	Excellent
Item 11 (Q15 c))	6	6	1.0	1.0	0.016	1.0	Excellent
Item 12 (Q16)	6	6	1.0	1.0	0.016	1.0	Excellent
Item 13 (Q17)	6	6	1.0	1.0	0.016	1.0	Excellent
Item 14 (Q18)	6	6	1.0	1.0	0.016	1.0	Excellent
Item 15 (Q19)	6	6	1.0	1.0	0.016	1.0	Excellent
Item 16 (Q20)	6	6	1.0	1.0	0.016	1.0	Excellent
			S-CVI/AVE	1.0			
S-CVI/UA				1.0			

Table II: Evaluation of Face validity of M-DRIPS (n=10)

Top of Form Question	Raters in Agreement	I-FVI	UNIVERSAL AGREEMENT /UA
Item 1 (Q8)	10	1.0	1.0
Item 2 (Q9)	10	1.0	1.0
Item 3 (Q10)	10	1.0	1.0
Item 4 (Q11)	9	0.9	0.0
Item 5 (Q12)	10	1.0	1.0
Item 6 (Q13)	10	1.0	1.0
Item 7 (Q14)	10	1.0	1.0
Item 8 (Q15)	10	1.0	1.0
Item 9 (Q15 a))	10	1.0	1.0
Item 10 (Q15 b))	10	1.0	1.0
Item 11 (Q15 c))	10	1.0	1.0
Item 12 (Q16)	10	1.0	1.0
Item 13 (Q17)	10	1.0	1.0
Item 14 (Q18)	9	0.9	0.0
Item 15 (Q19)	10	1.0	1.0
Item 16 (Q20)	9	0.9	0.0
S-FVI/AVE		0.98	
S-FVI/UA			0.81

Table III: Demographic characteristics of children with developmental disabilities that experienced drooling (n=31)

No	Variable	n (%)
1	**Child's Age**	
	2 - 3 years old	10(33.3)
	4 – 5 years olds	15(50.0)
	6 – 7 years olds	6(19.4)
2	**Child's Gender**	
	Male	24(77.4)
	Female	7(22.6)
3	**Prematurity**	
	Full term	21(67.7)
	Preterm	10(32.3)
4	**Child's Diagnosis**	
	Cerebral Palsy	11 (35.5)
	Global Developmental Delay	9(29.0)
	Autism spectrum disorder	11(35.5)

31 participants. These findings suggest that the Malay version of DRIPS demonstrates a commendable level of consistency, as shown in Table IV.

Table IV: Mean, Standard Deviation (SD), Item-Total Correlation, and Alpha Coefficient If Item Deleted

Variables	Mean (SD)	Item-total correlation 16-item	Alpha, if the item deleted 16-item
Item 1 (Q8)	2.94(1.46)	.59	.80
Item 2 (Q9)	2.61(1.33)	.66	.80
Item 3 (Q10)	2.77(1.80)	.55	.80
Item 4 (Q11)	3.42(1.73)	.56	.80
Item 5 (Q12)	2.13(1.41)	.61	.80
Item 6 (Q13)	1.16(1.32)	.34	.82
Item 7 (Q14)	1.29(1.30)	.17	.83
Item 8 (Q15)	2.9(1.04)	.48	.81
Item 9 (Q15 a))	3.16(1.07)	.50	.81
Item 10 (Q15 b))	3.23(1.20)	.34	.82
Item 11 (Q15 c))	3.16(1.40)	.38	.81
Item 12 (Q16)	1.90(1.54)	.52	.81

Stage 5: Test-Retest Reliability

The parametric test, Pearson correlation coefficient (r), was used to determine the correlation between the responses at two time points of the M-DRIPS, with a 2-week gap. Both the Pearson correlation coefficient (r) and Spearman's rank correlation coefficient (rs) were used to measure the strength of the linear relationship between two quantitative variables. The Pearson correlation coefficient revealed a strong or large relative strength of association between the total scores of the first and second responses of the M-DRIPS (initial test and retest), with Pearson's $r = 0.99$, $p < 0.001$ for the first factor, which is Activities. This indicates that the M-DRIPS strongly correlates with the original English version of DRIPS. Additionally, the Spearman's rank correlation coefficient (rs) also showed a strong or large relative strength of association between the total scores of the first and second responses (initial test and retest), with Spearman's rs ranging from 0.95 to 0.96, $p < 0.001$ for the second, third, and fourth factors—feeding, non-nutritive sucking, and sleep, respectively. This further supports that the M-DRIPS strongly correlates with the original English version of DRIPS. Table V below shows the mean (SD) and median (IQR) for each factor of M-DRIPS in both the initial test and retest.

DISCUSSION

Translation Process of M-Drips

In the translation phase, the process adhered to contemporary guidelines as outlined by Tsang et al. (14), which have been cited in similar studies by other researchers for the translation and validation of various questionnaires (16-18). Four independent translators were engaged, with each pair handling the forward and backward translation, respectively. This approach aligns with recommended guidelines, which specify that the initial translation from the source to the target language should involve at least two independent translators (19-20). Similarly, the backward translation should also be conducted by two independent translators (19).

Content Validity of M-Drips

Prior research lacks specific benchmarks or values that guide the modification and enhancement of question clarity, simplicity, and ambiguity. However, it is recommended to refine questions while ensuring that these adjustments preserve the relevance of the questions within the instrument (21). In this phase, all 16 items of the M-DRIPS exhibited a perfect I-CVI value of 1.0 for the relevance component, leading to the retention of all questions in the instrument. Currently, there is no published study regarding the CVI value for any version of DRIPS. However, a previous study demonstrated similar results in terms of study procedures for the translation and content validity examination of another drooling assessment, the Drooling Impact Scale (DIS). The DIS exhibited good content validity, with item generation based on parent and expert opinions (3,4,12). Additionally, other translations, cross-cultural adaptations, and validations of assessments into the Malay version have yielded similar results to this study, with a CVI value of 0.91, indicating good relevance as an outcome measure (22). Although this study demonstrated a high CVI value compared to previous studies, direct comparisons are challenging due to the use of different evaluation tools. Furthermore, the Content Validity Ratio (CVR) also yielded excellent results, aligning with the Korean version of DRIPS, which showed a good CVR value (13). While CVR informs us about the validity of individual items, CVI is preferable when assessing the content validity of the

Table V: Mean (SD) for Each Factors of M-DRIPS and the correlation between the responses at the two time points

Variables	Mean (SD) M-DRIPS	Mean (SD) for M-DRIPS after 2 weeks	Median (IQR) for M-drips	Median (IQR) for M-Drips after 2 weeks	Spearmen Correlation coefficient (r_s)	Pearson correlation coefficient (r)
Total score based on 4 factors:						
Factor 1 Activity	13.65 (6.17)	13.55(5.84)				0.99 (<0.00)
Factor 2 Feeding			2(1)	2(1)	0.96 (<0.00)	
Factor 3 Non-Nutritive sucking			2(4)	2(4)	0.95[a] (<0.00)	
Factor 4 Sleep			2(4)	2(4)	0.96[a] (<0.00)	

entire instrument or tool, as it is more efficient to report the overall CVI score than individual item CVRs. Both CVR and CVI provide researchers and consumers with a quantitative measure of the validity of a simulation evaluation instrument (23). In summary, the content validity results supported the decision to retain all items in the M-DRIPS, with the kappa value determined to be 1.0, indicating an excellent level of agreement.

Face Validity of M-Drips

Similar to previous face validity studies, this study yielded positive results, indicating good face validity and providing robust evidence for the response process, with an S-FVI/Ave of 0.867 (24). The FVI for clarity and comprehension ranged from 0.87 to 0.97 among the laypersons in the assessment, signifying a high level of face validity in terms of clarity and comprehensibility. This also indicates a strong response process (5,25).

Internal Consistency Reliability of M-Drips

The Cronbach's alpha value indicated that M-DRIPS demonstrated good internal consistency reliability, likely resulting from the interconnectedness of all factors within each item. According to Collins (26), Cronbach's alpha is a metric used to evaluate reliability, measuring the extent of shared variance (or covariance) among the components of an instrument compared to the overall variance. The underlying premise is that a reliable instrument should show substantial covariance among its items relative to the total variance. This finding aligns with the original English version of DRIPS by Van Hulst et al. (7), which showed high reliability across all factors, with Cronbach's $\alpha > 0.82$. Additionally, this study's results are consistent with those of other drooling assessments, such as the Modified Drooling Questionnaire, the French version of the Drooling Impact Scale (DIS-F), and the Brazilian Portuguese version of the Drooling Impact Scale, which reported Cronbach's α values ranging from > 0.87–0.88, α Cronbach = 0.71, and > 0.72, respectively (3,4,27). These findings establish the reliability of the translated version of M-DRIPS, affirming its suitability for use in measuring drooling severity and frequency.

Test-Retest Reliability of M-Drips

The analysis of test-retest reliability, using both Pearson and Spearman's rank correlation coefficients, revealed a strong correlation between responses at the two time points. This finding is consistent with previous studies reporting good test-retest reliability in assessments such as the Drooling Impact Scale (DIS), the French version of DIS, and the Modified Drooling Questionnaire. These assessments reported concordance correlation coefficients of 0.85 (standard error 0.05), 0.83 (standard error 0.06), Pearson correlation coefficients of 0.89, and intraclass correlation (ICC) values of 0.95 (95% CI 0.914–0.984, $p < 0.0001$) for the first investigator, and ICC of 0.96 (95% CI 0.944–0.99, $p < 0.0001$) for the second investigator (4,12,27). These results further confirm the reliability of M-DRIPS as an effective tool for measuring drooling frequency and severity in children with developmental disabilities.

CONCLUSION

The main objectives of this study centered on the translation and validation of the DRIPS assessment into the Malay language. By employing established methodologies and adhering to recognized guidelines, the M-DRIPS was successfully translated and adapted. A rigorous evaluation of its psychometric properties was conducted, affirming its good content validity, as evidenced by the retention of all 16 items in the instrument. Additionally, the face validity assessment, involving 10 caregivers of children with developmental disabilities experiencing drooling, further supported the instrument's relevance. The internal consistency reliability and test-retest reliability of the M-DRIPS were also found to be commendable, solidifying its standing as a valid and reliable instrument. In summary, the outcomes of this study affirm that the M-DRIPS exhibits strong psychometric properties, making it a valuable tool for assessing drooling severity and frequency, particularly within the population of children with developmental disabilities. However, several limitations were identified. First, the absence of preliminary pilot testing following the translation process poses risks, including potential issues with clarity and cultural relevance. While this omission may have been a time-saving strategy, pilot testing is crucial for identifying and addressing challenges early in the validation stages to ensure a well-structured and culturally appropriate questionnaire. Without this phase, unforeseen complications may arise, potentially compromising the study's validity. Furthermore, the study faced constraints regarding sample size, particularly in the internal consistency reliability and test-retest reliability assessments. Time limitations hampered participant recruitment, which affected the generalizability and statistical power of the study's outcomes. Future studies should prioritize a comprehensive examination of an instrument's psychometric properties, including a rigorous exploration of concurrent, construct, and criterion validity. Expanding the sample size to include a larger, more diverse population of children with developmental disabilities experiencing drooling, encompassing a variety of diagnostic backgrounds, would enhance the generalizability of the findings.

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