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Psychometric evaluation of the Chinese version of the Fonseca anamnestic index for temporomandibular disorders

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| INTRODUCTION 1

Abstract

Background: The Fonseca anamnestic index (FAI) offers a simple, low-cost, patientreported method for screening temporomandibular disorders (TMDs).

Objectives: This study described the development of the Chinese version of the FAI (FAI-C) and examined its reliability and validity when compared to the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD).

Methods: The FAI-C was created by translation and cross-cultural adaptation of the English instrument following international guidelines. Psychometric evaluation of the FAI-C was carried out on a sample of 613 patients with TMDs and 57 controls. Reliability of the FAI-C was determined by means of internal consistency and testretest methods while validity was ascertained by criterion-related validity. Criterion validity was examined via Cohen's kappa, sensitivity and specificity when compared with DC/TMD Axis I diagnoses.

Results: Cronbach's alpha value (internal consistency) for total FAI-C score was 0.669, and intra-class correlation coefficient (ICC) value (test-retest reliability) was 0.823. For criterion validity, kappa coefficient value was 0.633 while sensitivity and specificity was 95.9% and 71.9%, respectively.

Conclusion: The Chinese version of the FAI demonstrated acceptable reliability and good validity. The FAI-C could thus be used as an instrument for screening TMDs in Chinese literate populations.

KEYWORDS

Fonseca anamnestic index, reliability, temporomandibular disorders, translation, validity

Temporomandibular disorders (TMDs) is a collective term embracing a number of clinical problems concerning the temporomandibular joints (TMJs), masticatory musculature and/or their associated structures.¹ Signs and symptoms of TMDs include headache, masticatory muscle and/or TMJ pain, joint noises as well as deviated and/or limited mouth opening.² TMDs is a significant public health problem and affect 14.9%-61.9% of Chinese populations.³⁻⁷ A metaanalysis investigating the occurrence of TMDs from 1979 to 2017 in China showed an overall prevalence of 29.1% in Chinese youths.⁸ Epidemiological studies on adult Chinese populations have reported higher prevalence ranging from 33.3% to 61.9%.⁴⁻⁷

In the forementioned epidemiological studies,⁴⁻⁸ propriety selfreported questionnaires, the Helkimo index, Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) or Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) were employed. While some of these diagnostic methods are relatively complex and time-consuming involving face-to-face interviews and trained/calibrated clinical examinations,⁵⁻⁷ others (propriety self-reported questionnaires) have low methodological quality and accuracy.^{4,5} The RDC/TMD and DC/TMD were designed for use in both ILEY-REHABILITATION

clinical and research situations, but their comprehensive protocol is not pragmatic for large-scale studies.^{9,10} Therefore, abbreviated Axis I (physical) and Axis II (pain behaviour, psychological status and psychosocial functioning) screening tools including the DC/TMD Pain Screener and Jaw Functional Limitation Scale-8 (JFLS-8) were incorporated.¹¹⁻¹³ Most of these screening tools are, however, uni-dimensional and evaluate explicit Axis I or II characteristics of TMDs. The TMD Pain Screener as an example merely targets pain-related TMDs and non-painful TMJ disorders and diseases are not considered.¹¹ Furthermore, the TMD Pain Screener does not permit the severity of TMDs to be quantified. The aforementioned may limit its use as an assessment tool in population-based epidemiological studies.

To facilitate comparison between studies, there is a need for a standardised short and simple but reliable and valid patient-reported tool for epidemiological TMDs investigations. The Fonseca anamnestic index (FAI) is a 10-item multi-dimensional instrument that assesses pain frequency, psychological distress, jaw function limitations and parafunctional behaviours associated with TMDs.¹⁴ It was developed based on the Helkimo index and has been mooted as a simple, low-cost, patient-reported TMDs assessment tool.¹⁵ The FAI was found to be consistent with other instruments used to screen and diagnose TMDs including the American Association of Orofacial Pain Questionnaire and the Jaw Symptom and Oral Habit Questionnaire.¹⁶ It has high accuracy, sensitivity and specificity for identifying myogenous TMDs in community samples and allows severity of TMDs to be graded.^{15,17,18} The FAI has been utilised by clinicians and researchers for clinical screening and prevalence studies that have public health policy practice and policy implications.¹⁸⁻²³

The FAI was originally developed in Portuguese and translated into English.¹⁸⁻²³ Although the English FAI is widely used, it has limited utility in countries and cohorts based on the Chinese language due to literacy and cultural issues. For the FAI to be employed in China and other Chinese literate populations, it needs to be translated into the Chinese language and the translated instrument must be assessed for reliability and validity. The objectives of the present study were thus to translate and cross-culturally adapt the FAI from English into Chinese and to evaluate the psychometric properties of the Chinese FAI (FAI-C).

2 | METHODS

2.1 | Translation process

The International Network for Orofacial Pain and Related Disorders Methodology (INfORM) guidelines for establishing cultural equivalency of instruments were implemented.²⁴ The translation and cross-cultural adaption process involved the following stages:

- 1. Forward translation
- 2. Synthesis and resolution of discrepancies
- 3. Backward translation
- 4. Expert committee review and revision
- 5. Test of the pre-final version and revision

6. Psychometric evaluation of the final version

The forward-backward technique employed is detailed below^{25,26}:

2.1.1 | Forward translation

Two bilingual translators (a university language lecturer and a TMDs specialist) whose mother tongue was Chinese, independently translated the English FAI into Chinese. This resulted in two Chinese language versions of the FAI.

2.1.2 | Synthesis and resolution of discrepancies

Discrepancies in word choices between the two Chinese translations were discussed and resolved by a consensus committee comprising the translators and principal investigator (FKY). A synthesised common Chinese translation was subsequently produced.

2.1.3 | Back-translation

The synthesised Chinese translation was then back-translated into English by an independent translator (a university student whose mother tongue was English but understood Chinese) that was blinded to the original English FAI.

2.1.4 | Expert committee review and revision

An expert committee comprising a dental specialist with profound knowledge of TMDs and another language professional, who were not involved in any of the prior processes, consolidated and examined all versions of the FAI. Semantic, idiomatic, experiential and conceptual equivalences were reviewed and discussed with the principal investigator and the pre-final FAI-C was developed through consensus.

2.2 | Test of the pre-final FAI-C and revision

Congruency between the pre-final FAI-C and the source (English) instrument was carried out to ensure all meanings were retained. A total of 74 undergraduates aged over 18 years old from Peking University Health Science Center were recruited. The participants were effectively bilingual and had no knowledge of TMDs. Thirty-seven participants completed the English version, followed by the Chinese version while the other 37 participants completed the English version. Intra-subject variability was minimised by answering the two versions one after the other. The two versions were evaluated for congruencies or consistencies in replies.

The percentage of congruent/consistent scores of individual items reflected the agreement between the source (English) and translated (Chinese) version. Agreement rating of each item between the two versions was calculated using the following formula²⁷:

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Percentage of agreement = (Number of exact agreements/ Number of total possible agreements) × 100%.

The percentage of agreement should ideally be no <90%.²⁷ If this was not achieved, the expert committee would review the translated item and make the needed modifications to achieve cultural relevancy. The final version of the FAI-C was eventually created.

2.3 | Psychometric evaluation of the FAI-C

Approval from the Biomedical Institutional Review Board of Peking University was obtained before starting the study (PKUSSIRB-2012002). A total of 613 patients with TMDs, who visited the Center for TMDs and Orofacial Pain, Peking University School and Hospital of Stomatology, and 57 non-TMDs controls from Peking University were enrolled. Informed consents were obtained from all participants or their guardians if they were younger than 18 years old. All patients with TMDs underwent a standardised history taking and examination and were diagnosed with TMJ and/ or masticatory muscle disorders based on the DC/TMD.⁹ Subject exclusion criteria were as follows: (a) presence of suppurative TMJ arthritis and/or organic TMJ pathology; (b) presence of systematic joint diseases (eg rheumatoid arthritis); (c) history of psychiatric disorders (eg manic-depressive psychosis); and (d) unable to understand the FAI-C independently including illiteracy.

Age of the patients with TMDs ranged from 11 to 78 years, with a mean age of 29.48 \pm 13.97 years. The non-TMDs controls also underwent the standardised history taking and examination but showed no evidence of any TMDs signs and symptoms. Age of the non-TMDs controls ranged from 20 to 30 years, with a mean age of 24.32 \pm 2.32 years. All subjects were asked to complete the FAI-C (Table 1), and 41 randomly selected patients with TMDs were recalled at 1 week during which the FAI-C was re-administered. Any treatment was only prescribed after completion of the retest visit. For the FAI-C, subjects were required to score the individual items on a 3-point response scale with no, sometimes and yes conferring 0, 5 and 10 points, respectively. Summary scores for all 10 items were subsequently computed and used to classify severity of TMDs (Table 2). Data acquired from the surveys were used to determine internal consistency, test-retest reliability and criterion validity.

2.4 | Statistical analysis

Statistical analysis was performed with the Statistical Package for Social Sciences version 24 (IBM Corporation), and significance level was set at 0.05. Internal consistency was evaluated by calculating Cronbach's alpha coefficients. Internal consistency was considered acceptable when coefficient value was above 0.70. Test-retest reliability was assessed by intra-class correlation coefficients (ICC) using data from the 41 subjects who repeated the FAI-C after a 1-week interval. ICC scores of <0.40, 0.41-0.60, 0.61-0.80 and >0.80 denoted poor to fair, moderate, good and excellent agreement, respectively.

Criterion-related validity was examined by determining the agreement between the FAI-C and DC/TMD Axis I diagnoses

TABLE 1 The English and the Chinese version of the Fonsecaanamnestic index (FAI) questionnaires

	Answers		
Item number/Questions	No 否	Sometimes 有时	Yes 是
1. Do you have difficulty ope	ning your n	nouth wide?	

你是否有大张口困难? 2. Do you have difficulty moving your jaw to the sides?

你是否在下颌向侧方运动时有困难?

3. Do you feel fatigue or muscle pain when you chew? 你在咀嚼时是否感到肌肉疲劳或肌肉疼痛?

4. Do you have frequent headaches? 你是否经常头痛?

5. Do you have neck pain or stiff neck? 你是否感到颈部疼痛或颈部僵硬?

6. Do you have ear aches or pain in that area (temporomandibular ioint)?

你是否有耳痛或关节区域的疼痛?

7. Have you ever noticed any noise in your temporomandibular joint while chewing or opening your mouth?

当咀嚼或张口时, 你是否注意到关节内有声响?

8. Do you have any habits such as clenching or grinding your teeth? 你是否有紧咬牙或磨牙的习惯?

9. Do you feel that your teeth do not come together well? 你是否感觉上下牙齿没有接触好?

10. Do you consider yourself a tense (nervous) person? 你觉得自己是一个紧绷 (精神紧张)的人吗?

TABLE 2 Classification of TMDs severity based on the Fonseca

 anamnestic index
 Index

	Scores
TMD-free	≤15
Mild TMD	20-40
Moderate TMD	45-65
Severe TMD	70-100

with regard to the presence or absence of TMDs using Cohen's kappa. TMDs was deemed to be present if FAI-C scores were >15 or if a DC/TMD Axis I diagnoses (TMJ and/or masticatory muscle disorders) exists. TMDs was considered absent if FAI-C scores were ≤15 or if no DC/TMD Axis I diagnoses was present. Kappa coefficient (k) values of ≤0.40, 0.41-0.60, 0.61-0.80 and >0.80 indicated poor, moderate, good and excellent agreement, respectively. Criterion validity was further assessed by determining the sensitivity and specificity of the FAI-C when measured to the DC/ TMD gold standard. Sensitivity (capacity to recognise true positives, namely, the proportion of TMDs individuals determined by the FAI-C in relation to the total number of patients with TMDs established by the DC/TMD) was calculated using the following formula: Sensitivity = True Positive/(True Positive + False Negative). Specificity (capacity to recognise true negatives, namely, proportion of TMDs-free individuals determined by the WILEY REHABILITATION

Subscale	Internal consistency (Cronbach's alpha) if item deleted (n = 613)	Corrected item-total correlation (n = 613)	Test-retest (ICC) (n = 41)	ICC (95%) (n = 41)
Item 1	0.657	0.271	0.819	0.688-0.899
Item 2	0.638	0.368	0.576	0.333-0.747
Item 3	0.613	0.489	0.669	0.505-0.826
Item 4	0.631	0.414	0.780	0.627-0.876
Item 5	0.626	0.429	0.762	0.599-0.865
Item 6	0.634	0.389	0.726	0.544-0.843
Item 7	0.679	0.133	0.518	0.258-0.709
Item 8	0.664	0.237	0.849	0.736-0.916
Item 9	0.665	0.243	0.774	0.616-0.872
Item 10	0.640	0.356	0.677	0.604-0.867

FAI-C in relation to the total number of non-TMDs controls established by the DC/TMD) was calculated using the following formula: Specificity = True Negative/(True Negative + False Positive). Chi-square test was used to compare the diagnostic efficiency of FAI-C with DC/TMD.

3 | RESULTS

3.1 | Congruency testing

A total of 74 participants completed both the English and Chinese versions of the FAI. The percentage of agreement for all the items was over 90% (ranged from 90.5% to 98.6%). The items which were not congruent showed either 1- or 2-point variances on the 3-point response scale. The percentage of agreement was subsequently recalculated to allow for a 1-point intra-rater variability. Only item 3 (Do you feel fatigue or muscle pain when you chew?), item 4 (Do you have headaches?) and item 9 (Do you feel that your teeth do not come together well?) did not achieve a 100% congruency. Their percentage of congruency were, however, still very high and were 98.6%, 98.6% and 95.9%, respectively.

3.2 | Reliability testing

Cronbach's alpha value (internal consistency) for the total FAI-C score was 0.669. The corrected item-total correlations ranged from 0.133 (item 7) to 0.489 (item 3) (Table 3). All items except for item 7 (TMJ noise while chewing or mouth opening) reached the recommended minimum correlation of 0.20 (Table 3).

Test-retest reliability was calculated for the 41 participants who repeated the FAI-C after 1 week. The 95% confidence intervals of the means were computed. ICCs for the total score of FAI-C was 0.823 (95% CI = 0.694-0.901, P < .001), and values for the subscales ranged from 0.518 (95% CI = 0.258-0.709, P < .001) to 0.849 (95% CI = 0.736-0.916, P < .001) indicating moderate to excellent correlations, respectively (Table 3). Overall, these results suggested acceptable reliability for the FAI-C.

3.3 | Validity testing

Criterion validity was evaluated by kappa (k) coefficient, sensitivity and specificity. Good agreement (kappa coefficient = 0.633) was observed between the FAI-C and DC/TMD Axis I diagnoses. The sensitivity of the FAI-C was 95.9%, and specificity was 71.9%. No significant difference was noted between the two diagnostic methods (P = .211) (Table 4). Findings suggest that the FAI-C had acceptable reliability and good validity.

4 | DISCUSSION

This is the first study to translate and cross-culturally adapt the English version of the FAI into Chinese. The FAI-C showed acceptable reliability and good validity in the Chinese population studied. As the FAI is short and not time-consuming to administer, it is generally well accepted by participants (especially those with limited concentration) of epidemiological studies.¹⁷ In addition, it can also be utilised for telephone surveys.²⁸ The aforementioned warranted its translation and cross-cultural adaption into Chinese so that it can be used in Chinese literate populations in China and other countries.

Cross-cultural adaptation is a term that addresses both linguistic and cultural adjustment issues when translating an instrument into another language setting.²⁵ In this study, semantic, idiomatic, experiential and theoretical equivalence were achieved following international guidelines for establishing cultural equivalency of instruments. At the pre-testing stage, one group of participants completed the Chinese followed by the English version and the other group did the reverse. All items exhibited a percentage agreement above the critical 90% cut-off.²⁷ Based on a 1-point variance,²⁷ all items achieved a 100% agreement with the exception of items 3, 4 and 9. Item 9 (Do you feel that your teeth do not come together well?) resulted in a relatively lower congruency (95.9%) when compared to the other items. This may be contributed in part by the difficulty encountered when finding a semantic equivalence in the forward translation process. The phrase "come together well" was literally translated and

TABLE 4 Sample distribution based on FAI-C classification and DC/TMD diagnosis, respectively

	DC/TMD			
	With TMD	TMD-free	Total	Р
FAI-C				
With TMD	588	16	604	.211*
TMD-free	25	41	66	
Total	613	57	670	

Note: Kappa (k): 0.633; Sensitivity: 95.9%; Specificity: 71.9%. *Chi-square test.

meant "occlude well" in Chinese, which was chosen as it was considered the closest match. This semantic difficulty was also faced in the back-translation process where it was back-translated into English as "articulate well when you bite". A more appropriate Chinese phrase for this item may thus be desired.

With regard to the reliability of the FAI-C, Cronbach's alpha correlation was found to be 0.67 (items 1-10), and internal consistency was close to the critical value of 0.70. With the exception of item 7 (TMJ noises), all items attained the recommended minimum correlation of 0.20 (Table 3). There appears to be a relatively lower consistency between item 7 and other items of FAI-C as Cronbach's alpha correlation was slightly increased (from 0.67 to 0.68) when item 7 was deleted. TMJ sounds such as clicking or popping noises during chewing or mouth opening are, however, characteristics of TMDs and previous studies have shown that item 7 is a major item of the primary dimension of the FAI, even in its shortened form.^{14,21,28} Hence, deletion of item 7 was not recommended. Moreover, other researchers had reported an acceptable internal consistency coefficient of 0.56 for the FAI.²⁰

For the test-retest reliability, an interval of 1 week was chosen for this study. The test-retest reliability of all items showed good to excellent correlation, with the exception of items 2 and 7, which had moderate correlation (Table 3). TMJ noises (item 7) can sometimes be difficult to detect, even with auscultation using a stethoscope, and may be present only intermittently. In addition, TMDs signs and symptoms tend to fluctuate over time.^{29,30} Hence, it is possible that TMJ noises might disappear during the 7-day interval. As for item 2 (having difficulty moving jaw to the sides), the discrepancy could be attributed to the self-limiting nature of TMDs (symptom relieve may occur spontaneously over time) and the small range of normal lateral excursions. Findings suggest that the FAI-C is a reasonably reliable and stable instrument for assessing TMDs.

As for criterion-related validity, the FAI-C exhibited good agreement with DC/TMD Axis I diagnoses (kappa coefficient = 0.633) as well as good sensitivity (95.9%) and moderate specificity (71.9%) when compared to the DC/TMD in adolescents and adults. Other researchers found low sensitivity (53.40%) but comparable specificity (77.27%) in children and adolescents.³¹ Another study demonstrated excellent diagnostic accuracy, with sensitivity and specificity of 86.3% and 91.9%, respectively, in female subjects with myofascial pain.¹⁷ Results may thus vary depending on TMDs subtypes, age and gender and warrant further investigation. Moreover, TMD-free participants constituted only 8.5% of the total sample, which may possibly reduce the specificity of FAI-C and consequently lead to a higher detection rate of TMDs. Overall, findings suggested good validity of the FAI-C.

Although the present study showed acceptable reliability and good validity of the FAI-C, there were several limitations. Firstly, the FAI-C was translated from the English FAI and not the original Portuguese version. While some meaning may be lost with subsequent translations of the original source, direct translation from Portuguese to the Chinese language was not feasible due to need for multiple bilingual lay and dental translators as specified in the INFORM guidelines. Secondly, the participants were not recruited from the general population. This could result in a selection bias as the patients with TMDs and controls are not representative of the general population. Further studies involving the general population in different parts of China and Chinese communities in other countries are warranted. Thirdly, the FAI is a self-reported questionnaire that did not involve any clinical examinations. Recall and reporting bias may exist. Test-retest reliability, however, showed good correlations. Lastly, while previous studies showed that the FAI has good sensitivity and validity for muscular and pain-related TMDs.^{14,17,28} no data are currently available for joint disorders. This necessitates further investigation together with age and gender as possible confounders. Furthermore, all TMDs subtypes were included in our study and could have improved the sensitivity and specificity of the FAI-C. Further studies pertaining to the FAI-C should be conducted on general populations in China and other countries to confirm the generalisability of the current work. The FAI-C, like the FAI, does not measure TMDs pain severity and the pain-related disability. Furthermore, the FAI equates more symptoms to greater TMDs severity. Clinically, this assumption may not be accurate as a single symptom can result in more functional limitations, pain and psychosocial disability than multiple symptoms. There are also some flaws with its scoring system, for example positive answers to the three questions on headache, neck pain and the perception of emotional tension would result in a diagnosis of mild TMDs. However, these symptoms can also occur in isolation without the presence of TMDs. Several studies had also demonstrated better validity^{14,21,28} and reliability^{14,20,21,28} for the short-form FAI. Future work on the development of new TMDs screeners based on conceptual models of both the DC/TMD and FAI is necessary.

5 | CONCLUSIONS

The English FAI was successfully translated into Chinese and culturally adapted for use in Chinese populations. The present study provided preliminary evidence on the acceptable reliability and good validity of the FAI-C. The FAI-C holds promise as a screening instrument for TMDs in China and other Chinese literate populations.

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CONFLICT OF INTEREST

The authors declare no conflict of interests.

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