• Clinical Research •

Psychometric validation of the Chinese version of the dry eye-related quality-of-life score questionnaire

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Abstract

● **AIM:** To psychometrically validate the Chinese version of the dry eye-related quality-of-life score questionnaire (DEQS-CHN) among Chinese patients with dry eye.

● **METHODS:** This study involved 231 participants, including 191 with dry eye disease (DED) comprising the dry eye disease group, and 40 healthy participants forming the control group. Participants were required to complete the DEQS-CHN, and Chinese dry eye questionnaire and undergo clinical tests including the fluorescein breakup time (FBUT), corneal fluorescein staining (CFS), and Schirmer I test. To assess the internal consistency and retest reliability, Cronbach's α and the intraclass correlation coefficient (ICC) were employed. Content validity was assessed by item-level content validity index (ICV) and an average scale-level content validity index (S-CVI/Ave). Construct validity was assessed by confirmatory factor analysis. The concurrent validity was assessed by calculating correlations between DEQS-CHN and Chinese dry eye questionnaire. Discriminative validity was evaluated through non-parametric tests, with receiver operating characteristic (ROC) curve serving as conclusive indicators of the questionnaire's distinguishing capability.

● **RESULTS:** The Cronbach's α coefficients for frequency and degree of ocular symptoms, impact on daily life, and summary score were 0.736, 0.704, 0.811, 0.818, 0.861, and 0.860, respectively, and the ICC were 0.611, 0.677, 0.715, 0.769, 0.711, and 0.779, respectively. All I-CVI scores ranged from 0.833 to 1.000, with an S-CVI/Ave of 0.956. Confirmatory factor analysis results exhibited a well-fitting model consistent with the original questionnaire [χ^2/df=2.653, incremental fit index (IFI)=0.924, comparative fit index (CFI)=0.924, Tucker-Lewis index (TLI)=0.909, and root mean square error of approximation (RMSEA)=0.065]. There was a moderate positive correlation between the DEQS-CHN and the Chinese dry eye questionnaire (r^2=0.588). The dry eye group demonstrated significantly higher scores compared to the control group, and the area under the curve (AUC) value was 0.8092.

● **CONCLUSION:** The DEQS-CHN has been demonstrated as a valid and reliable instrument for assessing the impact of dry eye disease on the quality of life among Chinese individuals with DED.

● **KEYWORDS:** dry eye; quality-of-life; questionnaire

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INTRODUCTION

Dry eye disease (DED) is a multifactorial ocular surface condition that is characterized by tear film instability and accompanied by dryness, foreign body sensation, pain, irritation, and other discomforts[1-2]. The global incidence of dry eye ranges from 5%-50%[3-4], and it is expected to increase with lifestyle and environmental changes[5-6], making it a global health concern. Diagnosing DED requires combining ocular symptom assessment with clinical dry eye tests[7]. Ocular symptom assessment is an important indicator for diagnosing and evaluating treatment efficacy in DED; in some cases, patients may only exhibit symptoms without ocular

surface damage[7]. In a clinical setting, ocular symptoms and other indicators are obtained through patient history inquiries. However, standardizing and quantifying these indicators can be difficult, so many questionnaires have been developed to evaluate DED in various aspects.

According to the DEWS II report, as a chronic condition, DED not only affects overall and ocular health with bothersome eye symptoms and visual impairments but also significantly disrupts patients' daily lives, normal activities, and imposes substantial economic burdens related to medication and clinic expenses, among other factors[3,8-9]. These collectively have a severe adverse impact on patients' quality of life.

To comprehensively assess the impact of dry eye on the daily lives of Chinese patients, only the Impact of Dry Eye on Everyday Life (IDEEL) questionnaire was developed with a focus on evaluating DED's influence on daily life quality[10]. However, due to its complex content and lengthy testing duration (typically requiring 30min), its clinical application has been limited. To expedite the assessment of dry eye's impact on Chinese patients more efficiently, we intend to translate the Dry Eye-Related Quality-of-life Score Questionnaire (DEQS) questionnaire for the evaluation of DED's impact on the daily life of Chinese dry eye patients. The DEQS questionnaire was developed and validated by the Japanese Ophthalmological Society in 2013, aiming to facilitate the effective assessment of various aspects of the daily lives of dry eye patients[11]. Validations have shown that the DEQS exhibits excellent psychometric properties, with Cronbach's α coefficients of 0.93 and internal consistency coefficients of 0.91[11].

In China, the prevalence and prevalence of DED are higher compared to the United States and Europe, reaching up to 30%[12]. Therefore, there is a need for a convenient and culturally adapted questionnaire specific to Chinese DED patients for a more comprehensive assessment of DED's impact on daily life. Hence, our study aimed to conduct a psychometric evaluation of the culturally adapted Chinese version of the DEQS questionnaire and explore its applicability and application value within the Chinese dry eye population.

SUBJECTS AND METHODS

Ethical Approval This study was conducted at Xiamen University and was approved by the Medical Ethics Committee of the School of Medicine, Xiamen University (identifier: XDYX2022003, February 1, 2022), and registered with the Chinese Clinical Trial Registry (identifier: ChiCTR2200060796, June 11, 2022), in accordance with the Declaration of Helsinki. Informed consent was obtained from all participants after a complete explanation of the study.

Translation and Cross-Cultural Adaption of the DEQS After obtaining permission from the original authors, the Chinese version of the dry eye-related quality-of-life score questionnaire was meticulously translated in adherence to established guidelines[13-14]. The translation process was as follows: 1) Forward translation and cultural adaption: Two translators, both native Chinese speakers with a proficiency level of N1 in Japanese, independently generated two versions. Subsequently, these versions underwent multiple iterations of modification and adjustment through collaboration with two forward translators and a cultural debugging group composed of 15 individuals, including 4 physicians, 1 medical student, 2 patients, 2 nurses, and 6 healthy volunteers, resulting in the consolidation of a single version known as DEQS-C V1. 2) Backward translation: Without prior exposure to the original questionnaire, two Chinese-Japanese bilingual translators, whose native language is Japanese, conducted a back-translation of the Chinese text into Japanese and, following careful discussion, merged them into DEQS-J V1. Through evaluation, the back-translated DEQS-J V1 version demonstrated strong consistency with the original text (95%). 3) Cross-cultural adaption: After evaluation, discussion, and modification by six dry eye experts and a cultural adaptation team, the initial version of Chinese version of the DEQS (DEQS-CHN) V1.0 was established. 4) Pre-test: We randomly selected 20 dry eye patients who did not participate in this study for pre-testing and decided that no further modifications to the questionnaire were necessary. The final version of DEQS-CHN can be found in the supplementary materials.

Study Procedure The sample size should ideally be 5-10 times the item of questions in the questionnaire[15]. Given that our questionnaire comprises 15 items, it is recommended to have a minimum of 150 participants. Therefore, taking into account the potential for sample loss, we enrolled 191 participants with DED as the DED group and 40 healthy participants as the control group at Xiamen University. Since there are no specific treatment measures for the dry eye population in this research plan, it is ethically inappropriate to select individuals with severe dry eye. There is a certain degree of population selection bias, which can be addressed in the future by expanding the sample size.

To be eligible for the study, participants needed to be 18y or older, able to complete 2 follow-up visits as planned and provide informed consent. Participants in the dry eye group had to be diagnosed with dry eye according to the diagnostic criteria outlined in the Expert Consensus on Dry Eye in China: Examination and Diagnosis (2020)[16]. 1) Patients who complain of subjective symptoms such as dryness, foreign body sensation, burning, fatigue, discomfort, redness, and fluctuating vision in the eyes, with a Chinese Dry Eye Questionnaire score ≥7 points, and have a fluorescein breakup time (FBUT) ≤5s or noninvasive tear breakup time (NIBUT) <10s or Schirmer I test (without anesthesia) ≤5 mm/5min,

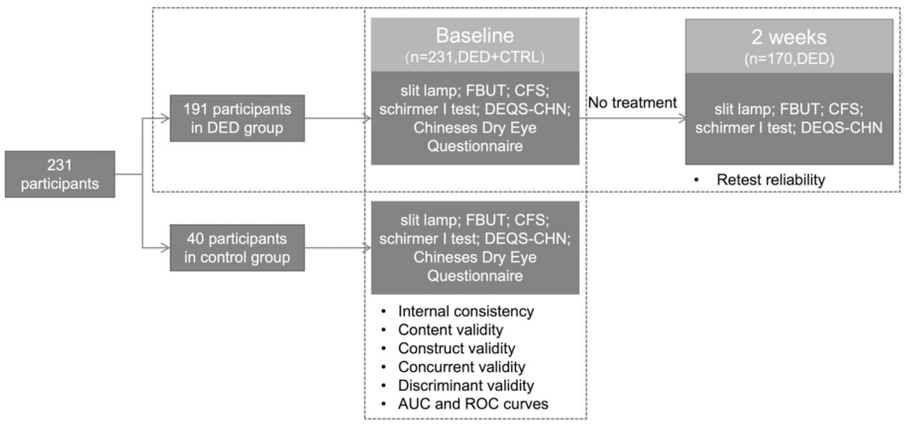

Figure 1 Flowchart of the research DED: Dry eye disease; CTRL: Control group; FBUT: Fluorescein breakup time; CFS: Corneal fluorescein staining; AUC: Area under the curve; ROC: Receiver operating characteristic.

can be diagnosed with dry eye. 2) Patients with dry eye-related symptoms, with a Chinese Dry Eye Questionnaire score ≥7 points, and an FBUT >5s and ≤10s or NIBUT of 10-12s, and Schirmer I test (without anesthesia) >5 mm/5min and ≤10 mm/5min, should undergo fluorescein sodium staining of the cornea. A positive staining result (≥5 spots) can diagnose dry eye. Participants in the control group had normal ocular structure and no dry eye or other ocular diseases that would affect the measured parameters.

Participants who had undergone hormone or immunosuppressant drug treatments for DED within one month before enrollment, used artificial tears within two hours before the examination, had a history of wearing contact lenses within the month before enrollment, intended to use or were currently using any dry eye treatment medications or physical therapy during the study, had active ocular inflammatory conditions, underwent eye surgery within six months before enrollment, or had participated in or were currently involved in other clinical trials within one month prior to enrollment were deemed ineligible to participate in the study.

The two groups were examined for dry eye (slit-lamp, FBUT, corneal fluorescein staining (CFS), and Schirmer I test) at baseline, and demographic characteristics and the subjective symptoms of the patients were quantitatively assessed by the Chinese Dry Eye Questionnaire and DEQS-CHN. After 2wk (during which no treatment was given to the dry eye group), the DED group was again evaluated by DEQS-CHN. The research flow chart was shown in Figure 1.

Instruments

Chinese version of the dry eye-related quality-of-life score questionnaire The DEQS-CHN consists of 15 items and two subscales [Bothersome Ocular Symptoms (Questions 1-6) and Impact on Daily Life (Questions 7-15)][11]. Each question was assessed in two steps: frequency (column A) and degree (column B). Frequency assessment ranges from 0 to 4, with 0 representing never, 1 representing occasionally, 2 representing sometimes, 3 representing often, and 4 representing always. Participants are required to continue answering the degree-related questions in column B only after the frequency score is 1-4. The degree is assessed on a scale of 1 to 4, with 1 being hardly bothered me, 2 being bothered me a little, 3 being bothered me, and 4 being bothered me very much. Then, answer a general feeling rating. The sum of the scores for all questions answered is the sum of the total scores for column B of Questions 1-15. The summary score is the sum of the scores for all questions×25/the total number of questions answered.

Chinese dry eye questionnaire According to the Expert Consensus on Dry Eye in China: Examination and Diagnosis (2020), the Chinese dry eye questionnaire is one of the most important reference indicators in the clinical diagnosis of dry eye in the Chinese population[16-17]. The Chinese dry eye questionnaire consists of 12 items and two subscales [History and Predisposing Factors (Questions 1-6) and Ocular Symptoms (Questions 7-12)]. The total is the sum of all the scores from questions 1 to 12.

Statistical Analysis IBM SPSS Statistics 26.0, AMOS 28.0 and GraphPad Prism software version 8.4.3 were the software packages used for statistical analysis. The significance level was set at $P<0.05$. As an electronic medical record system was utilized in this study, no missing data were found. For numerical data, the mean and standard deviation (SD) were used for normally distributed data, while the median, 25th percentile, and 75th percentile were used for non-normally distributed data [M (Q_1, Q_3)]. Descriptive statistical analysis was used to describe the demographics of the study participants.

The reliability of the questionnaire was assessed by examining internal consistency and retest reliability. After analyzing the responses from all participants' initial completion of the DEQS-CHN questionnaire (n=231), the Cronbach's α coefficient was used to measure internal consistency with a value of 0.7 or greater considered acceptable. For participants

Table 1 Demographic data, Chinese dry eye questionnaire, and clinical dry eye test results for participants

Characteristics	DED (*n*=191)	Control (*n*=40)	*P*
Age, M (Q1, Q3), y	24 (23 to 26)	26 (24 to 27)	0.016[a]
Gender, *n* (%)			
Male	65 (34.03)	20 (50.00)	0.057[b]
Female	126 (65.97)	20 (50.00)	
Ethnic groups, *n* (%)			
Han	183 (95.81)	37 (92.50)	0.409[c]
Minority	8 (4.19)	3 (7.5)	
Chinese Dry Eye Questionnaire, M (Q1, Q3)			
History and predisposing factors	1.00 (0.67 to 1.33)	0.33 (0.17 to 0.83)	<0.001[a]
Ocular symptoms	1.00 (0.83 to 1.33)	0.50 (0.33 to 0.83)	<0.001[a]
Summary score	12.00 (10.00 to 15.00)	6.00 (4.00 to 8.00)	<0.001[a]
Clinical dry eye tests, M (Q1, Q3)			
FBUT	3.09 (2.33 to 3.93)	6.01 (3.83 to 7.51)	<0.001[a]
Schirmer I test	16.00 (8.00 to 27.5)	23.00 (13.25 to 30.00)	<0.001[a]
CFS	0.50 (0.00 to 1.50)	0.00 (0.00 to 0.38)	<0.001[a]

DED: Dry eye disease; FBUT: Fluorescein breakup time; CFS: Corneal fluorescein staining. [a]The Mann-Whitney *U* test was used for statistical comparisons; [b]The χ^2 test was used for statistical comparisons; [c]Fisher's precision probability test was used for statistical comparisons.

with DED who completed the DEQS-CHN questionnaire twice (*n*=170), the intraclass correlation coefficient (ICC) was utilized to assess the retest reliability. A value of 0.6-0.8 represents moderate agreement[18-20]. The content validity was assessed by six dry eye experts who evaluated the relevance of each questionnaire item in two dimensions: the assessment of dry eye symptoms and the impact of dry eye on quality of life. They rated the relevance on a scale from 1 (not relevant at all) to 4 (highly relevant). An item-level content validity index (I-CVI) of 0.78 or higher was considered indicative of good content validity for each item, and an average scale-level content validity index (S-CVI/Ave) of 0.90 or higher was considered indicative of good content validity for the overall questionnaire[21-22]. Construct validity was assessed by confirmatory factor analysis (CFA) using responses from all participants' initial completion of the DEQS-CHN questionnaire (*n*=231)[23]. Concurrent validity of the DEQS-CHN questionnaire was assessed by calculating correlations (Spearman coefficients) with Chinese Dry Eye Questionnaire and dry eye clinical test (including FBUT, CFS, and Schirmer I test). The correlation values were interpreted as negligible=0.00-0.10, weak=0.10-0.39, moderate=0.40-0.69, strong=0.70-0.89, and very strong=0.90-1.00[24]. Discriminant validity was evaluated by comparing the DED group and the control group using the Mann–Whitney *U* test, based on responses from all participants' initial completion of the DEQS-CHN questionnaire (*n*=231). To further assess the classification performance, area under the curve (AUC) and receiver operating characteristic (ROC) curves were employed to compare the ability of DEQS-CHN to identify individuals with dry eye and those without dry eye[25]. This involved plotting the true positive rate (sensitivity) against the false positive rate (1-specificity) at various threshold values and calculating the AUC, with a value above 0.7 considered acceptable.

RESULTS

Characteristics of the Participants A total of 231 eligible participants were invited to this study, including 191 subjects aged 24 (23 to 26) in the dry eye group and 40 subjects aged 26 (24 to 27) in the control group, including 146 females and 85 males, with Han nationality accounting for the largest proportion. The participants' demographic and clinical data are shown in Table 1.

Reliability

Internal consistency and test-retest reliability The Cronbach's α coefficients for frequency and degree of the DEQS-CHN of ocular symptoms, impact on daily life, and summary score were 0.736, 0.704, 0.811, 0.818, 0.861, and 0.860, respectively. The ICCs for frequency and degree of the DEQS-CHN of ocular symptoms, impact on daily life, and summary score were 0.611, 0.677, 0.715, 0.769, 0.711, and 0.779, respectively (Table 2).

Validity

Content validity Based on the ratings of six experts on each item of the DEQS-CHN questionnaire, all I-CVI scores ranged from 0.833 to 1.000, with S-CVI/Ave of 0.956.

Construct validity Conducting a confirmatory factor analysis on the DEQS-CHN, each item demonstrated factor loadings exceeding 0.4. The model fit was excellent, with χ^2/df =2.653, incremental fit index (IFI) =0.924, comparative fit index (CFI) =0.924, tucker-Lewis index (TLI) =0.909, and root

Table 2 Reliability of the DEQS-CHN

Subscale	Internal consistency: Cronbach α (*n*=231)		Retest reliability: ICC (*n*=170)	
	Frequency	Degree	Frequency	Degree
Ocular symptoms	0.736	0.704	0.611	0.677
Impact on daily life	0.811	0.818	0.715	0.769
Summary	0.861	0.860	0.711	0.779

ICC: Intraclass correlation coefficient.

Table 3 Correlation between DEQS-CHN, Chinese dry eye questionnaire, and clinical dry eye tests

Test and subscale	Ocular symptoms		Impact on daily Life		Summary score
	Frequency	Degree	Frequency	Degree	
Chinese dry eye questionnaire					
History and predisposing factors	0.351[b]	0.370[b]	0.341[b]	0.335[b]	0.382[b]
Ocular symptoms	0.626[b]	0.591[b]	0.561[b]	0.524[b]	0.595[b]
Summary score	0.586[b]	0.571[b]	0.556[b]	0.521[b]	0.588[b]
Clinical dry eye tests					
FBUT	-0.202[b]	-0.176[b]	-0.104	-0.090	-0.126
Schirmer I test	-0.072	-0.102	-0.068	-0.010	-0.047
CFS	0.075	0.134[a]	0.026	0.070	0.095

FBUT: Fluorescein breakup time; CFS: Corneal fluorescein staining. [a]*P*<0.05; [b]*P*<0.01. Spearman correlation coefficients were calculated to assess the relationships of the DEQS-CHN with the Chinese dry eye questionnaire and dry eye clinical test results.

mean square error of approximation (RMSEA)=0.065. The modification model fitting results are shown in Figure 2.

Concurrent validity The DEQS-CHN showed moderate correlations with ocular symptoms and summary scores of the Chinese Dry Eye Questionnaire (0.521-0.626) and weak correlations between the history and predisposing factors of the Chinese Dry Eye Questionnaire (0.335-0.382) and each subscale and summary scores of the DEQS-CHN questionnaire. However, the DEQS-CNH showed a weak or negligible correlation with the clinical dry eye examination (0.01-0.202). Table 3 presents the correlations between the DEQS-CHN questionnaire, the Chinese Dry Eye Questionnaire, and clinical dry eye tests.

Discriminant validity The dry eye group demonstrated significantly higher frequencies and degrees of ocular symptoms and greater impact on daily life and summary scores compared to the control group. These results were found to be statistically significant (*P*<0.001). All details were shown in Table 4.

To further assess the classification performance, AUC and ROC curves were employed to compare the ability of DEQS-CHN to identify individuals with dry eye and those without dry eye. The AUC for the DEQS-CHN was 0.8092 (Figure 3), suggesting a reasonably good discriminatory ability of the DEQS-CHN in distinguishing between individuals with dry eye and those without.

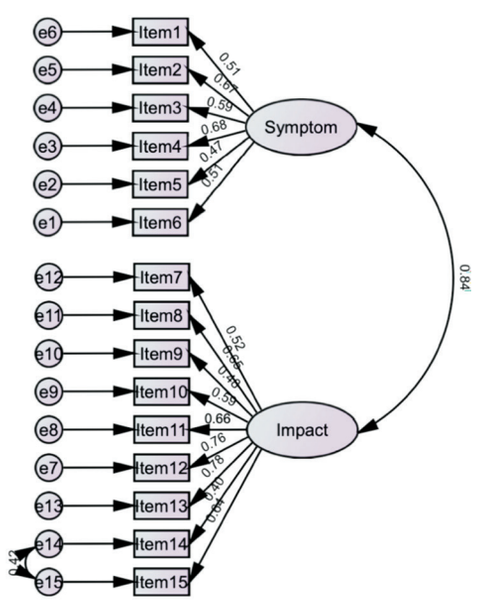

Figure 2 The fitting figure of the modification model of DEQS-CHN.

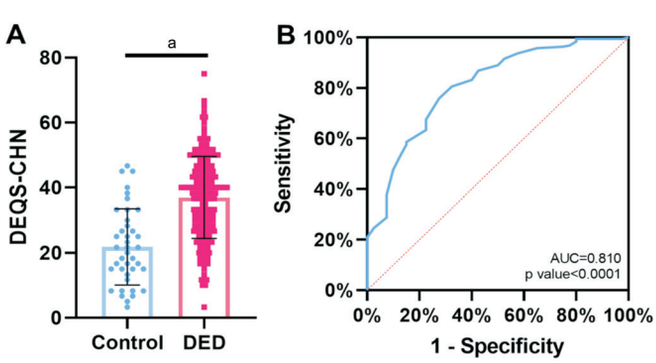

Figure 3 Sample distribution and receiver operating characteristic (ROC) curve of the DEQS-CHN [a]*P*<0.001.

DISCUSSION

Overall, this study demonstrated that the DEQS-CHN exhibits

Table 4 Discriminant validity of the DEQS-CHN M (Q_1, Q_3)

Parameters	Ocular symptoms		Impact on daily Life		Summary score
	Frequency	Degree	Frequency	Degree	
DED (n=191)	1.50 (1.00 to 1.83)	1.67 (1.33 to 2.00)	1.11 (0.78 to 1.56)	1.33 (0.89 to 1.78)	38.33 (28.33 to 45.00)
Control (*n*=40)	1.00 (0.67 to 1.33)	1.08 (0.71 to 1.33)	0.44 (0.22 to 0.89)	0.61 (0.25 to 1.19)	20.83 (13.75 to 29.58)
z	-6.152	-5.944	-5.956	-5.437	-6.152
P	<0.001[a]	<0.001[a]	<0.001[a]	<0.001[a]	<0.001[a]

[a]The Mann-Whitney *U* test was used for statistical comparisons. DED: Dry eye disease.

strong psychometric properties, confirming its reliability and validity as a valuable instrument for assessing the impact of dry eye on the quality of life in Chinese patients.

After inviting 191 DED patients and 40 healthy adults to participate in this study, no statistically significant differences were found in demographics such as gender and ethnicity. However, there was a statistically significant difference in age between the two groups. It is important to note that despite this age difference, it does not hold clear significance in terms of the occurrence of dry eye, as both groups consist of young individuals. The Cronbach's α coefficients of the summary score of the DEQS-CHN and each subscale were above 0.7, and ICC of the retest reliability was above 0.6, indicating good internal consistency and stability. Besides, the I-CVI scores ranging from 0.833 to 1.000 and an S-CVI/Ave of 0.956 generally indicate good content validity. Moreover, the CFA results showed that the DEQS-CHN had satisfactory construct validity. In addition, the DEQS-CHN has a good correlation with the Chinese Dry Eye Questionnaire. However, there was a low correlation coefficient between the DEQS-CHN and clinical dry eye tests, which can be attributed to the neurosensory abnormalities according to the TFOS DEWS II[26]. Moreover, this phenomenon has also been observed in clinical validation studies of other questionnaires related to dry eye, such as the reliability and validity verification of the Japanese version of the OSDI questionnaire in the Japanese population[27]. These results indicate the importance of the combination of questionnaires and clinical examination in the clinical diagnosis of DED. Moreover, there is a notable discriminative validity between the dry eye group and the control group. The ROC curve and AUC values further confirm that the DEQS-CHN questionnaire possesses a commendable ability to distinguish between individuals with dry eye and those without in the Chinese population.

However, there were several limitations. First, the study population consisted of university students, with a relatively lower proportion of moderate to severe dry eye patients. To comprehensively assess the psychometric validation of DEQS-CHN, it will be crucial to expand the sample size by including a greater number of patients with moderate and severe dry eye and at different ages. Second, in this study, the sample size of male participants in the dry eye group was smaller than that of female participants, although no statistically significant differences were observed between genders in this study. This occurrence is attributed to the higher prevalence of dry eye in females compared to males[28]. For future research, it is essential to increase the number of male dry eye patients to conduct a more comprehensive evaluation.

In conclusion, our study represents the initial psychometric validation of the DEQS-CHN and underscores its cross-cultural applicability. The DEQS-CHN questionnaire has been demonstrated as a valid and reliable instrument for assessing the impact of DED on the quality of life among Chinese individuals with DED. It serves as a valuable tool for managing DED within the Chinese population.

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