Prospective Study

Cross-Cultural Adaption and Psychometric Evaluation of the German Craniofacial Pain and Disability Inventory (CF-PDI)

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Background: The Craniofacial Pain and Disability Inventory (CF-PDI) is a cross-culturally adapted instrument designed from a biopsychosocial perspective to measure pain, disability, and function in orofacial head and neck pain with shown psychometric properties; however, the German cross-cultural adaption is lacking.

Objectives: To carry out a transcultural translation of CF-PDI into German and assess its psychometric properties in patients with painful temporomandibular disorders (TMD) with respect to construct and clinical validity, internal consistency and reproducibility.

Study Design: Multicenter, prospective, cross-sectional design.

Setting: Patients (n = 398) were recruited from dental and physical therapy clinics in middle and south Germany.

Methods: Structural validity was assessed using exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). We investigated know-group validity by means of the scale's potential to discriminate between affected and unaffected subjects. Multiple linear regression analysis was used to estimate convergent validity. We tested test-retest reliability by the intraclass correlation coefficient and the Internal consistency by Cronbach's α, or each dimension separately, and the total score. Multiple linear regression analysis was used to estimate convergent validity.

Results: Two hundred forty-six heterogeneous chronic craniofacial pain patients and 152 patients without complaints were recruited from the middle and south of Germany. The German version CF-PDI-G presents 21 items, 4 factors, and adequate psychometric properties. The test-retest reliability and internal consistency of the CF-PDI-G were both excellent for the entire instrument and also for all sub-scales (intraclass correlation coefficient [ICC] > 0.90) except for the comorbidities and interference with work which was acceptable (ICC = 0.69). Standard error of the measurement (SEM) and minimal detectable change values are sufficiently low. Assessment of clinical validity shows good potential of discrimination and classification into categories "no," "mild," "moderate," and "severe." The multiple linear regression model showed a strong association between neck disability index, Visual Analog Scale, and anamnestic questionnaire (supporting the scale's convergent validity).

Limitations: Our sample has a higher prevalence of women and the sample was not recruited consecutively, which may lead to a biased estimation of psychometric properties.

Conclusions: The CF-PDI-G represents valid and reliable instrument to assess pain and disability in patients with orofacial pain and headache suitable for research and clinical practice.

Key words: Craniofacial pain, cross-cultural, disability, German version, headache, neck pain, psychometric validation, questionnaire, reliability, temporomandibular disorders

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Temporomandibular disorders (TMD) are the most prevalent orofacial pain conditions. Their main features include pain in the facial region and preauricular area, and limitations and noises in the jaw (1). Pain-related diagnoses of TMD include headache attributed to TMD, arthralgia, and myalgia (2).

A large percentage of patients with painful TMD have comorbidities with other painful conditions (3,4), especially headache, neck pain, and back pain (3,5). The presence of painful comorbidities in patients with TMD increases the risk of chronicity and impairs treatment outcomes (6,7). An overlap of orofacial pain with other pains may be the result of neurosensory and affective processes that differentially amplify pain (5).

Patients with TMD who have a higher level of disability may have TMD that contributes to a worse prognosis (8), a more considerable expansion of pain (6), more areas of pain, and higher comorbidity (10). Several studies have found strong associations between psychological, physical variables and pain-related disability (11-14) Chronic TMDs have a multifactorial etiology, whereby physical, behavioral, and emotional factors overlap and interact with each other.

The current body of evidence confirms the need to quantify the pain-related disability and functional status of patients with craniofacial pain and TMD from a biopsychosocial perspective (1). Visscher et al (15) suggest that psychological and pain-related disability assessments can help oral health professionals make individualized treatment decisions.

The Craniofacial Pain and Disability Inventory (CF-PDI) is an instrument designed from a biopsychosocial perspective to measure pain, disability, and functional status of the mandibula rather than on diagnosis formation (16); therefore it may be an appropriate tool for clinical use. The original version of the CF-PDI is in Spanish. It consists of 21 items with 4 possible answers for each item. It has good structure, internal consistency, reproducibility, and construct validity, thereby providing an objective tool to evaluate pain and disability in patients with craniofacial pain (16).

Recently the CF-PDI has been cross-culturally adapted and tested for its psychometric properties to the Brazilian Portuguese (17), Italian (18), and Mandarin Chinese (19) languages; however, to date, the CF-PDI has not been cross-culturally transferred or psychometrically validated into the German language.

The methodological guidelines on cross-cultural adaptations suggest that the translation and cultural adaptation of the original elements of the self-records should be adequately captured in the target language so that an appropriate psychometric assessment of the instrument can be made subsequently (20,21). This study aims to carry out a transcultural translation of CF-PDI into the German language and assess its psychometric properties in patients with painful TMD.

Methods

Instruments

In this study, we used the original Spanish CF-PDI which has good reproducibility, good internal consistency, and moderate to good structure and construct validity (16). The measuring instrument consists of 21 Likert-type questions with 4 response options, of which the correct answer has to be selected. The CF-PDI measures 2 dimensions: pain and disability (1-8,16-20) and jaw functional status (9-15). The number of points gives an impression of the severity of craniofacial dysfunction and pain.

To perform the translation from Spanish into German, we used the "Guidelines for the Process of Cross-Cultural Adaption of Self-Report Measures" (20). A native speaker with a medical background translated the targeted language and afterwards a native speaker (also with a medical background) translated it back to the original language (back translation). The research team compared both translations, with 2 native German persons without medical background and a good knowledge of Spanish. An expert committee of 5 members (2 physical therapists, 2 dentists, and 1 Spanish instructor) assessed whether the questions were appropriate using a 4-level Likert scale ("complete disagreement," "some agreement," "neither agreement nor disagreement," and "complete agreement"), followed by refining the questions until an agreement was reached. During the last phase, 10 volunteers with orofacial pain completed the Amnestic Questionnaire (AQ), German Facial Disability Index (FDI) and the Oral Health Impact Profile-Germany (OHIP-G14) to get an impression for correlation analysis (CF-PDI/FDI: r = 0.79, P = 0.013 and CF-OHIP-G14: r = 0.54, P = 0.034) (Appendix A).

Psychometric Validation

Patients

In this multicenter, cross-sectional, descriptive survey study, we invited a random sample of 398 patients total, 246 heterogenous chronic head and face pain patients

and 152 without head or facial complaints. Patients were recruited from the middle and south of Germany, from dental and physical therapy clinics. Patients were included when they had adequate knowledge of the German language, no cognitive impairments, or psychiatric limitations. For the orofacial pain group, patients were selected if they met all of the following criteria: headache or facial pain attributed to TMD the diagnosis of which was based on the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD). All the patients were referred from a dentist with the diagnosis of: 1) TMD or headache related with TMD according the DC/TMD (2); 2) headache and facial pain according to the guidelines of the International Classification of Headache Disorders (22); 3) experiencing pain for at least 6 months prior to the study; 4) were at least 18 years of age; and 5) good understanding of the German language.

The local ethics authority of the University of Applied Science of Osnabrück granted ethical approval (WiSo_BA_ELP_HP-SS 17-01). Data collection was performed between December 2017 and October 2018.

On the first day of the visit, the patients completed the CF-PDI and a number of questionnaires, including a socio-demographic questionnaire collecting information about gender, date of birth, marital status, living arrangements, education level, and work status. The self-reports for demographic and pain variables, which supported the process of validation, included the Neck Disability Index (NDI), the Facial Disability Index (FDI), the Fatigue Severity Scale (FSS), the Tampa Scale for Kinesiophobia (TAMPA), the Anamnestic Questionnaire for TMD (AQ), and the Visual Analog Scale (VAS). The FSS and TAMPA questionnaires are not directly related to head and face problems, but were used to assess divergent validity. The other tests were utilized to evaluate convergent and clinical validity (AQ).

- The German version of the NDI measures perceived neck disability (22,23) (10 items, with 6 possible answers that range from 0 [no disability] to 5 [complete disability] points. The NDI (German version) has demonstrated acceptable psychometric properties (22).
- The German version of the FDI is a self-report instrument for assessing disability and related social and emotional well-being of patients with facial disorders (24,25). It is a 9-item self-report questionnaire scale, which has been applied in 25 multiple sclerosis (MS) patients, 29 patients with systemic lupus erythematosus (SLE), as well as in 20 healthy patients in a control group (26,27).
- Fatigue Severity Scale (FSS) was developed for the diagnosis of fatigue (tiredness, exhaustion) in patients with MS and SLE (27). A systematically translated and validated German version showed good internal consistency and high reproducibility (26,31,33)
- The TSK-GV (Tampa Scale for Kinesiophobia-German version) (13) is an instrument with 13 items for measuring fear of movement/(re)injury, which have been confirmed as significant predictors for the persistence of pain-related disability (28).
- The AQ contains 10 questions that are related to problems originating from the temporomandibular region. Each question has 3 ranking options (0 = none, 1 = present, and 3 = strong or bilateral). The likelihood of a TMD is divided into 4 subgroups: 4-9 = none, 9-14 = minimal, 15-21 = moderate, 21-23 = strong (29). The questionnaire has shown a strong statistical association with the Modified Helkimo's Clinical Dysfunction index (30).
- The VAS scale measures the head and facial pain intensity with acceptable reliability and validity (31). It consists of a 100 mm line with the left side representing "no pain" and the right side representing "the worst pain imaginable." All patients answered the test a second time.

Because the most instruments were also used with success in the Spanish-English translation we used nearly the same assortment of tests for verifying construct validity (16) We added the AQ because it measures the dimensions of pain and function, and has the advantage of sub classification (see results). Therefore we left out the Jaw Functional Limitation Scale (JFS) and the Graded Chronic Pain Scale (GCPS), which may be partwise covered by the FSS, TAMPA, TSK-GV(13).

Statistical Analysis

Sample Size

All analyses were performed by R Core Team (34), including the packages lavaan (35)and semPlot (36), which are designed to perform multivariate statistical models, including confirmatory factor analysis and path diagrams.We based our sample size calculation on the N to q (number of estimated parameters by CFA) rule. When a minimum recommended ratio of cases to estimated parameters of 5 is assumed, a minimum of 310 patients would be appropriate, assuming a 2-factor model as in CF-PDI (16). For the test-retest analysis, we aimed to

achieve an ICC > 0.9 based on other publications, which is significantly different from the acceptable agreement of 0.7, with a type-I error of 5% and power of 80%. The analysis resulted in a sample size of 23 patients.

Patients with AQ scores ≤ 3 were considered as healthy. For this study patients with AQ scores greater than 3 indicated patients with TMD (37).

Structural validity was investigated by both exploratory (EFA) and confirmatory factor analysis (CFA). We applied EFA with oblimin rotation to identify the optimal model by data-driven factor solution. The number of factors for extraction was based on Kaiser's eigenvalue criterion (eigenvalue ≥ 1) and evaluation of the scree plot. The quality of the factor analysis models was assessed using Bartlett's test for sphericity ($P < 0.05$) and the Kaiser-Meyer-Olkin (KMO) test (> 0.5). The optimal factor solution was planned to be transferred for model fit into CFA.

CFA was used to compare the model fits of competing models stemming from EFA analysis and previously published data. Here, we considered the 2-factor solution of the original CF-PDI and the 3-factor solution of the Brazilian version of the CF-PDI as relevant. Accordingly, we reported several goodness-of-fit indicators, including the Tucker–Lewis-Index (TLI), the comparative fit index (CFI), the root mean square error of approximation (RMSEA) with corresponding confidence intervals of 90%, and the Standardized Root Mean Square Residual (SRMR). TLI and CFI values ≥ 0.9 and RMSEA and SRMR values < 0.08 represent good fits. The best model was plotted as a path diagram presenting the standardized coefficients of each item and dimension/factor. Factors were assumed to be nonorthogonal.

In both EFA and CFA, loadings and coefficients are given as standardized values and interpreted as correlation coefficients. Hence, values close to 1 represent a high contribution to a dimension. Internal consistency was estimated using Cronbach's α for each dimension separately and the total score. Values > 0.7, > 0.8, > 0.9 were considered as "acceptable," "good," and "excellent" respectively. Multiple linear regression analysis was used to estimate convergent and divergent validity. The strength of associations between CF-PDI-G and other constructs is given by standardized regression coefficients and partial correlation coefficients. The total score of the CF-PDI-G (dependent variable) was predicted by the NDI, TSK, VAS, FSS, and AQ as predictor variables. Based on previous studies and theoretical reasoning (16), we expected associations as follows, in order to verify construct validity (convergent/divergent validity): a moderate to strong association for the predictors AQ, NDI, VAS and small to no association for the predictors TSK and FSS. The first regression model consisted of all predictors. We stepwise withdrew the least significant predictor until the model consisted of only significant predictors. As a measure of multicollinearity, the variance inflation factor (VIF) and residual diagnostics (homoscedasticity and check for normality and outliers) were performed to verify the model's appropriateness.

Test-retest reliability was tested by the ICC (2-way random effects, absolute agreement, single measurement), including its confidence interval (CI) for each identified dimension and the total score of the CF-PDI-G. We considered thresholds of ICC < 0.3 as "poor," 0.5-0.7 as "moderate," and > 0.7 as "excellent" agreement (38). We also constructed a Bland Altman Plot by calculating the mean difference between 2 measurements and the standard deviation (SD) of the differences. Based on ICCs, the standard error of the measurement (SEM) was calculated according to SEM = SD * √(1-ICC) and the smallest detectable change (SDC95%) according to SDC = 1.95* √2*SEM.

Know-group validity was investigated by the scale's potential for the discrimination between affected and unaffected patients; therefore, we divided patients based on TMD status according to AQ. Employing ROC curve analysis, we evaluated the degree of discrimination. Here we used the AQ thresholds as an anchor ("no," "mild," "moderate," "severe") to establish cut-offs for categorization into "no," "mild," "moderate," "severe," according to CF-PDI-G. The identified thresholds are based on multicategory ROC-statistics. Goodness-of-fit for agreement between AQ and CF-PDI-G categories are given as weighted kappa supported by the generalized Youden statistical method. Both methods yield values between 0 and 1 indicating "no" and "perfect" agreement or accuracy, respectively.

Results

Study Population

A total of 404 patients (290 women and 114 men) were invited for this study. Six patients were not included because they were not interested (n = 3) and their opinion, the study takes too long(n = 3). The mean age of the 398 patients (288 women and 110 men) was 38.91 ± 14.28; 72.4% were women. The patients were divided into two groups, those with TMD and thos without TMD, according to AQ < 4 and AQ ≥ 4. The

mean age and SD of individuals with TMD were 38.10 ± 13.5 and without 40.0 ± 15.4 ($P > 0.05$).

Structural Validity

Figure 1 shows the scree plot based on EFA. The KMO-Test was found to be 0.91 and Bartlett's Test of Sphericity was highly significant ($P < 0.001$), supporting the suitability of the PCA data. The first 4 factors explain 63% and exceed an eigenvalue of 1. Hence, either a 4-factor-solution or a 1-factor solution (expressed by the elbow at factor 2). The first factor explains 41% and 4 factors 63% of the total variance.

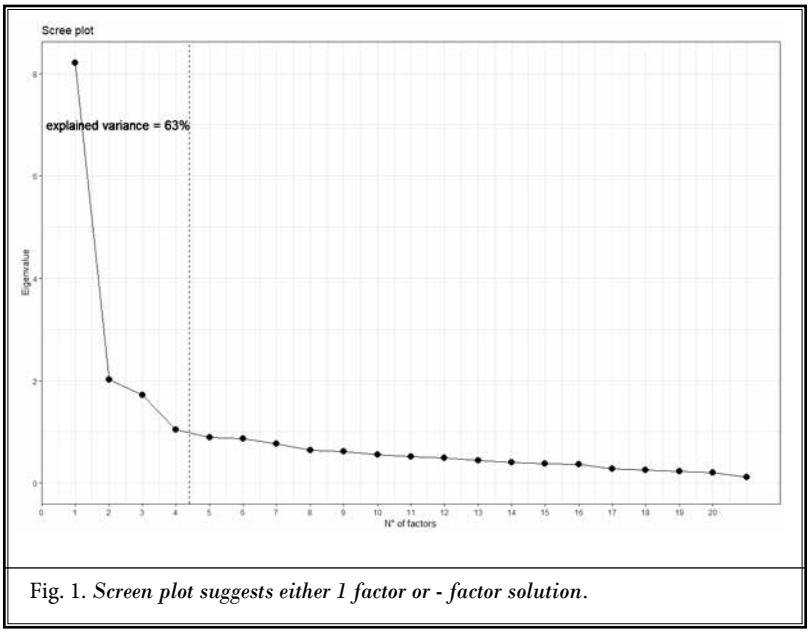

Fig. 1. *Screen plot suggests either 1 factor or - factor solution.*

Four competing models were transferred into CFA. The factor solution from EFA of the CF-PDI-G, the original 2-factor structure and the 3-factor structure from the Brazilian CF-PDI version. As depicted in Table 1, the 4-factor solution yields the best goodness-of-fit values indicating a good fit. All values pass or are very close to predefined thresholds.

The solution with the loadings of each item and dimension is provided in the path diagram (Fig. 2). The standardized coefficients of the loadings range between 0.55 and 0.94 and can be interpreted as correlation coefficients. The clinical dimensions are named functional and psychosocial limitation, jaw displacement, comorbidities and interference with work, and pain in jaw/face.

Table 1. *Four competing models to CFA: 1-factor of CF-PDI-G, Original 2 factor, Brazilian version 3 factor, CF-PDI-G 4 factor.*

	TLI	CFI	RMSEA	SRMR
1 factor	0.75	0.77	0.13 (0.12; 0.14)	0.075
2 factor (La Touche, 2014)	0.77	0.79	0.13 (0.12; 0.14)	0.077
3 factor (Greghi, 2018)	0.83	0.81	0.12 (0.11; 0.13)	0.07
4 factor (German version)	0.88	0.89	0.09 (0.08; 0.10)	0.06

TLI: Tucker Lewis Index; CFI: comparative fix index; RMSEA: root mean square error of approximation; SRMR: Standardized Root Mean Square Residual.

Reliability

The reliability, including test-retest reliability, measurement error, SDC, and internal consistency of each dimension and the total score, is presented in Table 2. ICC indicates excellent test-Retest Reliability, aside from the dimension of jaw displacement. Here, ICC represents moderate reliability; however, here the SEM and SDC are the lowest. Internal consistency is excellent in all dimensions. Only the dimension "comorbidities and interference with work" shows acceptable consistency.

Table 2. *Validity and reliability statistics according to confirmatory factor analysis of CF-PDI-G.*

Scores	ICC	SEM	SDC	Internal consistency
Functional and psychosocial limitation	0.926 (0.768 - 0.973)	0.933	2.586	0.971
Jaw displacement	0.983 (0.959 - 0.993)	0.573	1.589	0.991
Comorbidities and interference with work	0.639 (0.303 - 0.835)	0.734	2.035	0.780
Pain in jaw/face	0.952 (0,887 - 0.980)	0.871	2.415	0.974
Total	0.983 (0.957 - 0.993)	1.380	3.826	0.992

ICC: intraclass correlation coefficient; SEM: standard error of measurement; SDC: smallest detectable change;

Clinical Validity

Clinical validity is shown in Fig. 3. An area under the curve (AUC) of 94% indicates an excellent potential of discrimination between patients with and without TMD. The resulting threshold for the CF-PDI-G to cat-

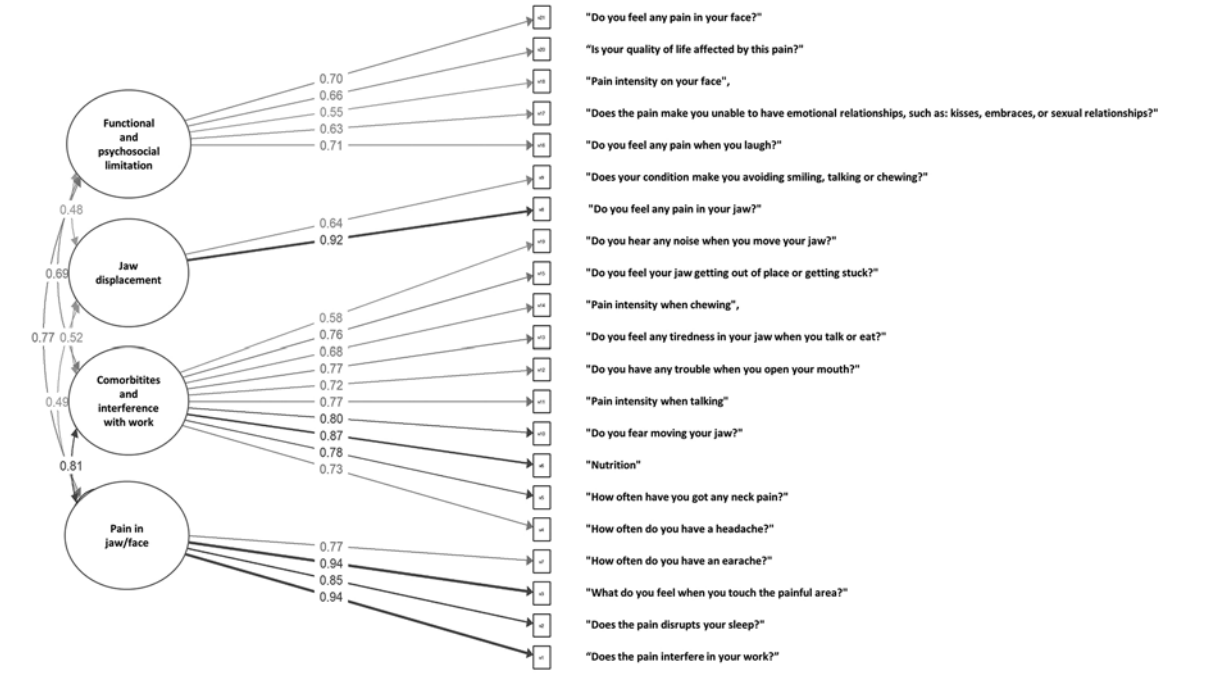

Fig. 2. *Structure of the CF-PDI-G with standardized coefficients (interpretation as correlation) represent contribution.*

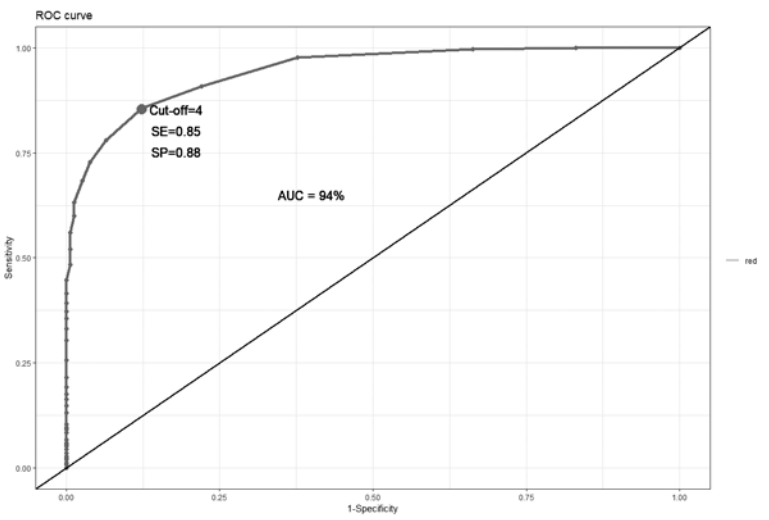

Fig. 3. *ROC shows excellent discrimination for patients with and without TMD (based on AQ > 3): AUC 0.94 with cut-off 4 based.*

egorize patients into health and affected is ≥ 4, with a sensitivity and specificity of 0.85 and 0.88 resulting in a Youden index of 0.73.

Table 3 presents the potential of discrimination into a more definite gradation as "no," "mild," "moderate," and "severe," as well as corresponding cut-offs calculated based on multicategory ROC. The agreement between CF-PDI-G and the anchor severity of TMD by AQ amounts to a weighted kappa of 0.7 and a generalized Youden index of 0.66, indicating good potential of classification into categories "no," "mild," "moderate," and "severe." Furthermore, Figure 4 shows the predicted probability, including CIs having "no," "mild," "moderate," or "severe" TMD depending on the CF-PDI-G score.

Convergent Validity

Finally, Table 4 provides the strength of associations between CF-PDI-G and other constructs (NDI, TSK, VAS, FSS, and AQ) by standardized regression coefficients, correlation coefficients, and partial correlation coefficients. As expected, we found a moderate to strong association for the predictors AQ, NDI, VAS, and small to no association for the predictors

TSK and FSS suggesting excellent convergent validity. Statistical assumptions for conducting multiple linear regression were not violated.

Discussion

This study aimed to perform a cross-cultural adaptation and psychometric validation of the CF-PDI into the German language (CF-PDI-G). Our findings suggest that the CF-PDI-G presents 21 items, 4 factors, and adequate psychometric properties, in terms of internal consistency, test-retest-reliability, and convergent validity. The psychometric results of the CF-PDI-G, except for the factor structure, are similar to the original Spanish version (16), the Brazilian version (17), the Italian version (18), and the Chinese version (19).

Factorial Structure and Internal Consistency

EFA and CFA support a 4-factor solution explaining 63% of the total variance, which is even greater than the original version (44.77%) (16) and the Brazilian version (51.54%) (17), but similar to the Chinese version (77.15%) (19).

The 4 factors (a. functional and psychosocial limitation; b. jaw displacement; c. comorbidities and interference with work; d. pain in the jaw/face.) represent a coherent theoretical structure that fits the current need for biopsychosocial assessment of patients with TMD (1). A great advantage of the CF-PDI-G represents the ability to measure pain and disability by means of 4 subscales that offer detailed information for clinical decisions.

However, the factor structures are not consistent with the original version and other versions (16-19). Only the Italian version of the CF-PDI (18) matches the same original factor structure of the original scale. The Chinese and Brazilian versions, unlike the original, include a factor that includes functional and psycho-

Table 3. *Agreement between severity of TMD and CF-PDI-G including identified thresholds by multicategory ROC-statistics.*

TMD	CF-PDI-G				Total
	No (≤ 3)	Mild (4 - 10)	Moderate (11 - 23)	Severe (< 23)	
No	120	33	1	0	154
Mild	23	75	27	3	128
Moderate	0	12	49	9	70
Severe	0	0	20	26	46
Total	143	120	97	38	398

CF-PDI-G: German version of the Craniofacial Pain and Disability Inventory.

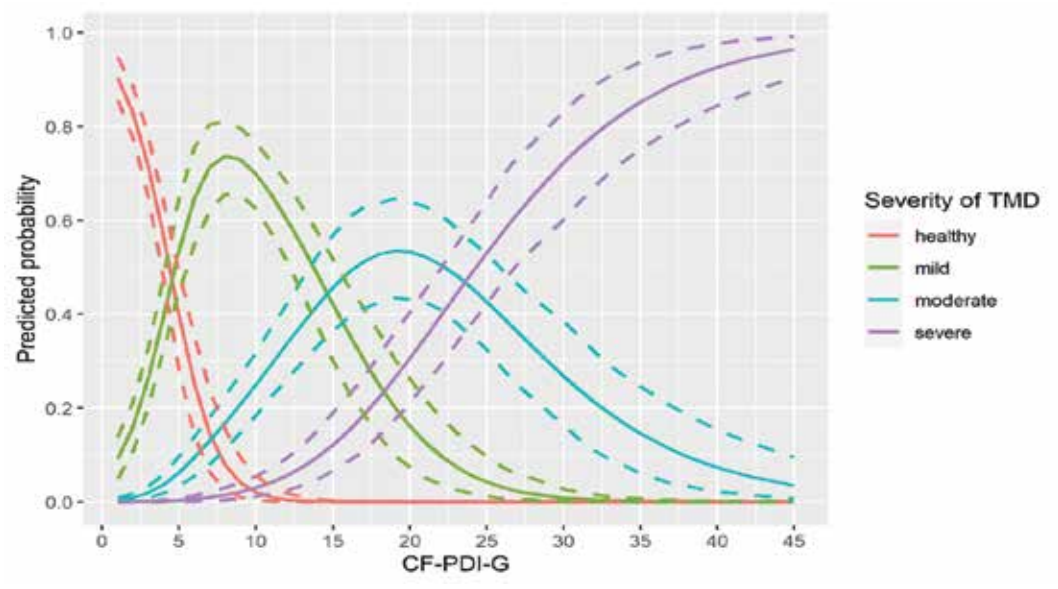

Fig. 4. *Predicted probability including CIs of having "no," "mild," "moderate," or "severe" TMD depending on the score of the CF-PDI-G.*

Table 4. *Correlation and Multiple Regression model showing excellent convergent validity. Model 2 contains only significant predictors.*

Model 1 R^2 = 83%	**B**	**Beta**	***P*-value**	**Correlation (not adjusted)**	**Partial correlation (adjusted)**	**VIF**
Intercept	7.33		0.01			
NDI	-0.11	-0.15	< 0.001	-0.75	-0.21	2.89
VAS	0.36	0.10	< 0.001	0.62	0.17	1.86
AQ	1.163	0.70	< 0.001	0.85	0.75	2.15
FSS	0.04	0.05	0.06	0.52	0.10	1.55
TSK	0.05	0.03	0.14	0.20	0.07	1.13
Model 2 R^2 = 83%	**B**	**Beta**	***P*-value**	**Correlation (not adjusted)**	**Partial correlation (adjusted)**	**VIF**
Intercept	9.27		< 0.001			
NDI	-0.12	-0.16	< 0.001	-0.75	-0.22	2.83
VAS	0.38	0.10	< 0.001	0.62	0.18	1.83
AQ	1.152	0.69	< 0.001	0.89	0.75	2.10
FSS	0.04	0.05	0.04	0.52	0.10	1.53

NDI: Neck Disability Index; VAS: Visual Analog Scale; AQ: Anamnestic Questionnaire for TMD; TSK-TMD: Tampa Scale for Kinesiophobia; FSS: Fatigue Severity Scale; VIF: variance inflation factor.

social characteristics, and another factor that includes comorbidities. These 2 factors are also included in the CF-PDI-G. It is important to note that the comorbidities factor includes items referring to headache and neck pain, which are among the most frequent conditions associated with patients with TMD (3,5,39). The fact that the factor structures vary across versions is mainly explained by the high degree of interrelation between factors (dimensions).

The internal consistency of the CF-PDI-G was very high (α > 0.90), similar to the other cross-culturally adapted versions and superior to the result of the original scale (α = 0.88) (16-19).

Reliability and Reproducibility

The test-retest reliability of the CF-PDI-G was excellent for the entire instrument and for all subscales (ICC > 0.90), except for the comorbidities and interference with work scale, which was acceptable (ICC = 0.69). The results are consistent with previous validations (16-19); however, the seemingly lower ICC is not a result of a greater measurement error, but of a lower variance of the measured scores in the study population. As a result, the measurement error in terms of SEM (1.38) is even less, when compared to other dimensions. Concerning the SDC, our results show the smallest change reported (SDC = 3.82) of all previous validations.

Low SEM and SDC are crucial to detect minimally significant changes with respect to health status (40).

Convergent and Clinical Validity

The multiple linear regression model showed a strong association between the NDI, VAS, and AQ (r = 0.60). Concerning neck disability, the results are similar to those of the original version (r = 0.65) and the Italian version (r = 0.66), and concur with a large number of studies with a similar association (41-44). For pain intensity and the relation with CF-PDI-G, a strong association was obtained, whereas it was moderate in previous versions. Finally, no association with TSK was found, which is in contrast with previously published validation studies. One reason might be that the TSK for temporomandibular disorders has not yet been validated in the German language. The Brazilian version of the CF-PDI obtained a strong association (r = 0.68) for the TSK/TMD-Br, possibly due to the specificity of the instrument (45).

An important finding of the CF-PDI-G is that the instrument's cut-off points were reported to serve as a classification system, which is the first time that these were calculated for previously published versions of the instrument in different languages. Several studies point out the importance of conducting a sensitivity study to obtain cut-off points, especially in instruments used to evaluate variables of a particular anatomical region (46,47).

Strengths

In our study, a large sample consisting of heterogeneous individuals was recruited, which allowed

us, on the one hand, to apply a variety of statistical analyses with enough power to yield robust results for psychometric properties, including reliability, validity, SEM, SDC, and the establishment of cut-off values. On the other hand, our sample stemming from various sources resulted in a study population that is representative of a majority of TMD patients and allows high generalizability.

Limitations

One of the limitations is the disproportion between genders present in the sample, which is likely due to the higher prevalence of craniofacial pain among women (48). At the same time, this is further evidence of the representativeness of our sample.

Since the study design was cross-sectional, the Minimum Clinically Important Difference could not be analysed. For future research, the authors propose a longitudinal design with an experimental intervention to assess how the scores of the CF-PDI change over time with the patients' improvement. Furthermore, our sample was not recruited consecutively, which may lead to a biased estimation of psychometric properties.

Conclusion

This study demonstrates that the cross-culturally adapted version of the CF-PDI-G has good psychometric properties. The results showed good structure, internal consistency, reproducibility, and construct validity. The CF-PDI-G may be considered a valid and reliable instrument to assess pain and disability in patients with orofacial pain and headache, which can be implemented in research and clinical practice.

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Appendix A. *German version of the Craniofacial Pain and Disability Inventory.*

Bitte lesen Sie die Anweisungen aufmerksam durch:

Dieser Fragebogen wurde gestaltet, um Informationen zu erhalten, inwiefern Gesichts-, Kopf- und Kieferschmerzen Ihren Alltag beeinträchtigen. Bitte beantworten Sie so viele Fragen wie möglich und kreuzen Sie in jeder Frage **NUR DIE ANTWORT AN, DIE AM ZUTREFFENSTEN IST**. Auch wenn Sie merken, dass eine Frage mehrere Möglichkeiten hat, die Sie betreffen, kreuzen Sie nur die Option an, die am besten Ihr Problem darstellt.

1. Haben Sie Schmerzen im Gesicht?

- o Ich habe keine Schmerzen.
- o Ich habe gelegentlich Schmerzen.
- o Ich habe häufig Schmerzen.
- o Ich habe immer Schmerzen.

2. Wurde Ihre Lebensqualität durch diese Schmerzen beeinträchtigt?

- o Sie wurde nicht beeinträchtigt.
- o Sie wurde etwas beeinträchtigt.
- o Sie wurde sehr beeinträchtigt.
- o Sie wurde stark beeinträchtigt.

3. Intensität der Gesichtsschmerzen:

- o Ich habe keine Schmerzen.
- o Ich habe leichte Schmerzen.
- o Ich habe mäßige Schmerzen.
- o Ich habe starke Schmerzen.

4. Werden Sie wegen Ihrer Schmerzen bei zärtlichen Handlungen wie beispielsweise Küssen, Umarmungen oder Geschlechtsverkehr behindert?

- o Bei zärtlichen Handlungen habe ich keine Beeinträchtigung.
- o Ich kann sie ausüben, allerdings mit leichten Schmerzen im Gesicht und/ oder Kiefer.
- o Ich kann sie ausüben, allerdings mit mäßigen Schmerzen im Gesicht und/ oder Kiefer.
- o Ich verzichte auf sie aufgrund der starken Schmerzen.

5. Haben Sie Schmerzen beim Lachen?

- o Ich habe keine Schmerzen.
- o Ich habe leichte Schmerzen.
- o Ich habe mäßige Schmerzen.
- o Ich habe starke Schmerzen.

6. Vermeiden Sie aufgrund Ihrer Schmerzen das Lächeln, Sprechen oder Kauen?

- o Ich kann die oben genannten Gesten oder Funktionen ohne Probleme durchführen.
- o Ich vermeide sie gelegentlich aufgrund der Schmerzen.
- o Ich vermeide sie häufig aufgrund der Schmerzen.
- o Ich vermeide sie immer aufgrund der Schmerzen.

7. Haben Sie Schmerzen im Kiefer?

- o Ich habe keine Schmerzen.
- o Ich habe Schmerzen, wenn ich ihn bewege.
- o Auch wenn ich ihn nicht bewege, habe ich gelegentlich Schmerzen.
- o Der Schmerz ist konstant und unabhängig von der Aktivität.

8. Hören Sie ein Geräusch beim Bewegen des Kiefers?

- o Ich höre kein Geräusch.
- o Bei einigen Bewegungen höre ich ein Geräusch.
- o Bei den meisten Bewegungen höre ich ein Geräusch und habe Schmerzen.
- o Bei allen Bewegungen höre ich ein Geräusch und habe Schmerzen.

9. Bemerken Sie, dass sich Ihr Kiefer ausrenkt?

- o Ich spüre nichts Außergewöhnliches.
- o Ich spüre gelegentlich, dass sich mein Kiefer ausrenkt.
- o Ich spüre häufig, dass sich mein Kiefer ausrenkt.
- o Ich spüre immer, dass sich mein Kiefer ausrenkt.

10. Intensität der Schmerzen beim <u>Kauen</u>:

- o Ich habe keine Schmerzen.
- o Ich habe leichte Schmerzen.
- o Ich habe mäßige Schmerzen.
- o Ich habe starke Schmerzen.
- o

11. Spüren Sie Ermüdung am Kiefer beim Sprechen oder beim Essen?

- o Ich spüre keine Ermüdung.
- o Ich spüre eine leichte Ermüdung.
- o Ich spüre eine mäßige Ermüdung.
- o Ich spüre eine starke Ermüdung.

12. Haben Sie Schwierigkeiten den Mund zu öffnen?

- o Ich habe keine Schwierigkeiten.
- o Ich habe leichte Schwierigkeiten.
- o Ich habe mäßige Schwierigkeiten.
- o Ich habe starke Schwierigkeiten.

13. Intensität der Schmerzen beim Sprechen:

- o Ich habe keine Schmerzen.
- o Ich habe leichte Schmerzen.
- o Ich habe mäßige Schmerzen.
- o Ich habe starke Schmerzen.

14. Haben Sie Angst den Kiefer zu bewegen?

- o Ich habe keine Angst den Kiefer zu bewegen.
- o Gelegentlich vermeide ich einige Bewegungen des Kiefers aus Angst, dass mein Problem sich verschlechtert.
- o Häufig vermeide ich einige Bewegungen des Kiefers aus Angst, dass mein Problem sich verschlechtert.
- o Ich mache nur die notwendigsten Bewegungen aus Angst, dass mein Problem sich verschlechtert.

15. Ernährung

- o Ich kann alle Lebensmittel essen.
- o Manche harte Lebensmittel kann ich nicht essen.
- o Ich kann nur weiche Lebensmittel essen.
- o Ich ernähre mich nur von Flüssigkeiten.

16. Wie häufig haben Sie Nackenschmerzen?

- o Ich habe keine Nackenschmerzen.
- o In manchen Situationen habe ich Nackenschmerzen.
- o Ich habe häufig Nackenschmerzen.
- o Ich habe immer Nackenschmerzen.

17. Wie häufig haben Sie Kopfschmerzen?

- o Ich habe keine Kopfschmerzen.
- o In manchen Situationen habe ich Kopfschmerzen.
- o Ich habe häufig Kopfschmerzen.
- o Ich habe immer Kopfschmerzen.

18. Wie häufig haben Sie Ohrenschmerzen?

- o Ich habe keine Ohrenschmerzen.
- o In manchen Situationen habe ich Ohrenschmerzen.
- o Ich habe häufig Ohrenschmerzen.
- o Ich habe immer Ohrenschmerzen.

19. Was fühlen Sie, wenn Sie die schmerzende Stelle berühren?

- o Wenn ich mit den Fingern das Gesicht leicht berühre, habe ich keinen Schmerz.
- o Wenn ich mit den Fingern das Gesicht leicht berühre, habe ich einen leichten Schmerz.
- o Wenn ich mit den Fingern das Gesicht leicht berühre, habe ich einen starken Schmerz.
- o Ich kann mein Gesicht nicht leicht berühren, weil sogar diese Berührung einen Schmerz verursacht.

20. Stören die Schmerzen Ihren Schlaf?

- o Die Schmerzen stören mich nicht beim Schlafen.
- o Gelegentlich wird das Einschlafen durch die Schmerzen beeinträchtigt.
- o Häufig wird das Einschlafen durch die Schmerzen beeinträchtigt.
- o Ich kann aufgrund der Schmerzen nicht schlafen.

21. Stören die Schmerzen Sie, bei der Ausübung Ihres Berufes?

- o Sie stören mich nicht in meinem Beruf.
- o Gelegentlich stören sie mich in meinem Beruf.
- o Häufig stören sie mich in meinem Beruf.
- o Sie stören mich immer in meinem Beruf.

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