# Cross-Cultural Adaptation and Psychometric Properties of The Thai Versions of The Patient-Reported Outcomes Measurement Information System Short Form – Anxiety 8a and the Pain Anxiety Symptoms Scale-20 in Individuals with Chronic Low Back Pain

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# Abstract:

**Objective:** To translate and cross-culturally adapt the Patient-Reported Outcomes Measurement Information System Short Form v1.0–Anxiety 8a and the Pain Anxiety Symptoms Scale–20 into Thai versions (T–PROMIS–Anx8a and T–PASS–20, respectively) and evaluate their psychometric properties in individuals with chronic low back pain (CLBP). **Material and Methods:** The translations and cultural adaptations were performed using the Functional Assessment of Chronic Illness Therapy (FACIT) guidelines. Thai individuals with CLBP completed the T–PROMIS–Anx8a and T–PASS–20. Psychometric evaluation including: internal consistency, test–retest reliability, and dimensionality. Construct validity was evaluated by computing correlations among the scores on the T–PROMIS–Anx8a, T–PASS–20, Thai version of the Hospital Anxiety and Depression Scale–Anxiety (T–HADS–A), and Thai version of the Fear Avoidance Beliefs Questionnaire (T–FABQ).

**Results:** A total of 269 individuals with CLBP were included in the analyses. The T-PROMIS-Anx8a showed unidimensionality and the T-PASS-20 evidenced a 4-factor structure. Both measures demonstrated good to excellent internal consistency (Cronbach's alphas ranged from 0.85 to 0.95), good test-retest reliability (ICC<sub>(2,1)</sub> ranged from 0.79 to 0.88), and neither ceiling nor floor effects were observed for any of the scales. Both measures evidenced acceptable convergent and discriminant validity, based on their associations with the T-HADS-A and T-FABQ.

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#### Thai Versions of PROMIS-Anx8a and PASS-20

**Conclusion:** The T-PROMIS-Anx8a and T-PASS-20 were culturally adapted and evidenced acceptable psychometric properties for assessing anxiety in Thai individuals with CLBP.

Keywords: anxiety, chronic low back pain, cross-cultural adaptation, pain-related anxiety, psychometric properties

# Introduction

Chronic low back pain (CLBP) is the most common chronic musculoskeletal pain problem. It has been found to be present in up to 20% of adults<sup>1</sup>, and is the leading cause of years lived with disability worldwide<sup>2</sup>. CLBP is also associated with significant economic and societal burden, including high healthcare costs, loss of productivity, absenteeism, presenteeism, and loss of social identity<sup>3,4</sup>. In Thailand, the annual prevalence of CLBP in adults has been reported to range from 27% to 30%<sup>5,6</sup>.

Anxiety is a psychological factor that plays an important role in the development and maintenance of chronic pain<sup>7</sup>. It is positively associated with pain severity (*r*'s range, .34 to .45) and disability (*r*'s range, .37 to .60)<sup>8,9</sup>. Nearly half of the individuals with chronic pain have been found to test positive for at least one anxiety disorder<sup>10</sup>. Approximately 10% to 24% of individuals with CLBP report having significant anxiety<sup>11,12</sup>. Treatment–related reductions in pain–related anxiety are associated with improvements in pain severity, disability, and daily activity in individuals with CLBP<sup>13</sup>.

Various measures have been developed in order to understand the role of anxiety in chronic pain. Currently, self-administered questionnaires for assessing anxiety can be classified into two types: generic and pain-specific<sup>14</sup>. Generic measures aim to measure the key components of anxiety in general. The most commonly used measures of general anxiety are the State and Trait Anxiety Inventory (STAI) and Hospital Anxiety and Depression Scale – Anxiety (HADS-A)<sup>14</sup>. To promote comparisons across chronic diseases and demographic groups, the National Institutes of Health has encouraged researchers and clinicians to use the Patient-Reported Outcomes Measurement Information System (PROMIS) for precise and efficient measurement of patient-reported symptoms<sup>15</sup>. In the context of anxiety measurement, the 8-item short form of the PROMIS (PROMIS SF v1.0 – Anxiety 8a) has been recommended as a static measure that balances the need for brevity with the need for content validity<sup>16</sup>.

Regarding the pain-specific measures for anxiety, they aim to evaluate anxiety in response to pain. The Pain Anxiety Symptoms Scale (PASS) was endorsed by a panel of experts as the preferred questionnaire for assessing anxiety in people at risk of developing persistent musculoskeletal pain<sup>17</sup>. A short form version, with 20 items (PASS-20)<sup>8</sup>, was shown to have equivalent psychometric properties to the original 40-items of PASS<sup>18</sup>.

In order to conduct cross-country pain research, translated versions of the generic and pain-specific measures of anxiety are needed. However, the PROMIS SF v1.0 – Anxiety 8a and PASS-20 are not yet available in the Thai language. Hence, the aims of this study were to translate and cross-culturally adapt the PROMIS SF v1.0 – Anxiety 8a and PASS-20 into the Thai language and to evaluate their psychometric properties among Thai individuals with CLBP.

## **Material and Methods**

The research study received ethical approval from the Research Ethics Review Committee of the University (COA No. 097/65 and 208/65). The study was conducted in two phases. All participants provided informed consent prior to participation.

#### Phase 1: Cross-cultural adaptation process

The original English versions of the PROMIS Short Form v1.0 – Anxiety 8a and the PASS-20 were crossculturally translated, using the Functional Assessment of Chronic Illness Therapy (FACIT) guidelines<sup>19</sup>. The FACIT translation methodology consists of 11 steps: forward translation, reconciliation, back-translation, back-translation review/quality control, pre-finalization review, finalization process, harmonization and quality assurance, formatting and proofreading, cognitive testing and linguistic validation, and evaluation of the cognitive testing participants' comments and finalization of translation (Figure 1). Finally, the Thai versions of the PROMIS SF v1.0 – Anxiety 8a (T-PROMIS-Anx8a) and PASS-20 (T-PASS-20) were ready to be evaluated for their psychometric properties.

# Phase 2: Evaluation of psychometric properties *Participants*

Potential participants were recruited from three public hospitals, five physical therapy clinics in Bangkok, and their nearby provinces; from November 2022 until May 2023. A sample size of at least 200 participants was determined a priori to be adequate for the planned analyses of based on established recommendations for the evaluation dimensional structure<sup>20</sup>.

Individuals having met the following inclusion criteria were eligible for the study: (1) having CLBP, (2) being 18 years old or above, and (3) being a native Thai speaker who could understand and communicate in the Thai language. CLBP was defined as pain in the region between the lower posterior margin of the rib cage and the horizontal gluteal fold that had persisted for at least three months and had resulted in pain for at least half a day in the past six months<sup>21</sup>. Exclusion criteria included having a history of severe pathology in the lumbar spine that had been diagnosed by a doctor or having serious medical conditions that might affect the ability to participate in the study procedures.

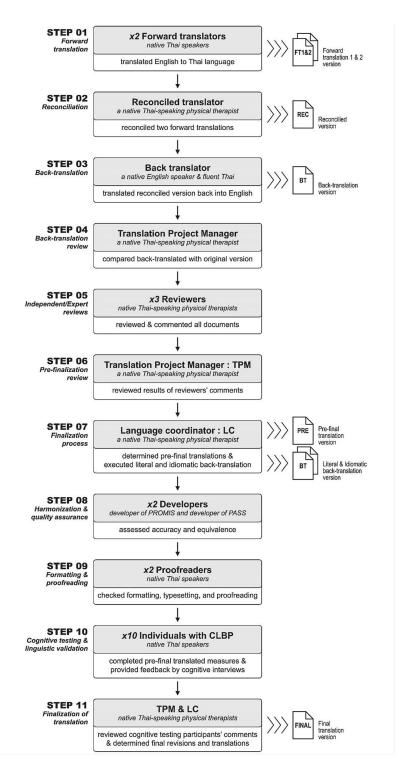
#### Measures

Demographic questionnaire. The participants were asked to provide information regarding basic demographics, pain duration, pain intensity, and backrelated disability. The respondents were asked to rate their current pain as well as average pain over the past seven days on the Thai versions of an 11-point Numerical Rating Scale (T-NRS), which consisted of a series of numbers ranging from 0 "No pain" to 10 "The worst pain imaginable." A great deal of research supports the reliability and validity of the NRS for measuring pain intensity in patients with low back pain<sup>22</sup>. The back-related disability was measured using the Thai version of the 10-item Functional Rating Index (T-FRI)<sup>23</sup>. The respondents were asked to rate each item on a 5-point Likert scale wherein 0 indicated no disability or no pain and 4 indicated inability to perform functions or worst pain. A total score is created by summing the item ratings, divided by the maximum possible total score, and then multiplying this by 100. Higher scores indicated more pain-related disability.

PROMIS Short Form v1.0 – Anxiety 8a scale. The 8–item PROMIS Short Form v1.0 – Anxiety 8a scale was translated and used in this study. Its items assess fear, anxiety, and hyperarousal. Responses for each item are rated on a 5–point Likert scale (1 "Never" to 5 "Always"). The total raw score is transformed into a *T*-score, using a conversion table with a mean of 50 and a standard deviation of 10 in the normative sample<sup>16, 24, 25</sup>. The *T*-scores of 55 to 59, 60 to 69, and ≥70 represent mild, moderate, and severe anxiety, respectively (see https://www.healthmeasures.net).

Pain Anxiety Symptoms Scale-20 (PASS-20). This scale consists of 20 items. Each item is rated on a 6-point Likert scale (0 "Never" to 5 "Always"). The scale can be scored as a total score or four subscale scores (made up of 5 items each: Fear of Pain, Cognitive Anxiety, Physiological Anxiety, and Escape/Avoidance)<sup>8</sup>. The total score can range from 0 to 100, and each subscale score can range from 0 to 25. Respondents can be classified as

## Thai Versions of PROMIS-Anx8a and PASS-20



FACIT=functional assessment of chronic illness therapy, TPM=translation project manager, LC=language coordinator, CLBP=chronic low back pain, FT=forward translator, REC=reconciled translator, BT=back translator

Figure 1 Modified FACIT translation methodology

having different levels of pain-related anxiety using the following ranges: 0 to 33 (mild), 34 to 67 (moderate), and 68 to 100 (severe)<sup>26</sup>.

*Hospital Anxiety and Depression Scale – Anxiety (HADS–A).* The HADS–A is a 7–item screening tool developed to measure generalized symptoms of anxiety in patients being treated in hospital–based outpatient clinics<sup>27</sup>. HADS–A, respondents rate each anxiety symptom in the past week on a 4–point Likert scale ranging from 0 to 3, with each response having a different meaning depending on the item. Responses to the seven items are summed to give a total score that can range from 0 to 21. Scores less than 7 indicate no or little anxiety, scores ranging from 8 to 10 indicate mild anxiety, 11 to 14 moderate anxiety, and 15 to 21 indicate severe anxiety. The Thai version of the HADS–A (T–HADS–A) has been reported to have acceptable psychometric properties in cancer patients, with good reliability (Cronbach's alpha 0.86)<sup>28</sup>.

Fear Avoidance Beliefs Questionnaire (FABQ). The FABQ is a 16-item questionnaire designed to measure patients' pain-related fear avoidance beliefs related to physical activity and work<sup>29</sup>. The respondents are asked to rate the extent to which they agree with each belief on a 7-point Likert scale (0 "Completely disagree" to 6 "Completely agree"). The responses are summed, with a higher score indicating a higher level of fear-avoidance beliefs. For subscale scores, only 11 items were used, of which four of the items are used to assess pain-related fear avoidance beliefs related to physical activity<sup>29</sup>. The maximum scores for the physical activity subscale, the work subscale, and the total scale are 24, 42, and 96, respectively. The Thai version of the FABQ (T-FABQ) has been reported to be reliable and valid for assessing fear avoidance beliefs in non-specific neck pain patients, with good reliability (Cronbach's alphas ranged from 0.87 to 0.88)<sup>30</sup>.

The 11-point Global Perceived Effect (GPE). The GPE is used to assess the participants' perceptions of change in overall condition, from its initial to second assessment<sup>31</sup>. The responses to the scale range from -5: "Vastly worse" to 5: "Completely recovered." It has been found to be test-retest reliable and valid for assessing perceived changes in musculoskeletal disorders<sup>31</sup>.

#### Procedures

Potential participants that were eligible and interested in participating were asked to read and sign an informed consent form, and then complete paperand-pencil versions of the study measures on two occasions. At the initial assessment, they completed the demographic questionnaire, T-PROMIS-Anx8a, T-PASS-20, T-HADS-A, and T-FABQ. They were then given a questionnaire packet that included the T-PROMIS-Anx8a, T-PASS-20, and T-GPE along with a stamped, addressed envelope. One week after the initial assessment, they were asked to complete the questionnaire packet again and mail it back to the researchers. Participants who provided a T-GPE rating from -1 to 1 (indicating little to no change) were included in the analyses to evaluate test-retest reliability analyses.

#### Statistical analysis

All data analyses were calculated by Statistical Package for Social Sciences (SPSS) version 29.0 except the confirmatory factor analyses which were calculated by Analysis of a Moment Structures (AMOS) version 29.0. A p-value<0.05 was considered to be statistically significant.

Baseline characteristics were examined using frequencies, means, and standard deviations to describe the sample and study variables. Ceiling and floor effects were tested by calculating the proportions of participants with the maximum or minimum possible score, respectively. With respect to these effects, proportions greater than 15% were viewed as being unacceptable<sup>32</sup>.

The dimensional structures of the T-PROMIS-Anx8a and T-PASS-20 were examined using the confirmatory factor analysis (CFA) model. A 1-factor model was used to investigate the unidimensionality of the T-PROMIS-Anx8a, because the PROMIS Anxiety item bank was developed with the assumption that the items assessed a single factor<sup>25</sup>. Because the PASS-20 has been shown to have four subscales in prior research<sup>33</sup>, the T-PASS-20 was tested for a 4-factor model. Each model was evaluated using maximum likelihood estimation. Model fit was assessed using the comparative fit index (CFI), Tucker-Lewis index (TLI), root mean square error of approximation (RMSEA), and standard root of mean square residual (SRMR). A good fit model was concluded by CFI values and TLI values >0.95, RMSEA values <0.06, and SRMR <0.08. An acceptable fit model was defined by CFI values and TLI values ranging from 0.90 to 0.95 and RMSEA values ranging from 0.06 to 0.08. RMSEA values between 0.08 and 0.10 indicated a mediocre fit, and values >0.10 defined a poor fit<sup>34</sup>. The fit evaluation focused on the index set.

Reliability of the T-PROMIS-Anx8a and T-PASS-20 (subscales and total scores) were evaluated in terms of internal consistency and test-retest reliability. The score from the first session was used for the internal consistency analysis. It was evaluated using Cronbach's alpha coefficient. Values greater than 0.70 were used to conclude that the internal consistency was acceptable, while a value greater than 0.90 might indicate redundancy<sup>35</sup>. Testretest reliability was assessed using intraclass correlation coefficients (ICC $_{(2,1)}$ ). ICC values greater than 0.75 were used to indicate that the test-retest reliability was acceptable<sup>36</sup>. The standard error of measurement  $(SEM_{test-retest})^{37}$  and the minimum detectable change at a 95% confidence level  $\left(\text{MDC}_{_{\text{\tiny ACP}}}\right)^{_{38}}$  were also calculated to estimate the amount of error associated with the administration of the questionnaires twice.

Construct validity of the measures was evaluated by computing Spearman's rank correlation coefficients between the two administrations of the measures. It was hypothesized that T-PROMIS-Anx8a and T-PASS-20 would demonstrate convergent validity with T-HADS-A, while showing discriminant validity with T-FABQ. The T-PROMIS-Anx8a and T-PASS-20 would demonstrate convergent validity with each other. Correlation coefficient (r) values less than 0.40 were used to conclude weak associations, 0.40  $\leq r < 0.70$  to conclude moderate associations, and  $r \ge 0.70$  to conclude strong associations<sup>39</sup>. An r value of 0.60 or higher was considered acceptable as support for convergent validity, and an r value of less than 0.40 was considered acceptable as support for discriminant validity<sup>40</sup>. Although, the criterion for convergent validity was not high, it is recommended for evaluating correlation coefficient. This is because studies designed for testing construct validity between two measures typically observe and record data without controlling the participants' environment; in which variability in the variables can be from other factors<sup>41</sup>.

# Results

The cross-cultural translation and adaptation of the PROMIS Short Form v1.0 – Anxiety 8a and PASS-20 into their Thai versions were successfully performed using the methods specified by the FACIT guidelines. All items were understood without any difficulties. The T-PROMIS-Anx8a and T-PASS-20 were therefore, deemed to be culturally suitable and understandable.

#### **Demographic characteristics**

In Phase 2 of the study, a total of 362 individuals with CLBP were invited to participate: 354 (98%) agreed to take part in the study. Of these, 269 met the eligibility criteria and provided data on the first assessment (response rate 74%). Details regarding the sample's demographic characteristics are presented in Table 1. The pain intensity

on the T-NRS and disability on the T-FRI scale indicated moderate levels of pain and disability, respectively. On average, the participants were shown to endorse mild anxiety measured on the T-HADS-A (mean=7.8) and T-PROMIS-Anx8a (mean=57.7), while it was shown to be moderate on the T-PASS-20 total score (mean=45.9).

#### Dimensionality

For the T-PROMIS-Anx8a, the CFA fit indices indicate a good fit to the 1-factor model with two indices (CFI and SRMR), an acceptable fit with one index (TLI) and a poor fit with one index (RMSEA). For the T-PASS-20, the indices indicate a good fit to 4-factor model with one index (SRMR), an acceptable fit with two indices (CFI and TLI), and a mediocre fit with one index (RMSEA) (Table 2).

#### Reliability, ceiling effect, and floor effect

The Cronbach's alpha of the T-PROMIS-Anx8a and T-PASS-20 (subscales and total score) ranged from 0.85 to 0.95, showing good to excellent internal consistency (Table 3). Cronbach's alpha, if the item was deleted, showed that removing any item did not significantly elevate the values of the T-PROMIS-Anx8a and T-PASS-20 (subscales and total score). No ceiling or floor effects were found for any of the scale scores. At one week after the initial assessment, 101 participants reported that their condition had not changed. The values of ICC<sub>(2,1)</sub> for these participants ranged from 0.79 to 0.88, indicating good test-retest reliability (Table 4).

Table 1 Demographic characteristics of the participants (n=269)

Characteristic	n (%)	Mean (S.D.)	
 Sex assigned at birth			
Female	189 (70)		
Male	80 (30)		
Age (years)		42.5 (16.6)	
Height (cm)		162.1 (8.9)	
Weight (kg)		63.6 (14.2)	
Body mass index (kg/m <sup>2</sup> )		24.1 (4.9)	
Employment status			
Employed	202 (75)		
Unemployed	67 (25)		
Pain Duration (months)		33.7 (35.8)	
Pain Intensity (T-NRS-11; 0-10)			
Current pain		5.9 (1.9)	
Average pain (7-day)		5.9 (1.8)	
Disability (T-FRI; 0-100)		45.5 (15.3)	
T-HADS-A (0-21)		7.8 (4.1)	
T-PROMIS-Anx8a		57.7 (9.7)	
T-PASS-20			
Total score (0-100)		45.9 (21.9)	
Cognitive Anxiety (0-25)		11.9 (6.5)	
Escape / Avoidance (0-25)		14.4 (6.1)	
Fear of Pain (0-25)		11.3 (7.1)	
Physiological Anxiety (0-25)		8.4 (6.0)	

T-FRI=Thai version of Functional Rating Index, T-HADS-A=Thai version of Hospital Anxiety and Depression Scale – Anxiety, T-NRS-11=Thai version of 11-point Numeric Rating Scale, T-PASS-20=Thai version of Pain Anxiety Symptoms Scale-20, T-PROMIS-Anx8a=Thai version of Patient-Reported Outcomes Measurement Information System Short Form v1.0-Anxiety 8a

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#### Table 2 Confirmatory factor analysis fit indices (n=269)

Scale	CFI	TLI	RMSEA (90%CI)	SRMR
T-PROMIS-Anx8a				
1-factor model	0.96	0.94	0.12 (0.10-0.14)	0.03
T-PASS-20				
4-factor correlated model	0.91	0.90	0.09 (0.08-0.10)	0.06

CFI=comparative fit index, TLI=Tucker-Lewis index, RMSEA=root mean square error of approximation, CI=confidence interval, SRMR=standard root of mean square residual.

Table 3 Internal consistency and ceiling and floor effect statistics for the T-PROMIS and the T-PASS-20 scales

(n=269)

Scale	Cronbach's alpha	Ceiling effect (%)	Floor effect (%)
T-PROMIS-Anx8a	0.95	0	10
T-PASS-20			
Total score	0.95	0	<1
Cognitive anxiety	0.93	<1	3
Escape/Avoidance	0.85	3	<1
Fear of pain	0.91	2	8
Physiological anxiety	0.88	<1	10

Table 4 Mean (S.D.) and the test-retest reliability coefficients (n=101)

Scale	Baseline score	1-week score	ICC <sub>(2,1)</sub> (95%CI)	SEM test-retest	MDC 95%
T-PROMIS-Anx8a	56.8 (9.6)	56.2 (10.3)	0.86 (0.80-0.90)	3.75	10.40
T-PASS-20					
Total score	41.6 (22.5)	39.8 (22.0)	0.88 (0.83-0.92)	7.74	21.45
Cognitive Anxiety	10.7 (6.0)	10.4 (6.0)	0.84 (0.77-0.89)	2.41	6.68
Escape / Avoidance	12.8 (6.2)	12.1 (6.0)	0.79 (0.70-0.85)	2.81	7.80
Fear of Pain	10.4 (7.6)	9.8 (7.1)	0.83 (0.76-0.89)	3.01	8.34
Physiological Anxiety	7.6 (6.3)	7.6 (5.9)	0.88 (0.83-0.92)	2.10	5.83

ICC=intraclass correlation coefficient, CI=confidence interval, SEM=standard error of measurement, MDC=minimal detectable change

### **Construct validity**

The T-PROMIS-Anx8a and T-PASS-20 (total score and 3 subscales) showed acceptable convergent validity (r's  $\geq$ 0.60; see Table 5). Only the subscale of Escape/ Avoidance of the T-PASS-20 showed a weak correlation with T-PROMIS-Anx8a (r=0.32) and T-HADS-A (r=0.37). Regarding the discriminant validity analyses, expected weak correlations (r < 0.40, r's range from 0.15 to 0.44) were found between the T-PROMIS-Anx8a and T-PASS-20 (total score and all subscales) and T-FABQ, respectively.

Scale	T-PROMIS-	T-HADS-A		T-FABQ		
	Anx8a		Physical activity	Work	Total	
T-PROMIS-Anx8a		0.79 <sup>a</sup>	0.15 <sup>b</sup>	0.27 <sup>a</sup>	0.28 <sup>a</sup>	
T-PASS-20						
Total score	0.65 <sup>a</sup>	0.67 <sup>a</sup>	0.32 <sup>a</sup>	0.37 <sup>a</sup>	0.44 <sup>a</sup>	
Cognitive anxiety	0.64 <sup><i>a</i></sup>	0.63 <sup>a</sup>	0.28 <sup>a</sup>	0.37 <sup>a</sup>	0.41 <sup>a</sup>	
Escape/avoidance	0.32 <sup>a</sup>	0.37 <sup>a</sup>	0.36 <sup>a</sup>	0.29 <sup>a</sup>	0.38 <sup>a</sup>	
Fear of pain	0.63 <sup>a</sup>	0.63 <sup>a</sup>	0.27 <sup>a</sup>	0.32 <sup>a</sup>	0.37 <sup>a</sup>	
Physiological pnxiety	0.63 <sup>a</sup>	0.67 <sup>a</sup>	0.19 <sup>a</sup>	0.29 <sup>a</sup>	0.34 <sup>a</sup>	

Table 5 Spearman correlation coefficients of the T-PROMIS and T-PASS-20, with the other questionnaires (n=269)

T-HADS-A=Thai version of hospital anxiety and depression scale-anxiety, T-FABQ=Thai version of the fear avoidance beliefs questionnaire, <sup>a</sup>=Correlation is significant at the 0.05 level (2-tailed), <sup>b</sup>=Correlation is significant at the 0.01 level (2-tailed)

# Discussion

This present study successfully cross-culturally translated and adapted the PROMIS Short Form v1.0 – Anxiety 8a and PASS-20 scales into the Thai language. The Thai versions; known as T-PROMIS-Anx8a and T-PASS-20, exhibited a similar dimensional structure as the original English versions, with acceptable reliability and construct validity when being assessed in individuals with CLBP.

The T-PROMIS-Anx8a scale showed a good fit with a 1-factor structure, providing support for the unidimensional characteristic of the PROMIS scale, as reported in previous studies<sup>25</sup>. The T-PROMIS-Anx8a scale also demonstrated a high level of internal consistency, with a Cronbach's alpha of 0.95; this was consistent with the reported value of 0.91 for the English version<sup>42</sup>. No reports on the ceiling and floor effects, as well as the test-retest reliability of the PROMIS Short Form v1.0 - Anxiety 8a, are available for comparisons. In comparison to the 4-item short form of PROMIS Anxiety in patients with CLBP (ICC<sub>(21)</sub>=0.63)<sup>43</sup>, the T-PROMIS-Anx8a in this study showed higher test-retest reliability (ICC $_{(2,1)}$ =0.86). Together with the absence of ceiling and floor effects, these findings support the reliability of the T-PROMIS for measuring anxiety in individuals with CLBP. In addition, the  $MDC_{_{95\%}}$  statistic for the T-PROMIS-Anx8a indicates that the change score must exceed 10.40 points to be 95% confident that this is not due to measurement error. This value was smaller than the 14.91 points reported for the Thai version of the 4-item short form PROMIS Anxiety<sup>43</sup>.

The T-PASS-20 scale demonstrated an acceptable fit with a 4-factor structure, which aligns with the original English version<sup>33</sup>. Higher internal consistency coefficients for the T-PASS-20 scales than those reported for the English version<sup>8</sup> were also found. No previous studies have reported on the ceiling and floor effects as well as the test-retest reliability of the English short form. Consistent with the findings from this study, the Persian version did not exhibit ceiling and floor effects<sup>43</sup>. Good test-retest reliability was also demonstrated for the Persian version (ICC $_{(2,1)}$  ranged from 0.70 to 0.91)^{44} and the Korean version (ICC  $_{_{(2,1)}}$  ranged from 0.89 to 0.91)  $^{\rm 45}$  . Regarding the  ${\rm MDC}_{_{95\%}}$  statistic of the T-PASS-20, the findings indicated that a change score of at least 21.45 points is needed to be able to detect a true change in an individual's pain-related anxiety: at a 95% confidence level. This finding was consistent with the Persian version of PASS-20 (MDC<sub>95%</sub>=20.14 points)<sup>44</sup>.

The scores of both the T-PROMIS-Anx8a and T-PASS-20 evidenced convergent validity with T-HADS-A. However, one subscale of the T-PASS-20 (Escape/ Avoidance) demonstrated weak associations with both the T-PROMIS-Anx8a and T-HADS-A (*r*'s<.60). This may have been due to the domain assessed by this specific subscale. Based on the fear-anxiety-avoidance model of chronic pain, anxiety consists of three dimensions: cognitive, physiological, and motivational (escape/avoidance) anxiety<sup>46</sup>. The items in T-PROMIS-Anx8a and T-HADS-A tend to focus primarily on the cognitive dimension, providing less emphasis on the escape/avoidance dimension. Support for this possibility could be found if differences in anxiety levels as measured by the different scales that emerged. An examination of the scale scores is consistent with this idea; at baseline, the T-PROMIS-Anx8a and T-HADS-A classified the participants as experiencing mild anxiety, while the T-PASS-20 indicated moderate anxiety.

Consistent with the study hypotheses, both T-PROMIS-Anx8a and T-PASS-20 scores showed discriminant validity with T-FABQ scores. These findings are consistent with previous studies that showed no significant association between the PROMIS Anxiety item banks and T-FABQ total score (r=0.18, p-value=0.15)<sup>47</sup> as well as weak to moderate correlations (*r*'s ranged from 0.18 to 0.45) between PASS-20 and T-FABQ physical activity and work subscale scores<sup>44</sup>. These results suggest that the T-PROMIS-Anx8a and T-PASS-20 may capture different aspects from the T-FABQ. The FABQ predominantly focuses on an individual's belief that affects their pain<sup>29</sup>, while the items in T-PROMIS-Anx8a and T-PASS-20 emphasize an individual's perception of anxiety and response to pain.

This present study has some limitations that should be acknowledged. First, the study population was limited to individuals with CLBP, and those with moderate pain intensity and disability. The extent to which the current findings generalize to individuals having other pain problems is unknown. Additionally, it would be interesting to conduct further research involving subgroups, based on varying levels of pain intensity and disability. Furthermore, this study focused on only one aspect of construct validity. Future research should investigate the scales' ability to detect changes in anxiety conditions over time. Moreover, the reported minimal detectable changes in this study may not have clinical relevance; as they represent the minimum amount that can be attributed to factors other than measurement error. Future studies should be specifically designed to evaluate the minimum clinically significant difference in anxiety measurements.

# Conclusion

This study demonstrated linguistically acceptable, reliable, and validity of T-PROMIS-Anx8a and T-PASS-20 in Thai individuals with CLBP. Both scales showed excellent internal consistency in addition to good test-retest reliability. However, the T-PROMIS-Anx8a and T-PASS-20 tend to emphasize different dimensions of anxiety.

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#### **Conflict of interest**

There are no potential conflicts of interest to declare.

#### References

- Meucci RD, Fassa AG, Faria NM. Prevalence of chronic low back pain: systematic review. Rev Saude Publica 2015;49:1.
- 2. Hoy DG, Smith E, Cross M, Sanchez-Riera L, Blyth FM,

Buchbinder R, et al. Reflecting on the global burden of musculoskeletal conditions: lessons learnt from the global burden of disease 2010 study and the next steps forward. Ann Rheum Dis 2015;74:4-7.

- Gore M, Sadosky A, Stacey BR, Tai K-S, Leslie D. The Burden of chronic low back pain: clinical comorbidities, treatment patterns, and health care costs in usual care settings. Spine 2012;37:668–77.
- Bailly F, Foltz V, Rozenberg S, Fautrel B, Gossec L. The impact of chronic low back pain is partly related to loss of social role: A qualitative study. Joint Bone Spine 2015;82:437–41.
- Sihawong R, Sitthipornvorakul E, Paksaichol A, Janwantanakul P. Predictors for chronic neck and low back pain in office workers: a 1-year prospective cohort study. J Occup Health 2016;58:16-24.
- Yiengprugsawan V, Hoy D, Buchbinder R, Bain C, Seubsman SA, Sleigh AC. Low back pain and limitations of daily living in Asia: longitudinal findings in the Thai cohort study. BMC Musculoskelet Disord 2017;18:19–25.
- Meints SM, Edwards RR. Evaluating psychosocial contributions to chronic pain outcomes. Prog Neuropsychopharmacol Biol Psychiatry 2018;87:168–82.
- McCracken LM, Dhingra L. A short version of the pain anxiety symptoms scale (pass-20): preliminary development and validity. Pain Res Manag 2002;7:45-50.
- Jiang Y, Wang Y, Wang R, Zhang X, Wang X. Differences in pain, disability, and psychological function in low back pain patients with and without anxiety. Front Physiol 2022;13:906461.
- Kroenke K, Outcalt S, Krebs E, Bair MJ, Wu J, Chumbler N, et al. Association between anxiety, health-related quality of life and functional impairment in primary care patients with chronic pain. Gen Hosp Psychiatry 2013;35:359–65.
- Stubbs B, Koyanagi A, Thompson T, Veronese N, Carvalho AF, Solomi M, et al. The epidemiology of back pain and its relationship with depression, psychosis, anxiety, sleep disturbances, and stress sensitivity: Data from 43 low- and middle-income countries. Gen Hosp Psychiatry 2016;43:63-70.
- Hu Y, Yang Z, Li Y, Xu Y, Zhou X, Guo N. Anxiety symptoms and associated factors among chronic low back pain patients in china: a cross-sectional study. Front Public Health 2022;10:878865.
- 13. McCracken LM, Gross RT. The role of pain-related anxiety

reduction in the outcome of multidisciplinary treatment for chronic low back pain: preliminary results. J Occup Rehabil 1998;8:179–89.

- Rose M, Devine J. Assessment of patient-reported symptoms of anxiety. Dialogues Clin Neurosci 2014;16:197–211.
- Cella D, Riley W, Stone A, Rothrock N, Reeve B, Yount S, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005–2008. J Clin Epidemiol 2010;63:1179–94.
- Cella D, Choi SW, Condon DM, Schalet B, Hays RD, Rothrock NE, et al. PROMIS® Adult Health Profiles: Efficient Short-Form Measures of Seven Health Domains. Value Health 2019;22:537-44.
- Bijker L, Sleijser-Koehorst MLS, Coppieters MW, Cuijpers P, Scholten-Peeters GGM. Preferred self-administered questionnaires to assess depression, anxiety and somatization in people with musculoskeletal pain – a modified delphi study. J Pain 2020;21:409–17.
- McCracken LM, Zayfert C, Gross RT. The Pain Anxiety Symptoms Scale: development and validation of a scale to measure fear of pain. Pain 1992;50:67–73.
- Eremenco SL, Cella D, Arnold BJ. A comprehensive method for the translation and cross-cultural validation of health status questionnaires. Eval Health Prof 2005;28:212–32.
- Kyriazos T. Applied psychometrics: sample size and sample power considerations in factor analysis (EFA, CFA) and SEM in general. psychology 2018;09:2207–30.
- Deyo RA, Dworkin SF, Amtmann D, Andersson G, Borenstein D, Carragee E, et al. Report of the NIH task force on research standards for chronic low back pain. J Pain 2014;15:569–85.
- 22. Chiarotto A, Maxwell LJ, Ostelo RW, Boers M, Tugwell P, Terwee CB. Measurement properties of visual analogue scale, numeric rating scale, and pain severity subscale of the brief pain inventory in patients with low back pain: a systematic review. J Pain 2019;20:245–63.
- Chansirinukor W. Thai version of the functional rating index for patients with back and neck pain: part 1 cross-cultural adaptation, reliability and validity. J Med Assoc Thai 2015;98 Suppl 5:97–105.
- 24. Fries JF, Bruce B, Cella D. The promise of PROMIS: using item response theory to improve assessment of patient-reported

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outcomes. Clin Exp Rheumatol 2005;23(5 Suppl 39):53-7.

- Pilkonis PA, Choi SW, Reise SP, Stover AM, Riley WT, Cella D. Item banks for measuring emotional distress from the Patient-Reported Outcomes Measurement Information System (PROMIS®): depression, anxiety, and anger. Assessment. 2011;18:263–83.
- Brede E, Mayer TG, Neblett R, Williams M, Gatchel RJ. The Pain Anxiety Symptoms Scale fails to discriminate pain or anxiety in a chronic disabling occupational musculoskeletal disorder population. Pain Pract 2011;11:430–8.
- Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand 1983;67:361–70.
- Nilchaikovit T, Lotrakul M, Phisansuthideth U. Development of Thai version of hospital anxiety and depression scale in cancer patients. J Psychiatr Assoc Thai 1996;41:18–30.
- Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-avoidance beliefs questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. Pain 1993;52:157-68.
- Wiangkham T, Phungwattanakul N, Tedsombun P, Kongmee I, Suwanmongkhon W, Chidnok W. Translation, cross-cultural adaptation and psychometric evaluation of the Thai version of the fear-avoidance beliefs questionnaire in patients with nonspecific neck pain. Scand J Pain 2020;21:247–55.
- Kamper SJ, Ostelo RW, Knol DL, Maher CG, de Vet HC, Hancock MJ. Global Perceived Effect scales provided reliable assessments of health transition in people with musculoskeletal disorders, but ratings are strongly influenced by current status. J Clin Epidemiol 2010;63:760–6.
- Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol 2007;60:34–42.
- Coons MJ, Hadjistavropoulos HD, Asmundson GJ. Factor structure and psychometric properties of the Pain Anxiety Symptoms Scale-20 in a community physiotherapy clinic sample. Eur J Pain 2004;8:511–6.
- Brown T. Confirmatory Factor Analysis for Applied Research, Second Edition. New York: The Guilford Press; 2015.
- Tavakol M, Dennick R. Making sense of Cronbach's alpha. Int J Med Educ 2011;2:53–5.
- 36. Koo TK, Li MY. A guideline of selecting and reporting intraclass

correlation coefficients for reliability research. J Chiropr Med 2016;15:155-63.

- de Vet HC, Terwee CB, Knol DL, Bouter LM. When to use agreement versus reliability measures. J Clin Epidemiol 2006;59:1033–9.
- 38. de Vet HC, Terwee CB, Ostelo RW, Beckerman H, Knol DL, Bouter LM. Minimal changes in health status questionnaires: distinction between minimally detectable change and minimally important change. Health Qual Life Outcomes 2006;4:54.
- Schober P, Boer C, Schwarte LA. Correlation coefficients: appropriate use and interpretation. Anesth Analg 2018;126:1763– 8.
- Fitzpatrick R, Davey C, Buxton MJ, Jones DR. Evaluating patient-based outcome measures for use in clinical trials. Health Technol Assess 1998;2:1–74.
- 41. Adams KA, Lawrence EK. Research methods, statistics, and applications. 2nd ed. Los Angeles: SAGE; 2019.
- Kroenke K, Baye F, Lourens SG. Comparative responsiveness and minimally important difference of common anxiety measures. Med Care 2019;57:890–7.
- 43. Rawang P, Janwantanakul P, Correia H, Jensen MP, Kanlayanaphotporn R. Cross-cultural adaptation, reliability, and construct validity of the Thai version of the patient-reported outcomes measurement information system-29 in individuals with chronic low back pain. Qual Life Res 2020;29:793-803.
- Shanbehzadeh S, Salavati M, Tavahomi M, Khatibi A, Talebian S, Khademi-Kalantari K. Reliability and validity of the pain anxiety symptom scale in persian speaking chronic low back pain patients. Spine (Phila Pa 1976) 2017;42:1238-44.
- 45. Cho S, Lee SM, McCracken LM, Moon DE, Heiby EM. Psychometric properties of a Korean version of the pain anxiety symptoms Scale-20 in chronic pain patients. Int J Behav Med 2010;17:108–17.
- Asmundson GJG NP, Vlaeyen JWS Fear-avoidance models of chronic pain: An overview. In: Asmundson GJG VJ, Crombez G editor. Understanding and treating fear of pain. New York: Oxford University Press;2004;p.3–24.
- Nayfe R, Chansard M, Hynan LS, Mortensen EM, Annaswamy T, Fraenkel L, et al. Comparison of patient-reported outcomes measurement information system and legacy instruments in multiple domains among older veterans with chronic back pain. BMC Musculoskelet Disord 2020;21:598–609.