Translation and Psychometric Validation of the Traditional Chinese Version of Patient-Reported Outcomes Measurement Information System Peaditaric-25 Profile version 2.0 (PROMIS-25) in Chinese Children with Cancer in Hong Kong

Stephen WW Chan, MSc, DHSc[1,2], CW Chien, PhD[2], Arnold YL Wong, PhD[2], Marco YC Pang, PhD [2]

[1]Allied Health Department (Physiotherapy), Hong Kong Children's Hospital, HKSAR, China;

[2]Department of Rehabilitation Sciences, The Hong Kong Polytechnic University, HKSAR, China

Corresponding author:

Dr. Arnold YL Wong, Department of Rehabilitation Sciences,

The Hong Kong Polytechnic University, HKSAR, China

E-mail address: arnold.wong@polyu.edu.hk

Abstract

Purpose: To translate and cross-cultural validate the PROMIS Paediatric-25 Profile 2.0 (PROMIS-25) into traditional Chinese, and to investigate its psychometric properties in children with cancer in Hong Kong.

Methods: The Functional Assessment of Chronic Illness Therapy translation methodology was adopted in this study. Three panel members evaluated the semantic equivalence and content validity. The psychometric properties were tested with 103 children with cancer (10 to 18 years). Internal consistency and structural validity were examined by Cronbach's alpha and Rasch analysis. Convergent and divergent validity were assessed by correlating it with traditional Chinese paediatric quality of life inventory^{TM} 4.0 domains (traditional Chinese

PedsQL™ 4.0), traditional Chinese Health Questionnaire-9 (C-PHQ-9), and the numeric pain rating scale (NPRS).

Results: The semantic equivalence score and content validity index were both 100%. All domains indicated good internal consistency (α=0.83-0.88) and unidimensionality (variance explained >55.5% and 1st contrast eigenvalues <2.0). All items showed good item fit (0.6 - 1.4). For convergent validity, the traditional Chinese PROMIS-25 domains demonstrated moderate to large correlations with traditional Chinese PedsQL™ 4.0 domains ($r \geq \pm 0.69$), C-PHQ-9 Item-4 and total score (r = 0.75-0.80), except NPRS (r =0.44). For divergent validity, traditional Chinese PROMIS-25 had low correlations with traditional Chinese PedsQL™ 4.0 domains ($r < \pm 0.21$), C-PHQ-9 item-4 (r =0.3) and NPRS (r = -0.12). The traditional Chinese PROMIS-25 fatigue domain was weakly correlated with NPRS (r =0.39).

Conclusion: The traditional Chinese PROMIS-25 is semantically and conceptually like the original PROMIS-25 with satisfactory internal consistency, structural validity, and construct validity.

Keywords: PROMIS, Health-Related Quality of Life, Oncology, Childhood Cancer

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Introduction

Paediatric cancers are disabling diseases affecting many children worldwide. The latest international incidence of childhood cancer report showed that more than 385,500 new cancer cases were diagnosed in children/adolescents aged between 0 to 19 years every year, and the incidence rate of cancer in children aged 0–14 years has increased to 140·6 per million kids in 2010[1]. Additionally, the National Central Cancer Registry of China revealed that the incidence rate of paediatric cancer in China was 10.78 per 10,000 and the mortality rate was 4.41 per 10,000 in 2012. Likewise, there were approximately 195 new cancer cases per year among children and adolescents aged under 20 years in Hong Kong [2], with leukemia (32.4%), brain and spinal tumours (21%), and lymphoma (20%) being the most common cancers [2].

Cancer treatments have deleterious effects on physical and psychosocial health of children with cancer [3]. A 20-year cohort study found that adult survivors of childhood cancer experienced greater adverse medical and psychological consequences, activity limitations, and participation restriction [4]. Therefore, it is crucial for clinicians to use validated patient-reported outcome (PRO) instruments to evaluate these side effects. PROs are defined as the reporting of a patient's perceived health condition without the interpretation by a clinician or other individuals [5]. PROs in paediatric oncology are an umbrella term to describe child-reported disease symptoms; functional outcomes or multidimensional constructs that are related to the health-related quality of life (HRQOL)[6]. Therefore, PROs can help clinicians understand patients' perspective regarding the impacts of cancer and cancer-related treatments on them [7,8].

The Patient-Reported Outcomes Measurement Information System (PROMIS) is an National Institutes of Health initiative established in 2004 to develop and validate PROs in global health, physical function, fatigue, pain, sleep/wake function, emotional distress, and social health [9]. The PROMIS paediatric profiles were

derived from different PROMIS paediatric item banks [10-14]. Each item bank was developed in a sample of approximately 3,000-4,000 children aged between 8 and 17 years with a mixture of gender, age, race, and medical conditions.

Although the traditional Chinese version of Child Health Questionnaire (C-CHQ) and Paediatric Quality of Life Inventory™ 4.0 (traditional Chinese PedsQL™ 4.0) have been used to evaluate HRQOL in children with chronic illness or cancer [15,16], they are not ideal in evaluating children with cancer. Specifically, they do not assess fatigue, pain interference, anxiety, and depression, which are common in children or adolescents with cancer. The Patient-Reported Outcomes Measurement Information System Paediatric-25 Profile version 2.0 (PROMIS-25) is a comprehensive HRQOL instrument including 24 questions and a single item on pain intensity to evaluate six health domains that are highly relevant to cancer: (1) physical function; (2) anxiety; (3) depressive symptoms; (4) fatigue; (5) peer relationships: and (6) pain interference [17].

Previous studies had cross-culturally adapted and validated the simplified Chinese version of pediatric PROMIS measures in mainland China [18,19]. However, children in Hong Kong differ from the mainland Chinese counterparts in terms of cultures, languages, and Chinese characters. In particular, children in Hong Kong speak Cantonese (a local dialect) and use traditional Chinese characters. As such, the simplified Chinese pediatric PROMIS shorts forms cannot be directly adopted in Hong Kong. To this end, an authorization has been obtained from the PROMIS Health Organization to develop the traditional Chinese version of the Patient-Reported Outcomes Measurement Information System Paediatric-25 Profile version 2.0 (PROMIS-25). The current study aimed to: (1) translate and culturally adapt the English PROMIS-25 to traditional Chinese; and (2)

investigate internal consistency, structural validity, and construct validity of the Chinese PROMIS-25 in Chinese children with cancers in Hong Kong.

Methods

Study Design

This study consisted of two stages. The first stage involved the translation process and cognitive debriefing interviews, while the second stage evaluated the psychometric properties of the traditional Chinese PROMIS-25.

Participants

Chinese children with cancer aged between 10 and 18 years who spoke Cantonese and read traditional Chinese were eligible for the studies. Children diagnosed with cancer who were followed up in an oncology ward of a public acute hospital in Hong Kong were recruited by convenience sampling. Children were excluded if they had cognitive problems, visual impairment, or were receiving end of life care. Parental consent and child assent were obtained according to the procedure approved by the Institutional Review Board of the involved hospital. There was no monetary payment to the research participants.

Five children were recruited for cognitive debriefing interviews as recommended by the Functional Assessment of Chronic Illness Therapy (FACIT) translation methodology [20]. The sample size of the validation study was estimated based on the sample size guideline suggested by Bujang and Baharum [21]. With the power set at 0.80, alpha level at 0.05 and a hypothesized correlation of 0.5 for convergent validity testing [22], the

estimated sample size was 80. For the structural validity assessments, a prior Rasch analysis study [23] found that compared to a sample size of 50 or less, larger samples (≥ 100) yielded less incorrectly ordered item characteristics. Therefore, a minimum of 100 children with cancer were recruited in the second stage study.

Translation and Cultural Adaptation of PROMIS

It involves seven steps: (1) **Forward Translation:** two native translators who were Cantonese speakers independently forward translated the questionnaire into traditional Chinese; (2) **Reconciliation**: another independent bilingual translator who was a native Cantonese speaker reconciled two translated versions; (3) **Backward Translation:** it was performed by a fourth bilingual translator who was fluent in Chinese. The translation should reflect similar meaning of what the English language represented; (4) **Expert Reviews:** three physiotherapists who were native Cantonese speakers reviewed the translation steps, and assessed the semantic equivalence and content validity. (5) **Finalization**: a language coordinator, who was a native Cantonese speaker, prepared the final translation by reviewing comments from the expert panel; (6) **Formatting and Proofreading:** Two proofreaders worked independently to identify any problems that might require further discussion; (7) **Cognitive Debriefing Interview**: The FACIT translation methodology [24] suggested that at least five participants were required in this process. As such, five participants (three males and two females; mean age: 13.2 ±2.3 years) were recruited. Three of them had leukemia, one had spinal tumors and one had bone tumor. Participants were asked several questions to solicit opinions regarding the difficulty of various items. They were asked to interpret the meaning of each item in their own words, or to provide reasons for choosing a specific answer.

Validation of Traditional Chinese Version of PROMIS-25

The stage 2 study involved data collection from 103 children volunteers with cancer. Participants' demographics data including age, gender, educational level, diagnosis, and types of curative cancer treatments were recorded. Additionally, each participant completed PROMIS-25 and two other questionnaires.

PROMIS-25 Paediatric Short Form

The original PROMIS-25 is a 25-item generic HRQOL instrument for children aged between 8 and 18 years old. It encompasses six domains (including physical function, anxiety, depressive symptoms, fatigue, peer relationships, and pain interference). Each domain has four items. All items are rated on a 5-point Likert scale, where 1 means "not able to do" and 5 means "with no trouble". It also contains a single-item Numeric Pain Rating Scale (NPRS) scored from 0 to 10 (0 means no pain, 10 means the worst imaginable pain). The raw scores on the 4 items in each domain are summed to obtain a total raw score and is transformed to the T-score metric. The PROMIS's T-score distributions are standardized so that a score of 50 represents the average (mean) score of the US general population, while the standard deviation around that mean is 10. A higher T-score indicates better functioning in the physical function or peer relationships domain. Conversely, higher T-scores indicate poorer functioning in the anxiety, depressive symptoms, fatigue, or pain interference domain. Each item is derived from different PROMIS pediatric item banks [10-14], and each item bank has shown to be unidimensional with good psychometric properties [10-14].

Traditional Chinese Version of Paediatric Quality of Life Inventory™ 4.0

The traditional Chinese PedsQL™ 4.0 is a 23-item HRQOL measurement tool for children aged between 5 and 18 years old [25]. It includes four domains: (1) physical functioning; (2) emotional functioning; (3) social functioning; and (4) school functioning [26]. The items are rated on a 5-point Likert scale from 0 (never) to 4 (almost always). Each item was reversely scored and linearly transformed to a 0-100 scale. To create the domain score, the mean is computed as the sum of the items over the number of items answered. It demonstrated good internal consistency (Cronbach's alpha = 0.84) and good test-retest reliability (ICC = 0.80) [27].

Traditional Chinese Version of the Patient Health Questionnaire-9

The C-PHQ-9 is a 9-item questionnaire used for screening and measuring the level of depression [27]. The items are rated on a 4-point Likert-like scale (0 indicates not at all, while 3 indicates nearly every day). The total score is obtained by adding the raw score of each item, and this total score is used for the construct validity tests in this study. The C-PHQ-9 can be used to assess the severity of depression at different ages or in different genders during adolescence (ages between 11 and 17 years) [28]. It has demonstrated good internal consistency (Cronbach's alpha = 0.84) and good test-retest reliability (ICC = 0.80) [27].

Data Analysis

Semantic Equivalence Score

The semantic equivalence of each item of the traditional Chinese PROMIS-25 was evaluated by the expert panel

on a 4-point Likert scale (1 = “not equivalent,” 2 = “somewhat equivalent,” 3 = “quite equivalent,” and 4 = “highly equivalent”). Semantic equivalence refers to the proportion of items rated as either 3 or 4 out of all items in a questionnaire [29].

Content Validity Index

The content validity index is the rating of the content relevance of the translated items as compared to the original one [30]. Each item was rated on a 4-point Likert scale (1 = “not relevant,” and 4 = “very relevant”) [30]. Content validity index refers to the proportion of items rated as either 3 or 4 out of all items in a questionnaire [29]. An index of at least 0.8 is considered as good semantic equivalence and content validity [31].

Internal Consistency

Internal consistency refers to the degree of interrelatedness among different items in the same test [32,33]. Each domain of the traditional Chinese PROMIS-25 was assessed by Cronbach’s alpha (α) and item-total correlations.

Structural Validity

Structural validity refers to the degree of the health domain adequately reflects the dimensionality of the construct to be measured [34]. A Rasch principal component analysis of residuals was conducted. If the raw data results explain more than 50% in the variance of an individual domain and the eigenvalue value of the secondary component is less than 2, it indicates good unidimensionality [35,36]. Additionally, the item fit statistics were used to examine how well each item fit with Rasch model’s expectation in terms of the hierarchy of difficulty

within each underlying domain [37]. The criterion of infit and outfit statistics between 0.6 and 1.4 was used to indicate good fit [38,39]. It was conducted using the WINSTEPS software 4.41 (Beaverton, USA) [40].

Convergent and Divergent Validity

The convergent validity examined the correlations between variables or measures of the same construct/similar concepts, which resulted in very high correlations. The evaluated correlation included: traditional Chinese PROMIS-25 physical function domain with the traditional Chinese PedsQL™ 4.0 physical functioning domain; the traditional Chinese PROMIS-25 anxiety domain with the traditional Chinese PedsQL™ 4.0 emotional functioning domain; the traditional Chinese PROMIS-25 depressive symptoms domain with the C-PHQ-9, the traditional Chinese PROMIS-25 fatigue domain with the C-PHQ-9 Item-4; the traditional Chinese PROMIS-25 peer relationships domain with the traditional Chinese PedsQL™ 4.0 social functioning domain; and the traditional Chinese PROMIS-25 pain interference domain with NPRS.

The divergent validity examined the correlations between variables or measures of dissimilar constructs, which yielded in negligible/low correlations. The examined associations included: traditional Chinese PROMIS-25 physical functions domain and the traditional Chinese PedsQL™ 4.0 social functioning domain; the traditional Chinese PROMIS-25 anxiety domain and the traditional Chinese PedsQL™ 4.0 physical functioning domain; the traditional Chinese PROMIS-25 depressive symptoms domain and the traditional Chinese PedsQL™ 4.0 physical functioning domain; the traditional Chinese PROMIS-25 fatigue domain and NPRS; the traditional Chinese PROMIS-25 peer relationships domain and NPRS; as well as the traditional Chinese PROMIS-25 pain interference domain and the CHPQ-9 Item-4. Polyserial correlations were classified as

negligible (0.0 to 0.3 or 0.0 to -0.3), low 0.3 to 0.5 or -0.3 to 0.5), moderate (0.5 to 0.7 or -0.5 to -0.7), high (0.7 to 0.9 or -0.7 to -0.9) and very high (0.9 to 1.0 or -0.9 to -1.0) [41]. All analyses were carried out using SPSS v. 23.0. (IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp).

Results

Demographics

Participants' clinical characteristics are presented in Table 1. A total of 103 participants (mean age of 13.1 ± 1.8 years; males: 58.3%) participated in the studies. Approximately, 51.5% of the participants had leukemia, 13.6% with lymphoma, 12.6% with brain and spinal tumors, 11.7% with bone tumor, 7.8% had soft tissue sarcoma. Majority of participants (i.e., 78.6%) received chemotherapy, while the others received radiotherapy, combination of surgery and chemotherapy, immunotherapy, or targeted therapy.

Semantic Equivalence

The semantic equivalence of items in the traditional Chinese PROMIS-25 was 100% (i.e., 9.3% and 90.7% of items had scores of 3 and 4, respectively) (Table 2). It indicated that the meanings of the items in the translated version were considered equivalent to the original items in the English version.

Content Equivalence

The content validity index was 100%, with 8% and 92% of items had scores of 3 and 4, respectively (i.e.,

quiet, or very relevant) (Table 2). It suggested that all items were relevant to the corresponding constructs of the traditional Chinese PROMIS-25 and the content validity of the translated version.

Translation and Cultural Adaptation

Majority of items had a consistent translation in the FACIT translation process. There were only minor inconsistencies related to different word selection or sentence structure. However, one item required more discussion in the translation team, "It was hard for me to walk one block when I had pain". One forward translator maintained the traditional Chinese translation as one "block" (一個街區), but another one translated it as the length of one "street" (一條街). Following discussion, the translation team members agreed to use "street" instead of "block" because it was deemed to be easier for Chinese children to understand.

Cognitive Debriefing Interviews

The interviews revealed that all participants demonstrated satisfactory understanding of each item. Two participants requested the interviewer to provide some examples of sports activities when they answered one item of physical function domain, "I could do sports and exercise that other kids my age could do". After discussing among the expert panel members, the interviewers were suggested to prepare some examples of sports activities to guide children in answering this question and to document any respondents who requested for examples of sports activities during the main study. However, there was no similar incidence subsequently. For the response options, all participants were able to provide reasons to justify their selection of answers. They had no difficulty in understanding the items. They commented that the items in each domain were relevant to their condition and functioning. All participants completed all the question items.

Patient Reported Outcomes Scores

The traditional Chinese PROMIS-25 and legacy scale scores are shown in Table 3. The scores of the traditional Chinese PROMIS-25 domains, the traditional Chinese PedsQL™ 4.0 domains, and NPRS were normally distributed, while the score of C-PHQ-9 item 4 and total scores of C-PHQ-9 had left skewed distribution. There was no evidence of ceiling or flooring effects in any of the patient reported outcomes instruments. The traditional Chinese PROMIS-25 domain scores were distributed across a broad range from a minimum of 23.1 (i.e.-2.69 SD) to a maximum of 77.6 (i.e. + 2.76 SD) (Table 3).

Internal Consistency

All traditional Chinese PROMIS-25 domains indicated good internal consistency. In particular, Cronbach's α values of physical function, anxiety, depressive symptoms, fatigue, peer relationships, and pain interference domains were 0.88, 0.86, 0.84. 0.82. 0.83 and 0.85, respectively (Table 4). The individual item-to-total correlations ranged from 0.60 to 0.83 (Table 4).

Structural Validity

The total variance explained by the principal component of the traditional Chinese PROMIS-25 domains ranged from 55.5% to 73.6% (Table 5). For each domain, the eigenvalue of the second major component was less than 2 (Table 5). These results supported the unidimensionality of the six PROMIS-25 domains. The goodness-of-fit

analysis found that all items of the traditional Chinese PROMIS-25 demonstrated acceptable levels of fit statistics (Table 6). No items were classified as misfitting. Therefore, no items were removed from the translated PROMIS-25.

Convergent Validity

The traditional Chinese PROMIS-25 anxiety domain showed a strong negative correlation with the traditional Chinese PedsQL™ 4.0 emotional functioning domain ($r = -0.83$, $P<0.01$) (Table 7). Conversely, there was strong positive correlations between the traditional Chinese PROMIS-25 depressive symptoms domain and the C-PHQ-9 ($r = 0.8$, $P<0.01$), between the traditional Chinese PROMIS-25 fatigue domain and the C-PHQ9 Item-4 ($r = 0.75$, $P<0.01$), between the traditional Chinese PROMIS-25 physical function domain and the traditional Chinese PedsQL™ 4.0 physical functioning domain ($r = 0.80$, $P<0.01$), and a moderate positive correlation between the traditional Chinese PROMIS-25 peer relationship domain and the traditional Chinese PedsQL™ 4.0 social functioning domain ($r = 0.69$, $P<0.01$)(Table 7). Only the traditional Chinese PROMIS-25 pain interference domain had a low positive correlation with NPRS ($r = 0.44$, $P<0.01$) (Table 7).

Divergent Validity

There were negligible correlations between the traditional Chinese PROMIS-25 anxiety domain and the traditional Chinese PedsQL™ 4.0 physical functioning domain ($r = -0.17$, $P<0.01$), between the traditional Chinese PROMIS-25 depressive symptoms domain and the traditional Chinese PedsQL™ 4.0 physical functioning domain ($r = -0.21$, $P<0.01$), between the traditional Chinese PROMIS-25 peer relationships domain

and NPRS (r = -0.12, P>0.05), between the traditional Chinese PROMIS-25 pain interference domain and the C-PHQ-9 Item-4 (r = 0.30, P<0.01), and between the traditional Chinese PROMIS-25 physical function domain and the traditional Chinese PedsQL^{TM} 4.0 social functioning domain (r = 0.17, P>0.05)(Table 8). Additionally, there was a low positive correlation between the traditional Chinese PROMIS-25 fatigue domain and NPRS (r = 0.39, P<0.01) (Table 8).

Discussion

The current study adopted a rigorous FACIT translation methdology, which involved multiple translation steps and cognitive debriefing interviews with children [24]. There are two types of cognitive interview techniques (i.e., think-aloud interviewing, and verbal probing approach [42]). We adopted the latter approach because it allows interviewers to ask specific questions focusing on particular areas that appear to be potential sources of response errors. Additionally, the targeted probing method enables the interviewer to guide participants in providing relevant comments and ideas [43]. Our interviewing method was comparable to the cognitive interviewing of the original PROMIS item banks [44] or the simplified Chinese version of paediatric PROMIS measures [19]. Our findings concurred with previous research that children aged between 8 and 17 years old had no difficulty in understanding the PROMIS measures, and could use PROMIS measures to self-report their health conditions [19,45].

This study revealed good internal consistency of the traditional Chinese PROMIS-25 in measuring HRQOL of children with cancer. The Cronbach's α values for the six domains ranged from 0.82 to 0.88. Our findings concurred with prior research. Westmoreland et al used the English version PROMIS-25 to evaluate

HRQOL of pediatric patients with lymphoma, and found that the Cronbach's α values of the physical function, anxiety, depressive symptoms, fatigue, peer relationships, and pain interference domains were 0.89, 0.89, 0.77, 0.9, 0.7, and 0.93, respectively [46].

This study found that the traditional Chinese PROMIS-25 contained six distinct unidimensional constructs, which was consistent with the six domains (i.e., physical function, anxiety, depressive symptoms, fatigue, peer relationships and pain interference) in the original English version of PROMIS-25 [47-51]. Since all items in the original PROMIS domain were extracted from the corresponding PROMIS item bank, each original domain has exhibited excellent unidimensional property, and high correlation ($r>0.9$) with the corresponding item bank [47-51]. Therefore, it was not surprising that each domain in the traditional Chinese PROMIS-25 also exhibited the unidimensional property.

Our study revealed a strong correlation between the domains of traditional Chinese PROMIS-25 and different legacy measures. The convergent validity of the traditional Chinese PROMIS-25 anxiety domain was supported by its strong negative correlation with the emotional functioning domain of the traditional Chinese PedsQL^{TM} 4.0. Previous research found a significant strong negative correlation between anxiety symptoms and the emotional functioning domain of the traditional Chinese PedsQL^{TM} 4.0 in youth [52]. Likewise, a close relationship between anxiety and emotion in children aged between 8 and 12 years was also reported [53]. Our results substantiated the negative correlation between anxiety and emotion in children with cancer.

Similarly, the traditional Chinese PROMIS-25 depressive symptoms domain scores were strongly related to the C-PHQ-9 scores, demonstrating good convergent validity. The C-PHQ-9 is an instrument designed for screening, measuring and monitoring the severity of depression [54]. Prior research revealed that a higher level

of depression was associated with higher PHQ-9 scores in children (r = 0.84) [55]. Another study found that increased PHQ-9 scores were related to more depressive and internalizing symptoms among adolescents [56]. These findings corroborated the convergent validity of the traditional Chinese PROMIS-25 depressive symptoms domain.

The traditional Chinese PROMIS-25 fatigue domain was strongly correlated with the C-PHQ-9 Item-4 (i.e., I was too tired to enjoy the things I like to do). Hinz et al.[57] have reported a significant correlation between fatigue and item-4 of the PHQ-9 in cancer patients (r = 0.7). They also found that children with cancer who reported fatigue usually had a poorer concentration and attention span, which might affect their motivation and enjoyment in daily activities and social events [58]. Our results indicate that the traditional Chinese PROMIS-25 is valid for fatigue measurements in children with cancer.

A moderate correlation was found between the traditional Chinese PROMIS peer relationships domain and the traditional Chinese PedsQL™ 4.0 social functioning domain. The finding partially accorded with a previous study that reported a strong correlation between these two domains in children (r > 0.9) [59]. A recent study showed that the PROMIS peer relationships domain evaluated both “friendship quality” and “peer acceptance”, which were two distinct aspects of social functioning in youth [60]. In this context, it supports the convergent validity of the traditional Chinese PROMIS peer relationships domain and its relationship with the traditional Chinese PedsQL™ 4.0 social functioning domain.

The current study had some limitations. Since our study excluded children with cognitive problems, visual impairment, or receiving end of life care, the results may not be generalized to all children with cancer. Additionally, our participants were recruited from a single oncology center. Future multicenter studies are

warranted to enhance the generalizability of results. Further, since the current study did not assess other psychometric properties (such as test-retest reliability or responsiveness), future research should address these issues.

The cross-cultural adaptation of PROMIS-25 have important clinical implications. The international normalized values of PROMIS instruments allow clinicians to directly compare patients' scores with the general population. In addition, PROMIS scaled scores have been adjusted to allow longitudinal follow-up of the same patient from childhood to adulthood. These special features are not available in other paedaitric HRQOL measures. More importantly, the use of this instrument can allow clinicians to identify specific health domain(s) that requiring extra attention. In other words, clinicians can be able to detect the patients' problems earlier and refer patients to proper services timely (e.g., counselling services or further evaluation by other disciplines).

Conclusions

The traditional Chinese PROMIS-25 is semantically and conceptually equivalent to the original English version. Each domain of the traditional Chinese PROMIS-25 is unidimensional and congruent with the original version. This study also provided evidence to substantiate internal consistency, structural validity, and construct validity of the traditional Chinese PROMIS-25. Future research should evaluate the test-retest reliability and responsiveness of each domain of the traditional Chinese PROMIS-25 in Chinese children with cancer in Hong Kong.

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TABLE 1 Clincial characteristics of participants

Variables	Cognitive debriefing interviews (n=5)	Structural and construct validity study (n=103)
Age, mean / SD	13.2 / 2.3	13.1 / 1.80
Sex		
Male	3	60
Female	2	43
Schooling		
Primary 5	0	5
Primary 6	1	11
Secondary 1-3	3	62
Secondary 4-6	1	25
Post-secondary	0	0
Diagnosis		
Leukemia	3	53
Brain and spinal tumours	1	13
Bone tumours	1	12
Soft tissue sarcoma	0	8
Lymphoma	0	14
Others	0	3
Time of diagnosis, years		
<1	2	52
>1	3	51
Under active cancer treatment course		
Yes	2	103
No	3	0
Treatment received		
Chemotherapy	4	81
Radiotherapy	0	7
Surgery + Chemotherapy	1	5
Others e.g. immunotherapy or targeted therapy	0	10

Table 2. The scoring of semantic equivalence and content validity of the traditional Chinese PROMIS-25 by the expert panel members

Traditional Chinese PROMIS-25 Domains	PROMIS Item codes	Panel Expert 1		Panel Expert 2		Panel Expert 3	
		Semantic equivalence score	Content validity index	Semantic equivalence score	Content validity index	Semantic equivalence score	Content validity index
Physical Function	235R1r	4	4	4	4	4	4
	4124R1r	4	4	4	4	4	4
	2707R2r	4	4	4	4	4	4
	5023R1r	4	4	4	4	4	4
Anxiety	2220R2r	4	4	3	3	4	4
	713R1r	4	4	4	4	4	4
	5044R1r	4	4	4	3	4	4
	3459bR1r	4	4	4	4	4	4
Depressive Symptoms	5041R1r	4	4	3	3	4	4
	711R1r	4	4	4	4	4	4
	228R1r	4	4	4	4	4	4
	3952aR2r	4	4	4	4	4	4
Fatigue	4239aR2r	4	4	4	4	4	4
	2876R1r	4	4	4	4	4	4
	4241R2r	4	4	4	4	4	4
	41961r	4	4	4	4	4	4
Peer Relationships	5018R1r	4	4	4	4	4	4
	5058R1r	4	4	4	4	4	4
	5055R1r	4	4	4	4	4	4
	233R2r	4	4	4	4	4	4
Pain Interference	3793R1r	4	4	4	4	3	4
	9004r	4	4	4	4	3	4
	2045R1r	4	4	4	4	3	4
	2049R1r	3	3	3	3	3	3
Pain Intensity	9033R1r	4	4	4	4	4	4

Semantic equivalence score: 1 = not equivalent, 2 = somewhat equivalent, 3 = quite equivalent, and 4 = highly equivalent

Content validity index: 1 = not relevant, 2 = somewhat relevant, 3 = quite relevant, and 4 = very relevant"

Table 3. The traditional Chinese PROMIS-25 and legacy scale scores in Chinese children with cancer

	N	Mean Score	SD	Median	Range	Min	Max
Traditional Chinese Version of Paediatric Quality of Life Inventory™ 4.0							
Physical functioning	103	45.08	23.11	56	100	0	100
Emotional functioning	103	56.17	22.86	55	100	0	100
Social functioning	103	54.13	20.18	54	90	10	100
School functioning	103	45.58	19.33	52	90	10	100
Numeric Pain Rating Scale (NPRS)							
NPRS	103	4.59	2.37	5	10	0	10
Traditional Chinese Version of the Patient Health Questionnaire-9							
Item-4	103	1.09	0.95	1	3	0	3
Total Score	103	3.75	3.33	3	14	0	14
Traditional Chinese PROMIS-25 Domains							
Physical Function	103	41.52	9.62	41.2	34.8	23.1	57.9
Anxiety	103	52.48	8.58	52.4	40.7	35.6	76.3
Depressive Symptoms	103	51.72	8.69	52.3	33	37.7	70.7
Fatigue	103	52.55	8.76	54.4	42.2	35.4	77.6
Peer Relationships	103	44.57	7.49	44.5	35.4	25.7	61.1
Pain Interference	103	51.57	8.71	53.2	37.3	36.7	74

Table 4. Internal consistency of the traditional Chinese PROMIS-25

Traditional Chinese PROMIS-25 Domains	PROMIS Item codes	Cronbach's α	Alpha if item deleted	Item-to-total correlations
Physical Function	235R1r	0.88	0.82	0.80
	4124R1r		0.88	0.64
	2707R2r		0.83	0.77
	5023R1r		0.83	0.77
Anxiety	2220R2r	0.86	0.85	0.65
	713R1r		0.80	0.79
	5044R1r		0.77	0.83
	3459bR1r		0.86	0.60
Depressive Symptoms	5041R1r	0.84	0.79	0.71
	711R1r		0.78	0.73
	228R1r		0.79	0.70
	3952aR2r		0.84	0.58
Fatigue	4239aR2r	0.82	0.79	0.61
	2876R1r		0.77	0.64
	4241R2r		0.76	0.68
	41961r		0.77	0.64
Peer relationships	5018R1r	0.83	0.77	0.67
	5058R1r		0.80	0.60
	5055R1r		0.75	0.71
	233R2r		0.79	0.62
Pain interference	3793R1r	0.85	0.80	0.70
	9004r		0.82	0.64
	2045R1r		0.80	0.70
	2049R1r		0.79	0.71

TABLE 5 Standardized residual variance in eigenvalue units of the traditional Chinese PROMIS-25 domains

Traditional Chinese PROMIS-25 domains	Raw variance explained by measures		
	First component dimension eigenvalue	First component dimension observed percentage	First contrast of residuals (second major component) eigenvalue
Physical Function	11.14	73.6%	1.84
Anxiety	5.12	56.1%	1.61
Depressive Symptoms	5.66	58.6%	1.57
Fatigue	5.35	57.2%	1.65
Peer relationships	5.08	56.0%	1.49
Pain interference	4.98	55.5%	1.91

TABLE 6 Measures and fit statistics for the items of the traditional Chinese PROMIS-25

Traditional Chinese PROMIS-25 Domains	PROMIS Item codes	Measure	Standard error	Infit MnSq	Out MnSq
Physical Function	235R1r	1.04	0.14	0.63	1.17
	4124R1r	-1.41	0.18	1.30	1.22
	2707R2r	-0.33	0.16	1.07	1.00
	5023R1r	0.70	0.15	1.00	0.88
Anxiety	2220R2r	-0.03	0.18	1.18	1.13
	713R1r	-0.54	0.17	0.75	0.76
	5044R1r	-0.36	0.17	0.64	0.64
	3459bR1r	0.93	0.18	1.39	1.40
Depressive Symptoms	5041R1r	-0.01	0.17	0.90	0.94
	711R1r	0.19	0.17	0.90	0.90
	228R1r	-0.39	0.16	0.84	0.86
	3952aR2r	0.21	0.17	1.34	1.35
Fatigue	4239aR2r	-0.37	0.15	1.11	1.11
	2876R1r	-0.54	0.15	0.92	0.92
	4241R2r	0.22	0.15	0.94	0.91
	41961r	0.69	0.15	1.01	1.00
Peer Relationships	5018R1r	0.12	0.16	1.01	1.01
	5058R1r	-0.28	0.17	1.12	1.03
	5055R1r	-0.50	0.17	0.93	0.81
	233R2r	0.66	0.15	1.03	0.98
Pain Interference	3793R1r	0.17	0.14	0.88	0.96
	9004r	0.04	0.14	1.11	1.08
	2045R1r	-0.63	0.13	1.07	1.02
	2049R1r	0.42	0.14	0.88	0.92

TABLE 7 Convergent validity – The correlation between the traditional Chinese PROMIS-25 domains and the traditional Chinese Patient Health Questionnaire-9 / Numeric pain rating scale / traditional Chinese Paediatric Quality of Life Inventory™ 4.0

Traditional Chinese PROMIS-25 Domains	Items/Domains of Instruments for Correlation	Correlation Coefficients (r value)	Hypotheses confirmed?
Physical Function	The traditional Chinese PedsQL™ 4.0 physical functioning domain	Expect: >0.5, Actual: 0.80*	Yes
Anxiety	The traditional Chinese PedsQL™ 4.0 emotional functioning domain	Expect: <-0.5, Actual: -0.83*	Yes
Depressive Symptoms	The traditional Chinese Patient Health Questionnaire-9	Expect: >0.5, Actual: 0.80*	Yes
Fatigue	The traditional Chinese Patient Health Questionnaire-9 (Item-4: I was too tired to enjoy the things I like to do)	Expect: >0.5, Actual: 0.75*	Yes
Peer relationships	The traditional Chinese PedsQL™ 4.0 social functioning domain	Expect: >0.5, Actual: 0.69*	Yes
Pain interference	Numeric pain rating scale	Expect: 0.3-0.5, Actual: 0.44*	Yes

*P < 0.01

Table 8 Divergent validity – The correlation between the traditional Chinese PROMIS-25 domains and the C-PHQ-9 / NPRS / traditional Chinese PedsQL™ 4.0

Chinese PROMIS-25 Domains	Items/Domains of Instruments for Correlation	Correlation Coefficients (r value)	Hypotheses confirmed?
Physical Function	The traditional Chinese PedsQL™ 4.0 social functioning domain	Expect: 0.1-0.3, Actual: 0.17	Yes
Anxiety	The traditional Chinese PedsQL™ 4.0 physical functioning domain	Expect: -0.1 to -0.3, Actual: -0.17*	Yes
Depressive Symptoms	The traditional Chinese PedsQL™ 4.0 physical functioning domain	Expect: -0.1 to -0.3, Actual: -0.21*	Yes
Fatigue	Numeric pain rating scale	Expect: 0.1-0.5, Actual: 0.39*	Yes
Peer relationships	Numeric pain rating scale	Expect: -0.1 to -0.3,, negative: -0.12	Yes
Pain interference	The traditional Chinese Patient Health Questionnaire-9 (Item-4: I was too tired to enjoy the things I like to do)	Expect: 0.1-0.3, Actual: 0.30*	Yes

*P < 0.01