

BMJ Open Translation, cross-cultural adaptation and validation of the traditional Chinese intermittent and constant osteoarthritis pain (ICOAP) questionnaire for knee osteoarthritis

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ABSTRACT

Objectives To translate and culturally adapt the Intermittent and Constant Osteoarthritis and Pain (ICOAP) measure to a traditional Chinese version, and to study its psychometric properties in patients with knee osteoarthritis (KOA).

Method The ICOAP was translated and cross-culturally adapted into traditional Chinese according to the recommended international guidelines. A total of 110 participants with KOA in Hong Kong were invited to complete the traditional Chinese ICOAP (tChICOAP), the Chinese Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale and the Chinese Short form of Health Survey (SF-12v2). Psychometric evaluations included content validity, construct validity, internal consistency and test and retest reliability.

Results All participants completed the tChICOAP questionnaire without missing items. The content validity index of all items ranged from 80% to 100%. The tChICOAP total pain and subscale scores had excellent internal consistency with Cronbach's alpha value (0.902–0.948) and good corrected item-total subscale correlations. It had high test and retest reliability (intra-class correlations 0.924–0.960). The tChICOAP constant, intermittent and total pain scores correlate strongly with the WOMAC pain subscale ($r=0.671$, 0.678 and 0.707 , respectively, $p<0.001$). The tChICOAP intermittent and total scores correlate strongly with SF-12v2 physical component score ($r=-0.590$ and -0.558 , respectively, $p<0.001$).

Conclusions The tChICOAP is a reliable and valid instrument to measure the pain experience of Chinese patients with KOA.

INTRODUCTION

Knee osteoarthritis (KOA) is a major cause of pain and disability contributing to the healthcare service burden worldwide.¹ Pain in KOA is multi-dimensional. While pain intensity is commonly assessed by a numerical or Visual Analogue Scale (VAS), this

Strengths and limitations of this study

- This is the first study to validate the Traditional Chinese version of the Intermittent and Constant Osteoarthritis and Pain (tChICOAP) questionnaire.
- The translation and validation of the tChICOAP followed a robust methodology.
- The content validity index of the ICOAP was first reported in this study.
- Responsiveness of the tChICOAP was not tested.

presents limitations, as it does not consider the dynamic nature of pain.² It is established that the characteristics of pain often change over time and the experience of chronic pain with episodic flares is often unpredictable and emotionally draining.³ Thus, The Osteoarthritis Research Society International (OARSI) has identified 'phenotyping' of OA pain as a research priority to 'better target pain therapies to individual patients'.⁴

The Intermittent and Constant Osteoarthritis and Pain (ICOAP) measure was developed by an international working group under the guidance of OARSI and Outcome Measures in Rheumatology Clinical Trials (OMERACT).⁵ The original English language ICOAP was used to widely in research to measure pain experience. It captures pain intensity as well as related distress and the impact of OA pain on quality of life.^{6,7} It has been tested to have good psychometric properties in multiple languages including Turkish, Portuguese, German and Greek.^{8–11} In view of the ever-increasing trend for multinational studies and international cooperation among medical organisations, there is a compelling need to increase the applicability of this instrument in the Chinese population.

Table 1 Characteristics of the participants

Characteristics	Total sample (n=110)
Age (years)	62.2±5.7
Gender	
Male	28 (25.5%)
Female	82 (74.5%)
BMI*	24.68±3.68
WOMAC pain score, mean (SD)	169.70 (124.37)
SF-12v2 (PCS), mean (SD)	39.22 (9.50)
SF-12v2 (MCS), mean (SD)	48.79 (9.29)
Duration of knee pain*	8.76±6.70
Kellgren and Lawrence Grading†	
Grade 1	17 (16.5%)
Grade 2	42 (40.8%)
Grade 3	36 (35%)
Grade 4	8 (7.7%)

*Missing six sets of data.

†Missing seven sets of data.

BMI, Body Mass Index; MCS, mental component scores; PCS, physical component score; SF-12, Short form of Health Survey-12; WOMAC, Western Ontario McMaster University Osteoarthritis Index.

A simplified Chinese version of ICOAP has been published by Zhang *et al.*¹² While simplified Chinese is the official language used in the People's Republic of China, Singapore and Malaysia, traditional Chinese is the common language used in Hong Kong, Taiwan, Macau and overseas Chinese communities. The aims of this study were to translate and culturally adapt ICOAP into traditional Chinese, to test the psychometric properties including the internal consistency, the construct validity, and the test and retest reliability of the traditional Chinese ICOAP (tChICOAP).

MATERIAL AND METHODS

Patient and public involvement

Patients were not involved in the design and conception of this study. Patients were not invited to contribute to the writing or editing of this document for readability and accuracy.

Step 1: Translation and cross-cultural adaptation

We followed the steps as suggested by the developer of the ICOAP in conducting the translation of the tChICOAP.¹³ In the first step, one English translator and one orthopaedic surgeon, who are native in Chinese and fully bilingual in English, translated independently the original English version into Traditional Chinese (Cantonese). In the second step, a single preliminary version was obtained after a simple consensus meeting with the two translators. In the third step, a backward translation was performed by an independent bilingual native English

speaker, blinded to the English original version. In the fourth step, a multidisciplinary expert committee was formed, which consisted of the initial two translators, one orthopaedic surgeon, one physiotherapist and one co-investigator (WW) who is very familiar with cross-cultural adaptation. The committee reviewed all the versions, discussed the phrasing of the target-language version and reached consensus on the final version of tChICOAP. In the fifth step, the final version was pretested for cognitive debriefing with 10 native Chinese participants with KOA. These participants completed the questionnaire in the presence of a study coordinator and each question was discussed to check whether it is fully acceptable and comprehensible. The cognitive debriefing was reviewed by the principal investigator (RS) and the co-investigator (WW) and the initial translation was modified accordingly.

Step 2: Psychometric testing using a cross-sectional cohort Participants

A total of 110 participants were recruited through poster advertisement and referrals by primary care physicians between July and December 2017 in the General Outpatients Clinics (GOPCs) in the New Territories East region of Hong Kong. Eligibility was screened by a trained research assistant using a phone interview and potential eligible participants were invited to meet the principal investigator at the study site, which is a teaching clinic operated by the Chinese University of Hong Kong. Written informed consents were obtained from all participants.

The inclusion criteria included participants with the diagnosis of primary knee OA based on clinical and radiological criteria as defined by the American Rheumatology Association, aged ≥ 45 to ≤ 75 years, and with knee pain for at least 3 months.¹⁴ Participants were excluded if they were not Cantonese speaking, they had other disease of the bones and joints of the lower limbs, or they had neurological disease, back problems or widespread pain, or an inability or unwillingness to complete the questionnaire.

Research instrument

The ICOAP: This is an 11-item questionnaire divided into two domains; a 5-item scale for constant pain and a 6-item scale for intermittent pain (so called 'pain that comes and goes'). The pain score is rated by pain intensity, frequency, impact on mood, sleep and quality of life.⁵ Previous study has supported the use of constant and intermittent subscales as one-dimensional measures of pain.¹⁵ Each score is rated from 0 to 4, and the sum is further standardised to a range of values from 0 to 100.

The Chinese WOMAC: The WOMAC is a disease-specific questionnaire recommended to be used during osteoarthritis clinical trials.¹⁶ It consists of 24 self-reported items, including knee pain (5 items), stiffness (2 items), and function (17 items). Each item is graded either on a five-point Likert scale or on a 100 mm VAS. In this study, we used the VAS to rate the pain subscale.¹⁷ The WOMAC pain subscale is recommended by the developer of ICOAP to test on the construct validity.⁵ The total score

Table 2 間歇性和持續性骨關節炎疼痛的測量 (ICOAP): 膝關節版本 (A measure of Intermittent and Constant Osteoarthritis Pain, ICOAP: KNEE Version)

Facet	Item of ICOAP: KNEE Version	No of patients (%) rated item as appropriate (n=10)	No of patients (%) rated items as clear (n=10)	No of patients (%) rated item as relevance (n=10)
甲) 持續性痛症 (Constant Pain)	請就以下每條問題, 選擇最能形容您過去一週持續性膝痛的平均情況的答案			
	一, 在過去一周中, 您的持續性膝痛有多強烈? (In the past week, how intense has your constant knee pain been?)	100%	100%	100%
	二, 過去一週, 您的持續性膝痛有多影響您的睡眠? (In the past week, how much has your constant knee pain affected your sleep?)	100%	100%	100%
	三, 在過去一周中, 您的持續性膝痛對您的整體生活質素有多大影響? (In the past week, how much has your constant knee pain affected your overall quality of life?)	100%	100%	100%
	四, 過去一週, 您的持續性膝痛症令您有多沮喪或煩擾? (In the past week, how frustrated or annoyed have you been by your constant knee pain?)	100%	100%	100%
	五, 過去一週, 您的持續性膝痛令您有多不安或擔憂? (In the past week, how upset or worried have you been by your constant knee pain?)	100%	100%	90%
乙) 間歇性疼痛 (Pain that Comes and Goes)	請就以下每條問題, 選擇最能形容您過去一週間歇性膝痛平均情況的答案			
	一, 在過去一周中, 您最嚴重的間歇性膝痛有多強烈? (In the past week, how intense has your most severe knee pain that comes and goes been?)	90%	90%	100%
	二, 過去一週, 這類間歇性膝痛發作得有多頻密? (In the past week, how frequently has this knee pain that comes and goes occurred?)	100%	100%	100%
	三, 在過去一周中, 您的間歇性膝痛對您的睡眠有多大影響? (In the past week, how much has your knee pain that comes and goes affected your sleep?)	100%	100%	100%
	四, 在過去一周中, 您的間歇性膝痛對您的整體生活質素有多大影響? (In the past week, how much has your knee pain that comes and goes affected your overall quality of life?)	90%	100%	100%
	五, 過去一週, 您的間歇性膝痛令您有多沮喪或煩擾? (In the past week, how frustrated or annoyed have you been by your knee pain that comes and goes?)	90%	100%	100%
	六, 過去一週, 您的間歇性膝痛令您有多不安或擔憂? (In the past week, how upset or worried have you been by your knee pain that comes and goes?)	100%	80%	90%

will be determined by adding corresponding items for each dimension. We use the validated Chinese WOMAC in this study.¹⁸

The Chinese Short form of Health Survey (SF-12v2): This consists of 12 items measuring eight subscales on physical functioning, role physical, bodily pain, general

Table 3 Internal consistency and reliability of the Intermittent and Constant Osteoarthritis and Pain subscales and total pain

Scale	Mean score (SD)		Intra- class correlation (95% CI)	Cronbach's α coefficient	SEM	Minimal detectable change
	First	Second				
Constant	30.23 (21.11)	31.18 (20.62)	0.959 (0.940 to 0.972)	0.934*	4.27	11.85
Intermittent	38.11 (18.12)	36.74 (18.56)	0.924 (0.889 to 0.948)	0.902*	5.00	13.85
Total	34.52 (18.54)	34.21 (18.77)	0.960 (0.941 to 0.972)		3.71	10.28

*Excellent reliability >0.75.

health, vitality, social functioning, and emotional and mental health.¹⁹ The sub-scale scores can be summarised into physical component (PCS) and mental component (MCS) scores. The measure has strong construct validity, responsiveness and clinometric profile. Study has shown that the Chinese SF-12 explained 88% and 90% of the variance of the SF-36 PCS and MCS scores, respectively. The correlations between the corresponding SF-36 and SF-12 summary scores all reached the expected standard of 0.9 and the effect size differences between the standard SF-36 and SF-12 scores were less than 0.3.²⁰ We

hypothesised that the ICOAP total and subscales would correlate strongly with the SF-12v2 PCS.

ICOAP, WOMAC pain subscale and SF-12v2 are self-reported questionnaires. Participants completed the questionnaires with the help of a research assistant at the study site. The interviews were repeated by the same research assistant 5 days later at the same study site. An interval of 5 days was chosen after considering the possible change in pain score with time; we believe the memory effect should be minimal given that our participants were mostly older people with KOA. Age, sex, body mass index, duration of

Table 4 Correlation of each item and total Intermittent and Constant Osteoarthritis and Pain scores (n=110)

ICOAP items	Corrected item-total coefficients*	Corrected item-total coefficients†	Cronbach's α if item deleted*	Cronbach's α if item deleted†
Constant pain subscale				
1. In the past week, how intense has your constant knee pain been?	0.853	0.802	0.913	0.941
2. In the past week, how much has your constant knee pain affected your sleep?	0.697	0.698	0.940	0.945
3. In the past week, how much has your constant knee pain affected your overall quality of life?	0.869	0.833	0.910	0.940
4. In the past week, how frustrated or annoyed have you been by your constant knee pain?	0.855	0.847	0.912	0.940
5. In the past week, how upset or worried have you been by your constant knee pain?	0.852	0.850	0.914	0.940
Intermittent pain subscale				
6. In the past week, how intense has your most severe knee pain that comes and goes been?	0.716	0.728	0.887	0.944
7. In the past week, how frequent has this knee pain that comes and goes occurred?	0.620	0.623	0.900	0.948
8. In the past week, how much has your knee pain that comes and goes affected your sleep?	0.680	0.739	0.892	0.944
9. In the past week, how much has your knee pain that comes and goes affected your overall quality of life?	0.841	0.803	0.869	0.942
10. In the past week, how frustrated or annoyed have you been by your knee pain that comes and goes?	0.787	0.794	0.876	0.942
11. In the past week, how upset or worried have you been by your knee pain that comes and goes?	0.755	0.711	0.882	0.945

*Generated from constant and intermittent pain subscales of ICOAP.

†Generated from the total pain score of ICOAP.

knee pain and Kellgren-Lawrence grading of the knees were collected.

Sample size

A sample size of 10 was set for cognitive debriefing as we followed the international team for the same translation and cultural adaptation process.¹³ For the psychometric testing, we calculated our sample size based on an expected intra-class correlation of 0.70, width of 0.2 of the 95% CI and the number of measurement to be 2; with two sided type I error of 5%, the target sample size was calculated to be 100. To compensate for potential dropout rate of 10%, we set our enrolment target at 110 subjects.²¹

Statistical analysis

Content validity was evaluated with content validity index (CVI). Construct validity was evaluated using the correlation coefficients between the domain scores and total scores of tChICOAP, WOMAC pain subscale and SF-12v2; with >0.5, 0.35–0.50 and <0.35 considered as strong, moderate and weak, respectively.¹⁸ Internal consistency was assessed using the Cronbach’s alpha and corrected item-total scale correlations. Cronbach’s alpha ≥ 0.7 is generally regarded as acceptable for group comparison.²² Corrected item-total scale correlation between domains and their constituent item with ≥ 0.4 was considered as acceptable.²³ Test and retest reliability was assessed with an interval of 5 days in between using intra-class correlation (ICC; two-way mixed effects model); an ICC >0.75 is considered as excellent, 0.59–0.75 as good, 0.40–0.58 as fair and <0.4 as showing poor reliability.²⁴ The SEM is estimated from the SD of a sample of scores at baseline and a test–retest reliability index of the measurement instrument. Minimal detectable change (MDC) was estimated from SEM and a degree of confidence. The data were entered and analysed using the SPSS V.21.0. P value <0.05 was considered as statically significant.

RESULTS

The demographics of 110 participants are summarised in table 1.

Cross-cultural adaptation and content validity

Slight differences were identified in the structure of the sentences between the original and translated versions and minor adjustments were made. Two participants found it difficult to understand the difference between ‘frustrated or annoyed’ versus ‘upset or worried’ in Chinese (Cantonese) and the words were rephrased to guarantee the exact meaning. Minor modifications were made to the Chinese terms to improve the succinctness of the questionnaire (online supplementary file). The CVI on ‘clarity’, ‘appropriateness’ and ‘relevance’ ranged from 80% to 100% (table 2). Participants felt that the questionnaire was easy to understand, the content covered the essential pain experience and that the questions aligned well with their feelings.

Internal consistency and reliability

The internal consistency was good. The Cronbach’s alpha values were 0.934, 0.902 and 0.948 for the constant pain score, the intermittent pain score and the total pain score, respectively. The corrected item-total subscale correlations ranged from 0.70 to 0.87 for the constant pain score and 0.62 to 0.84 for the intermittent pain score. It has excellent test and re-test reliability, with ICC values of 0.959 for the constant pain score and 0.924 for the intermittent score. The SEM and MDC of the tChICOAP total score are 3.71 and 10.28, respectively (tables 3 and 4).

Construct validity

The tChICOAP constant, intermittent, and total score correlated strongly with the WOMAC pain subscale ($r=0.671, 0.678$ and 0.707 , respectively, $p<0.001$). The tChICOAP intermittent pain score and total pain score correlated strongly with the SF12 PCS ($r=-0.590$ and -0.558 , respectively, $p<0.001$), and the constant pain score correlated moderately with SF12 PCS ($r=-0.487$, $p<0.001$). Moderate correlations were found for constant, intermittent and total pain score with the SF12 MCS score ($r=-0.398, -0.418$ and -0.431 , respectively, $p<0.001$) (table 5).

Table 5 Criterion and Construct validity of Intermittent and Constant Osteoarthritis and Pain (ICOAP) subscales and total pain (n=110)

	SF12 Physical Component Summary	SF12 Mental Component Summary	WOMAC Pain Subscale
ICOAP			
Constant	-0.487 (P<0.001)*	-0.398 (P<0.001)*	0.671 (P<0.001)†
Intermittent	-0.590 (P<0.001)†	-0.418 (P<0.001)*	0.678 (P<0.001)†
Total	-0.558 (P<0.001)†	-0.431 (P<0.001)*	0.707 (P<0.001)†

Spearman’s correlation coefficients, $p<0.001$.

*Moderate correlation ($r=0.35-0.50$).

†Strong correlation ($r\geq 0.5$).

DISCUSSION

The translation and cultural adaptation process were not challenging and produced an accurate tChICOAP. The Chinese wordings in all the question and response items are easily understandable, and the questionnaire is simple to complete. The items' CVIs on 'clarity', 'appropriateness' and 'relevance' all achieved the standard of good content validity with CVI of 80% or above.²⁵ In order to ensure, we would evaluate and measure the impact of KOA as in other multinational trials, we followed the translation steps as recommended by the OARSI/OMERACT.¹³

The internal consistency of the tChICOAP total score is excellent, with high Cronbach's alpha and corrected item-total subscale correlation. It is comparable to the original version, (Cronbach's alpha 0.93), the simplified Chinese version (Cronbach's alpha 0.94), and other language versions (Cronbach's alpha 0.82–0.95).^{5 12 26} The performance of the test and re-test reliability is the best among the original version (ICC 0.85), the simplified Chinese version (ICC 0.932) and other language versions such as Turkish (ICC 0.942), Portuguese (ICC 0.92) and Greek (ICC 0.88).^{5 8 9 11 12}

Like other language versions, the tChICOAP correlated strongly with the WOMAC pain subscale, as both were constructed to measure osteoarthritic pain.^{5 12 26} As expected, the tChICOAP's intermittent and total scores have a strong correlation with SF-12v2 PCS, and only moderate correlation with SF-12v2 MCS. This indicates that the measures are evaluating similar constructs, and the intermittent pain may be the major contributor of reduced physical activity in KOA. The tChICOAP constant pain score correlates moderately with both SF-12v2 PCS and MCS. This can be explained by the complex heterogeneity of pain in KOA. Nociceptive pain, neuropathic pain, central pain sensitisation, pain catastrophizing and the underlying biological activity of joint destruction all contribute to the level of constant pain in KOA, making it difficult to be constructed by SF-12v2.²⁷

This is the first traditional Chinese version of ICOAP and the study followed a robust methodology in its translation and validation. The measure of content validity using CVI is a merit, given that CVIs are not available in any of the existing language versions of ICOAP.^{8–12} One limitation of this study is that responsiveness of the tChICOAP was not tested, and a future prospective study will be needed to address this.

In summary, the tChICOAP is a reliable and valid instrument to measure the pain experience of Chinese patients with KOA. The study is going to increase the applicability of ICOAP in research conducted in the Chinese population, and the availability of tChICOAP will facilitate cross-cultural comparison of outcomes in different interventional trials for KOA.

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Patient consent for publication Obtained.

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