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Keywords:	ICOAP, Traditional Chinese, Knee Osteoarthritis, Pain

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 different severities of KOA in Hong Kong were invited to complete the traditional Chinese ICOAP (tChICOAP), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale, and the Chinese Short form of Health Survey (SF-12v2). Psychometric evaluations included construct validity, internal consistency, and test and re-test reliability.

Results: All participants completed the tChICOAP questionnaire without missing items. 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 re-test 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 patients with different severity of KOA.

Keywords: ICOAP, Traditional Chinese, Knee Osteoarthritis, Pain

Strengths and Limitations:

- This is the first study to validate the Traditional Chinese version of the ICOAP questionnaire.
- The tChICOAP has the best test and re-test reliability among the original and other validated language versions.
- The study validated the tChICOAP across different severity of KOA.
- Responsiveness of the tChICOAP was not tested.

Introduction

Knee osteoarthritis is a common, disabling, and expensive global disease. Up to 6% of the population over the age of 30 years has symptomatic, painful KOA[1]. Its incidence increases up to 10-fold from ages 30 to 65 years and even more thereafter[2]. Pain in KOA is multi-dimensional. While pain intensity is commonly assessed by a numerical or visual analogue scale, this presents limitations, as it does not consider the dynamic nature of pain[3]. 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[4]. 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"[5].

In this context, an international working group was established under the guidance of OARSI and Outcome Measures in Rheumatology Clinical Trials (OMERACT), with the aim to create a composite index that could define states of severity and theoretical requirement for surgery of knee and hip osteoarthritis, and for use in clinically evaluating potential disease-modifying drugs[6]. Pain, physical function, and joint structure are the three main domains in OA, among which pain experience is considered to be inadequately captured in existing measures and so there is a requirement for a new OA pain measure[7]. In view of this, the Intermittent and Constant Osteoarthritis and Pain (ICOAP) measure was developed, based on the pain data from a qualitative study[8].

The ICOAP was developed in the English language. It 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"). Each domain captures pain intensity as well as related distress and the impact of OA pain on quality of life. The ICOAP has been widely used in research[9,10]. It has been tested to have good psychometric properties in multiple languages including Turkish, Portuguese, German and Greek[11-14]. In view of the ever-increasing trend for multinational studies and international cooperation among medical organizations, there is a compelling need to increase the applicability of this instrument in the Chinese population.

A simplified Chinese version of ICOAP has been published by Zhang et al[15]. Whilst 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 re-test reliability of the traditional Chinese ICOAP (tChICOAP).

Material and Methods:

Study Design:

The study was divided into two steps: (1) translation and cross-cultural adaptation of the English version of the ICOAP into traditional Chinese; (2) evaluation of the psychometric properties of the tChICOAP. This study has been approved by the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (CREC no. 2016.601).

Patient and Public Involvement:

Authors' prior research focused on the use of Visual Analogue Scale and WOMAC questionnaire to assess the pain severity in KOA. However, participants express that the pain severity always changes with time, and their pain experience is inadequately captured. The ICOAP is one of the questionnaire developed to capture the pain experience; however, the Traditional Chinese version of ICOAP is lacking. Therefore, the study was conducted to produce the Traditional Chinese version of ICOAP.

How did you involve patients in the design of this study?

10 Patients were involved in the cognitive debriefing and they provided valuable advice in the questionnaire.

Were patients involved in the recruitment to and conduct of the study?

Patients referred their friends and relatives with KOA to participant in this study.

How will the results be disseminated to study participants?

This is a questionnaire validation study and the dissemination of results to patients would be less applicable. However, the validated questionnaire will be administered to patients in future studies.

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[16]. In the first step, one English translator and one orthopedic 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 orthopedic 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 pre-tested 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 between July and December 2017 in the General Outpatients Clinics (GOPCs) in the New Territories East (NTE) 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 inform 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, age ≥ 45 to ≤ 75 years old, and with knee pain for at least 3 months[17]. 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. The pain score is rated by pain intensity, frequency, impact on mood, sleep and quality of life[8]. A Rasch analysis has been performed and the results supported the use of constant and intermittent subscales as one-dimensional measures of pain[18]. Each score is rated from 0 to 4, and the sum is further standardized to a range of values from 0-100.

The WOMAC: This is a disease-specific questionnaire recommended to be used during osteoarthritis clinical trials[19]. 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-millimeter Visual Analogue Scale (VAS). In this study, we used the VAS to rate the pain subscale[20]. The WOMAC pain subscale is recommended by the developer of ICOAP to

test on the construct validity[8]. The total score will be determined by adding corresponding items for each dimension. We use the validated Chinese WOMAC in this study[21].

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 health, vitality, social functioning, and emotional and mental health.[22] The sub-scale scores can be summarized 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[23]. We hypothesized 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. The interviews were repeated by the same research assistant 2 days later. Age, sex, body mass index, duration of 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[16]. At least 7 subjects would be needed for each item for psychometric testing, which is generally considered to be sufficient for factor

analysis[24]. In our study, 10 subjects for each item were recruited, which contributes to a sample size of 110. Therefore, the total sample size needed was 120, with 10 for cognitive debriefing and 110 for psychometric testing.

Statistical Analysis:

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[25]. 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[26]. Corrected item-total scale correlation between domains and their constituent item with $p \geq 0.4$ was considered as acceptable[27]. Test and re-test 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[28]. The data were entered and analyzed using the statistical package for Social Sciences (SPSS) software (version 21.0). p-value < 0.05 was considered as statically significant.

Results:

The demographics of 110 participants are summarized in Table 1.

Cross-cultural adaptation:

Slight differences were identified in the structure of the sentences between the original and translated versions and minor adjustments were made. Participants felt that the questionnaire was easy to understand, the content was good and that the questions aligned well with their feelings. Two participants found it difficult to understand the difference between "frustrated or annoyed" versus "upset or worried" in Chinese (Cantonese) and the problem was solved by explaining the concept. Minor modifications were made to the Chinese terms to improve the succinctness of the questionnaire. (Supplementary File)

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. (Table 2 and Table 3)

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 4)

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. In order to ensure we would evaluate and measure the impact of KOA as in other multinational trials[29]. we followed the translation steps as recommended by the OARSI/OMERACT[16].

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)[8,15,30] . The performance of the test and re-retest 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)[8,11,12,14,15].

Like other language versions, the tChICOAP correlated strongly with the WOMAC pain subscale, as both were constructed to measure osteoarthritic pain[8,15,30]. 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 sensitization, 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[31-33].

The strength of the study is that we validated the tChICOAP across different severity of KOA, i.e., from Kellgren-Lawrence (KL) grading 1 to 4[34]. The original version, the simplified Chinese version and other language versions only included patients with KL grade 2 and 3[8,11-15]. The 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 patients with different severities of KOA.

Declarations

Ethics approval and consent to participate:

The study complies with the Declaration of Helsinki and has been approved by the Joint Chinese University of Hong Kong - New Territories East Cluster Clinical Research Ethics Committee. (Reference No.: 2016-601). Written inform consent was obtained from all participants.

Consent to publish:

Not applicable

Availability of data and material:

All data generated or analysed in this study are included in this published article.

Conflict of interest:

The authors declare no completing interest.

Role of the funding source:

The study is funded by the Chinese University of Hong Kong Direct Grant for Research 2017 (HKD 56,084). The funding body has no role in the study other than providing funding.

Author Contributions:

The following authors had made substantial contributions to the following: the concept and design of the study (RS and WW), collection and assembly of data (RS and LC), analysis and interpretation of data (RS, DC and BY), drafting the article (RS and SW), revising critical important intellectual content (RS, DC, WW, BY and SW). All the authors approved final version of the manuscript.

Data sharing statement:

All data in this study are available upon request

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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 6 sets of data,#Missing 7 sets of data

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

Table 2. Internal consistency and reliability of the Intermittent and Constant Osteoarthritis and Pain (ICOAP) subscales and total pain

Scale	Mean score (SD)		ICC (95% CI)	Cronbach's α coefficient
	First	Second		
Constant	30.23 (21.11)	31.18 (20.62)	0.959 (0.940-0.972)	.934*
Intermittent	38.11 (18.12)	36.74 (18.56)	0.924 (0.889-0.948)	.902*
Total	34.52 (18.54)	34.21 (18.77)	0.960 (0.941-0.972)	

*Excellent reliability >0.75

Table 3. Correlation of each item and total Intermittent and Constant Osteoarthritis and Pain (ICOAP) scores (N=110)

ICOAP items	Corrected item-total coefficients[1]	Corrected item-total coefficients[2]	Cronbach's α if item deleted[1]	Cronbach's α if item deleted[2]
Constant pain subscale				
1. In the past week, how intense has your constant knee pain been?	.853	.802	.913	.941
2. In the past week, how much has your constant knee pain affected your sleep?	.697	.698	.940	.945
3. In the past week, how much has your constant knee pain affected your overall quality of life?	.869	.833	.910	.940
4. In the past week, how frustrated or annoyed have you been by your constant knee pain?	.855	.847	.912	.940
5. In the past week, how upset or worried have you been by your constant knee pain?	.852	.850	.914	.940
Intermittent pain subscale				
6. In the past week, how intense has your most severe knee pain that comes and goes	.716	.728	.887	.944

	been?				
7.	In the past week, how frequent has this knee pain that comes and goes occurred?	.620	.623	.900	.948
8.	In the past week, how much has your knee pain that comes and goes affected your sleep?	.680	.739	.892	.944
9.	In the past week, how much has your knee pain that comes and goes affected your overall quality of life?	.841	.803	.869	.942
10.	In the past week, how frustrated or annoyed have you been by your knee pain that comes and goes?	.787	.794	.876	.942
11.	In the past week, how upset or worried have you been by your knee pain that comes and goes?	.755	.711	.882	.945

[1]generated from constant and intermittent pain subscales of ICOAP

[2]generated from the total pain score of ICOAP

Table 4. 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	-.487 ($p < 0.001$)[2]	-.398 ($p < 0.001$)[2]	.671 ($p < 0.001$)[1]
Intermittent	-.590 ($p < 0.001$)[1]	-.418 ($p < 0.001$)[2]	.678 ($p < 0.001$)[1]
Total	-.558 ($p < 0.001$)[1]	-.431 ($p < 0.001$)[2]	.707 ($p < 0.001$)[1]

Spearman's correlation coefficients, $p < 0.001$

[1]Strong correlation (r = > 0.5)

[2]Moderate correlation (r = 0.35-0.50)

參加者編號：_____ 參加者簽署：_____

日期：_____

間歇性和持續性骨關節炎疼痛的測量（ICOAP）：膝關節版本

我們知道，很多人都曾經歷過不同類型的膝痛（包括酸痛或不適），為了更好地瞭解不同類型的膝痛，我們想分別詢問您有關「持續性疼痛」（時刻都感受到疼痛）及「間歇性疼痛」（不定時感到膝痛）的情況。以下問題是關於您在過去一周中感到膝痛的情況。請回答所有問題。

甲）持續性痛症

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

1. 在過去一周中，您的持續性膝痛有多強烈？

☐	☐	☐	☐	☐
完全沒有／沒有持續性膝痛	輕微	中等	嚴重	極度

2. 過去一週，您的持續性膝痛有多影響您的睡眠？

☐	☐	☐	☐	☐
完全沒有／沒有持續性膝痛	輕微	中等	嚴重	極度

3. 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？

☐	☐	☐	☐	☐
完全沒有／沒有持續性膝痛	輕微	中等	嚴重	極度

4. 過去一週，您的持續性膝痛症令您有多沮喪或煩擾？

☐	☐	☐	☐	☐
完全沒有／沒有持續性膝痛	輕微	中等	嚴重	極度

5. 過去一週，您的持續性膝痛令您有多擔心？

☐	☐	☐	☐	☐
完全沒有／沒有持續性膝痛	輕微	中等	嚴重	極度

乙) 間歇性疼痛

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

6. 在過去一周中，您最嚴重的間歇性膝痛有多強烈？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	輕微	中等	嚴重	極度

7. 過去一週，這類間歇性膝痛發作得有多頻密？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	很少	有時	常常	經常

8. 在過去一周中，您的間歇性膝痛對您的睡眠有多大影響？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	輕微	中等	嚴重	極度

9. 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？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	輕微	中等	嚴重	極度

10. 過去一週，您的間歇性膝痛令您有多沮喪或煩擾？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	輕微	中等	嚴重	極度

11. 過去一週，您的間歇性膝痛令您有多擔心？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	輕微	中等	嚴重	極度

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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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 re-test 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 ranged from 0.869 to 0.948, and good corrected item-total subscale correlations. It had high test and re-test reliability (intra-class correlations 0.924-0.960). The tChICOAP constant, intermittent, and total pain scores correlated 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.

Keywords: ICOAP, Traditional Chinese, Knee Osteoarthritis, Pain

Strengths and Limitations:

- This is the first study to validate the Traditional Chinese version of the ICOAP questionnaire.
- The study followed the international guidelines in the translation and validation process.
- Responsiveness of the tChICOAP was not tested.

Introduction

Knee osteoarthritis (KOA) is a major cause of pain and disability contributing to the health-care service burden worldwide[1]. Pain in KOA is multi-dimensional. While pain intensity is commonly assessed by a numerical or visual analogue scale, this 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 under the guidance of OARSI and Outcome Measures in Rheumatology Clinical Trials (OMERACT)[5] in 2008. 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 organizations, there is a compelling need to increase the applicability of this instrument in the Chinese population.

A simplified Chinese version of ICOAP has been published by Zhang et al[12]. Whilst 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 content validity, internal consistency, the construct validity, and the test and re-test 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 orthopedic 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 orthopedic 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 pre-tested 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 (NTE) 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 inform 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, age ≥ 45 to ≤ 75 years old, 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 standardized to a range of values from 0-100.

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-millimeter Visual Analogue Scale (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 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 health, vitality, social functioning, and emotional and mental health[19]. The sub-scale scores can be summarized 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 hypothesized 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 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% confidence interval and the number of measurement to be 2; with 2 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 re-test 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 standard error of measurement (SEM) is estimated from the standard deviation 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 analyzed using the statistical package for Social Sciences (SPSS) software (version 21.0). P-value < 0.05 was considered as statically significant.

Results:

The demographics of 110 participants are summarized 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. (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:

The internal consistency was good with the Cronbach's alpha values ranged from 0.869 to 0.940 for the constant and intermittent scores, and 0.940 to 0.948 for the total score. 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. (Table 3)

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 4)

Test and Retest Reliability:

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 were 3.71 and 10.28, respectively. (Table 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-retest 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 sensitization, 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].

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.

Declarations

Ethics approval and consent to participate:

The study complies with the Declaration of Helsinki and has been approved by the Joint Chinese University of Hong Kong - New Territories East Cluster Clinical Research Ethics Committee.

(Reference No.: 2016-601). Written inform consent was obtained from all participants.

Consent to publish:

Not applicable

Availability of data and material:

All data generated or analyzed in this study are included in this published article.

Conflict of interest:

The authors declare no completing interest.

Role of the funding source:

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Author Contributions:

The following authors had made substantial contributions to the following: the concept and design of the study (RS and WW), collection and assembly of data (RS and LC), analysis and interpretation of data (RS, DC and BY), drafting the article (RS and SW), revising critical important intellectual content (RS, DC, WW, BY and SW). All the authors approved final version of the manuscript.

Data sharing statement:

All data in this study are available upon request

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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 6 sets of data,#Missing 7 sets of data

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

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Table 2 Content validity index of tChICOAP items on appropriateness, clarity and relevance.

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	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			

Goes)	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%

Table 3. Internal consistency of the tChICOAP (N=110)

ICOAP items	Corrected item-total coefficients[1]	Corrected item-total coefficients[2]	Cronbach's α if item deleted[1]	Cronbach's α if item deleted[2]
Constant pain subscale				
1. In the past week, how intense has your constant knee pain been?	.853	.802	.913	.941
2. In the past week, how much has your constant knee pain affected your sleep?	.697	.698	.940	.945
3. In the past week, how much has your constant knee pain affected your overall quality of life?	.869	.833	.910	.940
4. In the past week, how frustrated or annoyed have you been by your constant knee pain?	.855	.847	.912	.940
5. In the past week, how upset or worried have you been by your constant knee pain?	.852	.850	.914	.940
Intermittent pain subscale				
6. In the past week, how intense has your most severe knee pain that comes and goes	.716	.728	.887	.944

	been?				
7.	In the past week, how frequent has this knee pain that comes and goes occurred?	.620	.623	.900	.948
8.	In the past week, how much has your knee pain that comes and goes affected your sleep?	.680	.739	.892	.944
9.	In the past week, how much has your knee pain that comes and goes affected your overall quality of life?	.841	.803	.869	.942
10.	In the past week, how frustrated or annoyed have you been by your knee pain that comes and goes?	.787	.794	.876	.942
11.	In the past week, how upset or worried have you been by your knee pain that comes and goes?	.755	.711	.882	.945

[1]generated from constant and intermittent pain subscales of ICOAP

[2]generated from the total pain score of ICOAP

Table 4. Construct validity of the tChICOAP (N =110)

	SF12 Physical Component Summary	SF12 Mental Component Summary	WOMAC Pain Subscale
ICOAP			
Constant	-.487 ($p < 0.001$)[2]	-.398 ($p < 0.001$)[2]	.671 ($p < 0.001$)[1]
Intermittent	-.590 ($p < 0.001$)[1]	-.418 ($p < 0.001$)[2]	.678 ($p < 0.001$)[1]
Total	-.558 ($p < 0.001$)[1]	-.431 ($p < 0.001$)[2]	.707 ($p < 0.001$)[1]

Spearman's correlation coefficients, $p < 0.001$

[1]Strong correlation (r = > 0.5)

[2]Moderate correlation (r = 0.35-0.50)

Table 5. Test and retest reliability of the tChICOAP (N=100)

Scale	Mean score (SD)		ICC (95% CI)	Cronbach's α coefficient	SEM	MDC
	First	Second				
Constant	30.23 (21.11)	31.18 (20.62)	0.959 (0.940-0.972)	.934*	4.27	11.85
Intermittent	38.11 (18.12)	36.74 (18.56)	0.924 (0.889-0.948)	.902*	5.00	13.85
Total	34.52 (18.54)	34.21 (18.77)	0.960 (0.941-0.972)		3.71	10.28

*Excellent reliability >0.75

SD= Standard Deviation

CI=Confident Interval

ICC=Intraclass correlation

SEM=Standard Error of Measurement

MDC= Minimal Detectable Change

456

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參加者編號：_____ 參加者簽署：_____

日期：_____

間歇性和持續性骨關節炎疼痛的測量（ICOAP）：膝關節版本

我們知道，很多人都曾經歷過不同類型的膝痛（包括酸痛或不適），為了更好地瞭解不同類型的膝痛，我們想分別詢問您有關「持續性疼痛」（時刻都感受到疼痛）及「間歇性疼痛」（不定時感到膝痛）的情況。以下問題是關於您在過去一周中感到膝痛的情況。請回答所有問題。

甲）持續性痛症

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

1. 在過去一周中，您的持續性膝痛有多強烈？

☐	☐	☐	☐	☐
完全沒有／沒有持續性膝痛	輕微	中等	嚴重	極度

2. 過去一週，您的持續性膝痛有多影響您的睡眠？

☐	☐	☐	☐	☐
完全沒有／沒有持續性膝痛	輕微	中等	嚴重	極度

3. 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？

☐	☐	☐	☐	☐
完全沒有／沒有持續性膝痛	輕微	中等	嚴重	極度

4. 過去一週，您的持續性膝痛症令您有多沮喪或煩擾？

☐	☐	☐	☐	☐
完全沒有／沒有持續性膝痛	輕微	中等	嚴重	極度

5. 過去一週，您的持續性膝痛令您有多擔心？

☐	☐	☐	☐	☐
完全沒有／沒有持續性膝痛	輕微	中等	嚴重	極度

乙) 間歇性疼痛

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

6. 在過去一周中，您最嚴重的間歇性膝痛有多強烈？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	輕微	中等	嚴重	極度

7. 過去一週，這類間歇性膝痛發作得有多頻密？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	很少	有時	常常	經常

8. 在過去一周中，您的間歇性膝痛對您的睡眠有多大影響？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	輕微	中等	嚴重	極度

9. 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？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	輕微	中等	嚴重	極度

10. 過去一週，您的間歇性膝痛令您有多沮喪或煩擾？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	輕微	中等	嚴重	極度

11. 過去一週，您的間歇性膝痛令您有多擔心？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	輕微	中等	嚴重	極度

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract **P.1**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **P.2-3**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **P.4-5**
Objectives	3	State specific objectives, including any prespecified hypotheses **P.5**
Methods		
Study design	4	Present key elements of study design early in the paper **P.5-6**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection4 **P.5**
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants **P.6-7**
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable **P.7-8**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group **P.7-8**
Bias	9	Describe any efforts to address potential sources of bias **(NA)**
Study size	10	Explain how the study size was arrived at **P.8**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why **P.9**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **P.9**
		(*b*) Describe any methods used to examine subgroups and interactions **(NA)**
		(*c*) Explain how missing data were addressed **(NA)**
		(*d*) If applicable, describe analytical methods taking account of sampling strategy **(NA)**
		(*e*) Describe any sensitivity analyses **(NA)**
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. **P. 9 and Table 1**
		(b) Give reasons for non-participation at each stage **(NA)**
		(c) Consider use of a flow diagram **(NA)**
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and

		information on exposures and potential confounders **(Table 1)**
		(b) Indicate number of participants with missing data for each variable of interest **(NA)**
Outcome data	15*	Report numbers of outcome events or summary measures **(P.9-11, Table 2-5)**
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included **(Table 2-5)**
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period **(NA)**
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses **(NA)**
Discussion		
Key results	18	Summarise key results with reference to study objectives **(P.12)**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias **(P.12)**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence **(P.12)**
Generalisability	21	Discuss the generalisability (external validity) of the study results **(P.12)**
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based **(P.13)**

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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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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 re-test reliability.

Results: All participants completed the tChICOAP questionnaire without missing items. The content validity index of all items ranged from 80-100%. 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 re-test 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.

Keywords: ICOAP, Traditional Chinese, Knee Osteoarthritis, Pain

Strengths and Limitations:

- This is the first study to validate the Traditional Chinese version of the ICOAP 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.

Introduction

Knee osteoarthritis (KOA) is a major cause of pain and disability contributing to the health-care service burden worldwide[1]. Pain in KOA is multi-dimensional. While pain intensity is commonly assessed by a numerical or visual analogue scale, this 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 organizations, there is a compelling need to increase the applicability of this instrument in the Chinese population.

A simplified Chinese version of ICOAP has been published by Zhang et al[12]. Whilst 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 re-test 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 orthopedic 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 orthopedic 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 pre-tested 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 (NTE) 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 inform 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, age ≥ 45 to ≤ 75 years old, 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 standardized to a range of values from 0-100.

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-millimeter Visual Analogue Scale (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 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 health, vitality, social functioning, and emotional and mental health[19]. The sub-scale scores can be summarized 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 hypothesized 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 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% confidence interval and the number of measurement to be 2; with 2 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 re-test 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 standard error of measurement (SEM) is estimated from the standard deviation 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 analyzed using the statistical package for Social Sciences (SPSS) software (version 21.0). P-value < 0.05 was considered as statically significant.

Results:

The demographics of 110 participants are summarized 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. (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. (Table 3 and Table 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)

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-retest 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 sensitization, 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.

Declarations

Ethics approval and consent to participate:

The study complies with the Declaration of Helsinki and has been approved by the Joint Chinese University of Hong Kong - New Territories East Cluster Clinical Research Ethics Committee.

(Reference No.: 2016-601). Written inform consent was obtained from all participants.

Consent to publish:

Not applicable

Availability of data and material:

All data generated or analyzed in this study are included in this published article.

Conflict of interest:

The authors declare no completing interest.

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Author Contributions:

The following authors had made substantial contributions to the following: the concept and design of the study (RS and WW), collection and assembly of data (RS and LC), analysis and interpretation of data (RS, DC and BY), drafting the article (RS and SW), revising critical important intellectual content (RS, DC, WW, BY and SW). All the authors approved final version of the manuscript.

Data sharing statement:

Extra data can be accessed via the Dryad data repository at http://datadryad.org/ with the doi:10.5061/dryad.30r34f7

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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 6 sets of data,#Missing 7 sets of data

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

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	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			

Pain)	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%

Table 3. Internal consistency and reliability of the Intermittent and Constant Osteoarthritis and Pain (ICOAP) subscales and total pain

Scale	Mean score (SD)	ICC (95% CI)	Cronbach's αcoefficient	SEM	MDC

	First	Second				
Constant	30.23 (21.11)	31.18 (20.62)	0.959 (0.940-0.972)	.934*	4.27	11.85
Intermittent	38.11 (18.12)	36.74 (18.56)	0.924 (0.889-0.948)	.902*	5.00	13.85
Total	34.52 (18.54)	34.21 (18.77)	0.960 (0.941-0.972)		3.71	10.2

*Excellent reliability >0.75

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

ICOAP items	Corrected item-total	Corrected item-total	Cronbach's α if item	Cronbach's α if item

		coefficients[1]	coefficients[2]	deleted[1]	deleted[2]
Constant pain subscale					
1.	In the past week, how intense has your constant knee pain been?	.853	.802	.913	.941
2.	In the past week, how much has your constant knee pain affected your sleep?	.697	.698	.940	.945
3.	In the past week, how much has your constant knee pain affected your overall quality of life?	.869	.833	.910	.940
4.	In the past week, how frustrated or annoyed have you been by your constant knee pain?	.855	.847	.912	.940
5.	In the past week, how upset or worried have you been by your constant knee pain?	.852	.850	.914	.940
Intermittent pain subscale					
6.	In the past week, how intense has your most severe knee pain that comes and goes been?	.716	.728	.887	.944
7.	In the past week, how frequent has this knee pain that comes and goes occurred?	.620	.623	.900	.948
8.	In the past week, how much has your knee pain that comes and goes affected your	.680	.739	.892	.944

	sleep?				
9.	In the past week, how much has your knee pain that comes and goes affected your overall quality of life?	.841	.803	.869	.942
10.	In the past week, how frustrated or annoyed have you been by your knee pain that comes and goes?	.787	.794	.876	.942
11.	In the past week, how upset or worried have you been by your knee pain that comes and goes?	.755	.711	.882	.945

[1]generated from constant and intermittent pain subscales of ICOAP

[2]generated from the total pain score of ICOAP

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	-.487 ($p < 0.001$)[2]	-.398 ($p < 0.001$)[2]	.671 ($p < 0.001$)[1]
Intermittent	-.590 ($p < 0.001$)[1]	-.418 ($p < 0.001$)[2]	.678 ($p < 0.001$)[1]
Total	-.558 ($p < 0.001$)[1]	-.431 ($p < 0.001$)[2]	.707 ($p < 0.001$)[1]

Spearman's correlation coefficients, $p < 0.001$

[1]Strong correlation ($r = > 0.5$)

[2]Moderate correlation ($r = 0.35$-0.50)

參加者編號：_____ 參加者簽署：_____

日期：_____

間歇性和持續性骨關節炎疼痛的測量（ICOAP）：膝關節版本

我們知道，很多人都曾經歷過不同類型的膝痛（包括酸痛或不適），為了更好地瞭解不同類型的膝痛，我們想分別詢問您有關「持續性疼痛」（時刻都感受到疼痛）及「間歇性疼痛」（不定時感到膝痛）的情況。以下問題是關於您在過去一周中感到膝痛的情況。請回答所有問題。

甲）持續性痛症

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

1. 在過去一周中，您的持續性膝痛有多強烈？

☐	☐	☐	☐	☐
完全沒有／沒有持續性膝痛	輕微	中等	嚴重	極度

2. 過去一週，您的持續性膝痛有多影響您的睡眠？

☐	☐	☐	☐	☐
完全沒有／沒有持續性膝痛	輕微	中等	嚴重	極度

3. 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？

☐	☐	☐	☐	☐
完全沒有／沒有持續性膝痛	輕微	中等	嚴重	極度

4. 過去一週，您的持續性膝痛症令您有多沮喪或煩擾？

☐	☐	☐	☐	☐
完全沒有／沒有持續性膝痛	輕微	中等	嚴重	極度

5. 過去一週，您的持續性膝痛令您有多擔心？

☐	☐	☐	☐	☐
完全沒有／沒有持續性膝痛	輕微	中等	嚴重	極度

乙) 間歇性疼痛

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

6. 在過去一周中，您最嚴重的間歇性膝痛有多強烈？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	輕微	中等	嚴重	極度

7. 過去一週，這類間歇性膝痛發作得有多頻密？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	很少	有時	常常	經常

8. 在過去一周中，您的間歇性膝痛對您的睡眠有多大影響？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	輕微	中等	嚴重	極度

9. 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？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	輕微	中等	嚴重	極度

10. 過去一週，您的間歇性膝痛令您有多沮喪或煩擾？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	輕微	中等	嚴重	極度

11. 過去一週，您的間歇性膝痛令您有多擔心？

☐	☐	☐	☐	☐
完全沒有／沒有間歇性膝痛	輕微	中等	嚴重	極度

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract **P.1**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **P.2-3**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **P.4-5**
Objectives	3	State specific objectives, including any prespecified hypotheses **P.5**
Methods		
Study design	4	Present key elements of study design early in the paper **P.5-6**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection4 **P.5**
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants **P.6-7**
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable **P.7-8**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group **P.7-8**
Bias	9	Describe any efforts to address potential sources of bias **(NA)**
Study size	10	Explain how the study size was arrived at **P.8**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why **P.9**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **P.9**
		(*b*) Describe any methods used to examine subgroups and interactions **(NA)**
		(*c*) Explain how missing data were addressed **(NA)**
		(*d*) If applicable, describe analytical methods taking account of sampling strategy **(NA)**
		(*e*) Describe any sensitivity analyses **(NA)**
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. **P. 9 and Table 1**
		(b) Give reasons for non-participation at each stage **(NA)**
		(c) Consider use of a flow diagram **(NA)**
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and

		information on exposures and potential confounders **(Table 1)**
		(b) Indicate number of participants with missing data for each variable of interest **(NA)**
Outcome data	15*	Report numbers of outcome events or summary measures **(P.9-11, Table 2-5)**
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included **(Table 2-5)**
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period **(NA)**
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses **(NA)**
Discussion		
Key results	18	Summarise key results with reference to study objectives **(P.12)**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias **(P.12)**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence **(P.12)**
Generalisability	21	Discuss the generalisability (external validity) of the study results **(P.12)**
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based **(P.13)**

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.