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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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Translation, Cross-Cultural Adaptation and Validation of the Traditional Chinese 1 2 Intermittent and Constant Osteoarthritis Pain (ICOAP) Questionnaire for Knee 3 **Osteoarthritis** 4 Regina WS Sit*¹MBBS, Dicken CC Chan MSc¹, Wendy Wong PhD², Benjamin HK Yip PhD¹, 5 Lyan LY Chow BSc¹, Samuel YS Wong MD¹ 6 7 ¹The Jockey Club School of Public Health and Primary Care, The Chinese University of Hong 8 9 Kong, Hong Kong ² The School of Chinese Medicine, The Chinese University of Hong Kong, Hong Kong 10 11 Regina WS Sit: reginasit@cuhk.edu.hk 12 13 Dicken CC Chan: dicken@cuhk.edu.hk Wendy Wong: wendy.wong@cuhk.edu.hk 14 15 Benjamin HK Yip: benyip@cuhk.edu.hk 16 Lyan LY Chow: chowlyan@cuhk.edu.hk Samuel YS Wong: yeungshanwong@cuhk.edu.hk 17 18 *Corresponding author: 19 20 Regina WS Sit Address: 4/F School of Public Health Building, Prince of Wales Hospital, Shatin, Hong Kong 21 22 Special Administrative Region 23 Tel: (852) 2503-9406, Email: reginasit@cuhk.edu.hk

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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.

37 Results: All participants completed the tChICOAP questionnaire without missing items. The
38 tChICOAP total pain and subscale scores had excellent internal consistency with Cronbach's
39 alpha value (0.902-0.948) and good corrected item-total subscale correlations. It had high test
40 and re-test reliability (intra-class correlations 0.924-0.960). The tChICOAP constant,

41 intermittent, and total pain scores correlate strongly with the WOMAC pain subscale (r=0.671, 42 0.678 and 0.707 respectively, p < 0.001). The tChICOAP intermittent and total scores correlate 43 strongly with SF-12v2 physical component score (r=-0.590 and -0.558 respectively, p < 0.001).

45 Conclusions: The tChICOAP is a reliable and valid instrument to measure the pain experience of46 patients with different severity of KOA.

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6	48	Keywords: ICOAP, Traditional Chinese, Knee Osteoarthritis, Pain
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10 11	50	
12 13	51	
14 15 16	52	Strengths and Limitations:
17 18	53	• This is the first study to validate the Traditional Chinese version of the ICOAP questionnaire.
19 20	54	• The tChICOAP has the best test and re-test reliability among the original and other validated
21 22	55	language versions.
23 24	56	• The study validated the tChICOAP across different severity of KOA.
25 26 27	57	• Responsiveness of the tChICOAP was not tested.
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70 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 KOA¹. Its incidence increases up to 10-fold from ages 30 to 65 years and even more thereafter². 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 pain³. 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 draining⁴. 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 drugs⁶. 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 measure⁷. In view of this, the Intermittent and Constant Osteoarthritis and Pain (ICOAP) measure was developed, based on the pain data from a qualitative study⁸.

91 The ICOAP was developed in the English language. It is an 11-item questionnaire, divided into
92 two domains; a 5-item scale for constant pain and a 6-item scale for intermittent pain (so-called

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93 "pain that comes and goes"). Each domain captures pain intensity as well as related distress and 94 the impact of OA pain on quality of life. The ICOAP has been widely used in research^{9,10}. It has 95 been tested to have good psychometric properties in multiple languages including Turkish, 96 Portuguese, German and Greek¹¹⁻¹⁴. In view of the ever-increasing trend for multinational studies 97 and international cooperation among medical organizations, there is a compelling need to 98 increase the applicability of this instrument in the Chinese population.

A simplified Chinese version of ICOAP has been published by Zhang et al¹⁵. 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).

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 - 108 Material and Methods:
- 0 109
 - 110 Study Design:

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

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2 3	116	Patient and Public Involvement:
4 5 6	117	Authors' prior research focused on the use of Visual Analogue Scale and WOMAC questionnaire
7 8	118	to assess the pain severity in KOA. However, participants express that the pain severity always
9 10 11	119	changes with time, and their pain experience is inadequately captured. The ICOAP is one of the
12 13	120	questionnaire developed to capture the pain experience; however, the Traditional Chinese version
14 15 16	121	of ICOAP is lacking. Therefore, the study was conducted to produce the Traditional Chinese
17 18	122	version of ICOAP.
19 20 21	123	
21 22 23	124	How did you involve patients in the design of this study?
24 25	125	10 Patients were involved in the cognitive debriefing and they provided valuable advice in the
26 27 28	126	questionnaire.
20 29 30	127	
31 32	128	<i>Were patients involved in the recruitment to and conduct of the study?</i>
33 34 25	129	Patients referred their friends and relatives with KOA to participant in this study.
35 36 37	130	
38 39	131	How will the results be disseminated to study participants?
40 41 42	132	This is a questionnaire validation study and the dissemination of results to patients would be less
42 43 44	133	applicable. However, the validated questionnaire will be administered to patients in future
45 46	134	studies.
47 48 40	135	
49 50 51	136	Step 1: Translation and cross-cultural adaptation
52 53	137	
54 55 56	138	We followed the steps as suggested by the developer of the ICOAP in conducting the translation
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of the tChICOAP¹⁶. 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.

- - 155 <u>Step 2: Psychometric testing using a cross-sectional cohort</u>
- ² 156

157 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

162 clinic operated by the Chinese University of Hong Kong. Written inform consents were obtained163 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, $age \ge 45$ to ≤ 75 years old, and with knee pain for at least 3 months¹⁷. 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.

172 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 life⁸. A Rasch analysis has been performed and the results supported the use of constant and intermittent subscales as one-dimensional measures of pain¹⁸. Each score is rated from 0 to 4, and the sum is further standardized to a range of values from 0-100.

180 The WOMAC: This is a disease-specific questionnaire recommended to be used during 181 osteoarthritis clinical trials¹⁹. It consists of 24 self-reported items, including knee pain (5 items), 182 stiffness (2 items), and function (17 items). Each item is graded either on a five-point Likert 183 scale or on a 100-millimeter Visual Analogue Scale (VAS). In this study, we used the VAS to rate 184 the pain subscale²⁰. The WOMAC pain subscale is recommended by the developer of ICOAP to

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test on the construct validity⁸. The total score will be determined by adding corresponding items
for each dimension. We use the validated Chinese WOMAC in this study²¹.

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.

³ 198

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.

5 203

204 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 process¹⁶. At least 7 subjects would be needed for each item for psychometric testing, which is generally considered to be sufficient for factor

analysis²⁴. 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.

212 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, respectively²⁵. 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 comparison²⁶. Corrected item-total scale correlation between domains and their constituent item with $p \ge 0.4$ was considered as acceptable²⁷. 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 reliability²⁸. 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.

- **224**
- ⁴² 225 **Results:**
- 45 226

- The demographics of 110 participants are summarized in Table 1.
- **22**8 50
 - 229 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 annoved" 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

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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 trials²⁹. we followed the translation steps as recommended by the OARSI/OMERACT¹⁶. 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.

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Consent to publish:

Not applicable

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302	Availability of data and material:
303	All data generated or analysed in this study are included in this published article.
304	
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306	The authors declare no completing interest.
307	
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316	important intellectual content (RS, DC, WW, BY and SW). All the authors approved final
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318	
319	Data sharing statement:
320	All data in this study are available upon request
321	

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12 13	326	the par	ticipants in the study.			
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3 ⊿	437		
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8	439	Table 1. Characteristics of the participa	ints
9		1 1	
10		Characteristics	Total sample $(N = 110)$
11		Characteristics	Total sample (IV TTO)
12			
13		Age (years)	62.2 ± 5.7
14			
15		Gender	
16			
17		Male	28 (25.5%)
18			
19		Female	82 (74 5%)
20		1 ciliule	
21			24.60 ± 2.60
22		DIVII	24.08 ± 3.08
25 24			
24		WOMAC pain score, mean (SD)	169.70 (124.37)
26			
27		SF-12v2 (PCS), mean (SD)	39.22 (9.50)
28			
29		SF-12v2 (MCS), mean (SD)	48.79 (9.29)
30			
31		Duration of knee pain	8.76 ± 6.70
32		2 anaron of mor pain	
33		Kellgren and Lawrence Grading [#]	
34		Kengren and Lawrence Grading	
35		Creada 1	17 (16 50/)
20 27		Glade I	17 (10.576)
32			
39		Grade 2	42 (40.8%)
40			
41		Grade 3	36 (35%)
42			
43		Grade 4	8 (7.7%)
44			
45	440	[^] Missing 6 sets of data, [#] Missing 7 sets	of data
46			
47	<i>AA</i> 1	BMI = Body Mass Index WOMAC = W	lestern Ontario McMaster University Osteoarthritis Index
48	771		estern ontario meritaster oniversity osteourunnis maex,
49 50	442	SE 12- Short form of Health Surrow 1'	2 DCS- physical component score MCS- montal
50	442	SI-12- Short form of freath Survey-1.	2, 1 CS- physical component score, MCS- mental
52	440	<u>,</u>	
53	443	component scores	
54			
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445					
446					
447	Table 2. Intern	al consistency and i	eliability of the Int	termittent and Constant (Osteoarthritis and
448	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)	
449	*Excellent reli	ability >0.75			
450					
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 (ICOAP) scores (N=110) ICOAP items Corrected Corrected Cronbach's Cronbach's item-total item-total a if item a if item total item-total a if item a if item coefficients¹ coefficients² deleted¹ deleted constant pain subscale In the past week, how intense has your .853 .802 .913 .941 constant knee pain been? In the past week, how much has your .697 .698 .940 .945 constant knee pain affected your sleep? In the past week, how much has your .869 .833 .910 .940 constant knee pain affected your overall quality of life? In the past week, how frustrated or .855 .847 .912 .940 annoyed have you been by your constant knee pain? In the past week, how upset or worried .852 .850 .914 .940 have you been by your constant knee pain? In the past week, how intense has your .716 .728 .887 .944 					inis and rain	
ICOAP items Corrected Corrected Corrected Cronbach's Corrected item-total item-total item-total item-total item-total deleted Constant pain subscale .<	(IC	OAP) scores (N=110)				
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coefficients1coefficients2deleted1deleted1Constant pain subscale.853.802.913.9411.In the past week, how intense has your constant knee pain been?.853.802.913.9412.In the past week, how much has your constant knee pain affected your sleep?.697.698.940.9453.In the past week, how much has your constant knee pain affected your overall quality of life?.869.833.910.9404.In the past week, how frustrated or annoyed have you been by your constant knee pain?.855.847.912.9405.In the past week, how upset or worried have you been by your constant knee pain?.852.850.914.940futuremittent pain subscale.852.850.914.940			item-total	item-total	α if item	α if iter
Constant pain subscale 1. In the past week, how intense has your .853 .802 .913 .941 constant knee pain been? .697 .698 .940 .945 2. In the past week, how much has your .697 .698 .940 .945 constant knee pain affected your sleep? 940 .945 3. In the past week, how much has your .869 .833 .910 .940 . <th></th> <th></th> <th>coefficients¹</th> <th>coefficients²</th> <th>deleted¹</th> <th>deleted</th>			coefficients ¹	coefficients ²	deleted ¹	deleted
 In the past week, how intense has your In the past week, how much has your In the past week, how frustrated or In the past week, how frustrated or In the past week, how frustrated or In the past week, how upset or worried In the past week, how intense has your 	Co	nstant pain subscale				
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Intermittent pain subscale6. In the past week, how intense has your.716.728.887.944		have you been by your constant knee pain?				
6. In the past week, how intense has your .716 .728 .887 .944	Inte	ermittent pain subscale				
	6.	In the past week, how intense has your	.716	.728	.887	.944

1 2 3 4 5			been?				
6 7 8		7.	In the past week, how frequent has this	.620	.623	.900	.948
9 10			knee pain that comes and goes occurred?				
11 12 13		8.	In the past week, how much has your knee	.680	.739	.892	.944
14 15			pain that comes and goes affected your				
16 17 18			sleep?				ć
19 20		9.	In the past week, how much has your knee	.841	.803	.869	.942
21 22			pain that comes and goes affected your				c
23 24 25		10	overall quality of life?	707	70.4	07(0.42
26 27		10.	In the past week, how trustrated or	./8/	./94	.8/6	.942
28 29 30			that comes and goes?				
31 32		11.	In the past week, how upset or worried	.755	.711	.882	.945
33 34 35			have you been by your knee pain that				
36 37			comes and goes?				ę
38 39 40	467	lger	nerated from constant and intermittent pain su	bscales of	ICOAP		
41 42	468	² ger	nerated from the total pain score of ICOAP				
43 44 45	469						
46 47	470						
48 49 50	471						
51 52	472						
53 54 55	473						
56 57	474						
58 59 60			For peer review only - http://bmjopen.l	omj.com/sit	e/about/guidelines.x	html	23
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475				
476				
477	Table 4. Criterion and	nd Construct validity of Inter	mittent and Constant Os	steoarthritis and Pai
478	(ICOAP)subscales a	and total pain ($N=110$)		
		SF12 Physical	SF12 Mental	WOMAC
		Component Summary	Component Summary	Pain Subscale
	ICOAP	0	·	
	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 $(p < 0.001)^1$
479	Spearman's correlat	ion coefficients, p < 0.001		
480	¹ Strong correlation ((r = > 0.5)		
481	² Moderate correlation	on (r = $0.35 - 0.50$)		
	F		hmi.com/sita/about/guidal	inor yhtml

參加者	編號:			參加者領	簽署:
日期:					
	間歇性利	口持續性骨關領	节炎疼痛的測量	(ICOAP):膝關領	節版本
我們知 我們想 情況。	口道,很多人都曾經歷始 思分別詢問您有關「持約 ,以下問題是關於您在該	過不同類型的腳 賣性疼痛」(時 過去一周中感到	漆痛(包括酸痛或 刻都感受到疼痛 到膝痛的情況。	不適),為了更好 i)及「間歇性疼 請回答所有問題	⁴ 地瞭解不同類型的膝症 痛」(不定時感到膝痛) 。
甲) 摂 請就り	痔續性痛症 以下每條問題,選擇最能	能形容您過去-	一週持續性膝痛	的平均情况的答案	Ŕ
1 . 右	E過去一周中,您的持续	賣性膝痛有多望	 後烈?		
	口 完全沒有/沒 有持續性膝痛	回輕微	口中等	□ 嚴重	□ 極度
2. 述	過去一週,您的持續性的	膝痛有多影響的	您的睡眠?		
	口 完全沒有/沒 有持續性膝痛	□ 輕微	中等	□ 嚴重	□ 極度
3. 右	E過去一周中,您的持续	賣性膝痛對您的	的整體生活質素	有多大影響?	
	口 完全沒有/沒 有持續性膝痛	□ 輕微	口中等	□嚴重	□ 極度
4. 述	過去一週,您的持續性	膝痛症令您有	多沮喪或煩擾?		
	口 完全沒有/沒 有持續性膝痛	□ 輕微	口中等	□ 嚴重	□ 極度
5. 述	過去一週,您的持續性的	膝痛令您有多措	詹心?		
	口 完全沒有/沒 有持續性膝痛	□ 輕微	口中等	□ 嚴重	□ 極度

6. 在避	去一周中,您最嚴	重的間歇性膝夠	 南有多強烈?		
					C
	完全沒有/沒 有間歇性膝痛	輕微	中等	嚴重	極
7. 過去	一週,這類間歇性	膝痛發作得有多	多頻密?		
					Γ
	完全沒有/沒 有間歇性膝痛	很少	有時	常常	
8. 在遥	去一周中,您的間	歇性膝痛對您的	的睡眠有多大影響	聲 ?	
					Γ
	完全沒有/沒 有間歇性膝痛	輕微	中等	嚴重	極
9. 在遛	去一周中,您的間	歇性膝痛對您的	的整體生活質素為	有多大影響?	
					Γ
	完全沒有/沒 有間歇性膝痛	輕微	中等	嚴重	極
10. 過去	一週,您的間歇性	膝痛令您有多济	且喪或煩擾?		
					[
	完全沒有/沒 有間歇性膝痛	輕微	中等	嚴重	極
11. 過去	一週,您的間歇性	膝痛令您有多措	詹心?		
					[

Translation, Cross-Cultural Adaptation and Validation of the Traditional Chinese Intermittent and Constant Osteoarthritis Pain (ICOAP) Questionnaire for Knee Osteoarthritis

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Primary Subject Heading :	Rheumatology
Secondary Subject Heading:	Research methods
Keywords:	ICOAP, Traditional Chinese, Knee Osteoarthritis, Pain

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1	Translation, Cross-Cultural Adaptation and Validation of the Traditional Chinese
2	Intermittent and Constant Osteoarthritis Pain (ICOAP) Questionnaire for Knee
3	Osteoarthritis
4	
5	Regina WS Sit*1MBBS, Dicken CC Chan MSc1, Wendy Wong PhD2, Benjamin HK Yip PhD1,
6	Lyan LY Chow BSc ¹ , Samuel YS Wong MD ¹
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24 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).

46 Conclusions: The tChICOAP is a reliable and valid instrument to measure the pain experience of

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2 3 4	47	Chinese patients with KOA.
5 6	48	
7 8 9	49	Keywords: ICOAP, Traditional Chinese, Knee Osteoarthritis, Pain
10 11	50	
12 13 14	51	Strengths and Limitations:
15 16	52	• This is the first study to validate the Traditional Chinese version of the ICOAP
17 18	53	questionnaire.
19 20 21	54	• The study followed the international guidelines in the translation and validation process.
22 23	55	Responsiveness of the tChICOAP was not tested.
24 25 26	56	
27 28	57	
29 30	58	
31 32 33	59	
34 35	60	
36 37 38	61	
39 40	62	
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Introduction

Knee osteoarthritis (KOA) is a major cause of pain and disability contributing to the health-care service burden worldwide¹. 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 pain². 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 draining³. 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.⁶⁷ It has been tested to have good psychometric properties in multiple languages including Turkish, Portuguese, German and Greek⁸⁻¹¹. 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.

91 A simplified Chinese version of ICOAP has been published by Zhang et al¹². Whilst simplified
92 Chinese is the official language used in the People's Republic of China, Singapore and Malaysia,

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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:

101 Patient and Public Involvement:

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

105 <u>Step 1: Translation and cross-cultural adaptation</u>

³ 106

We followed the steps as suggested by the developer of the ICOAP in conducting the translation of the tChICOAP¹³. 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 \geq 45 to \leq 75 years old, and with knee pain for at least 3 months¹⁴. 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

1 2		
3 4	139	unwillingness to complete the questionnaire.
5 6	140	
7 8	141	Research Instrument:
9 10 11	142	The ICOAP: This is an 11-item questionnaire divided into two domains; a 5-item scale for
12 13	143	constant pain and a 6-item scale for intermittent pain (so called "pain that comes and goes). The
14 15	144	pain score is rated by pain intensity, frequency, impact on mood, sleep and quality of life ⁵ .
16 17	145	Previous study has supported the use of constant and intermittent subscales as one-dimensional
18 19 20	146	measures of pain ¹⁵ . Each score is rated from 0 to 4, and the sum is further standardized to a
20 21 22	147	range of values from 0-100.
23 24	148	
25 26	149	The Chinese WOMAC: The WOMAC is a disease-specific questionnaire recommended to be
27 28 20	150	used during osteoarthritis clinical trials ¹⁶ . It consists of 24 self-reported items, including knee
30 31	151	pain (5 items), stiffness (2 items), and function (17 items). Each item is graded either on a five-
32 33	152	point Likert scale or on a 100-millimeter Visual Analogue Scale (VAS). In this study, we used
34 35	153	the VAS to rate the pain subscale ¹⁷ . The WOMAC pain subscale is recommended by the
36 37	153	developer of ICOAP to test on the construct validity ⁵ . The total score will be determined by
38 39 40	104	adding comparison ding items for each dimension. We use the validated Chinese WOMAC in this
40 41 42	155	adding corresponding items for each dimension. We use the validated Chinese WOWAC in this
43 44	156	study ¹⁸ .
45 46	157	
47 48	158	The Chinese Short form of Health Survey (SF-12v2): This consists of 12 items measuring eight
49 50 51	159	subscales on physical functioning, role physical, bodily pain, general health, vitality, social
52 53	160	functioning, and emotional and mental health ¹⁹ . The sub-scale scores can be summarized into
54 55	161	physical component (PCS) and mental component (MCS) scores. The measure has strong
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162 construct validity, responsiveness and clinometric profile. Study has shown that the Chinese SF-163 12 explained 88% and 90% of the variance of the SF-36 PCS and MCS scores, respectively. The 164 correlations between the corresponding SF-36 and SF-12 summary scores all reached the 165 expected standard of 0.9 and the effect size differences between the standard SF-36 and SF-12 166 scores were less than 0.3²⁰. We hypothesized that the ICOAP total and subscales would correlate 167 strongly with the SF-12v2 PCS.

169 ICOAP, WOMAC pain subscale and SF-12v2 are self –reported questionnaires. Participants 170 completed the questionnaires with the help of a research assistant at the study site. The 171 interviews were repeated by the same research assistant 5 days later at the same study site. An 172 interval of 5 days was chosen after considering the possible change in pain score with time; we 173 believe the memory effect should be minimal given that our participants were mostly older 174 people with KOA. Age, sex, body mass index, duration of knee pain and Kellgren-Lawrence 175 grading of the knees were collected.

177 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 process¹³. 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 subjects²¹.

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Statistical Analysis:

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	186	Content validity was evaluated with content validity index (CVI).Construct validity was
	187	evaluated using the correlation coefficients between the domain scores and total scores of
)	188	tChICOAP, WOMAC pain subscale and SF-12v2; with > 0.5 , 0.35-0.50, and < 0.35 considered
<u>)</u> }	189	as strong, moderate and weak, respectively ¹⁸ . Internal consistency was assessed using the
 ;	190	Cronbach's alpha and corrected item-total scale correlations. Cronbach's alpha ≥ 0.7 is generally
) 7 }	191	regarded as acceptable for group comparison ²² . Corrected item-total scale correlation between
)	192	domains and their constituent item with ≥ 0.4 was considered as acceptable ²³ . Test and re-test
2	193	reliability was assessed with an interval of 5 days in between using intra-class correlation (ICC;
5 	194	two-way mixed effects model); an ICC >0.75 is considered as excellent, 0.59-0.75 as good,
5 7	195	0.40–0.58 as fair, and <0.4 as showing poor reliability ²⁴ . The standard error of measurement
3	196	(SEM) is estimated from the standard deviation of a sample of scores at baseline and a test-retest
)	197	reliability index of the measurement instrument. Minimal detectable change (MDC) was
- 6 1	198	estimated from SEM and a degree of confidence. The data were entered and analyzed using the
5	199	statistical package for Social Sciences (SPSS) software (version 21.0). P-value < 0.05 was
8	200	considered as statically significant.
)	201	
<u>)</u> 5	202	Results:
 ;	203	
) 7 }	204	The demographics of 110 participants are summarized in Table 1.
)	205	
)	206	Cross-cultural adaptation and content validity:

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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 annoved" 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 -0.558respectively, 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)

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45 46	248
47 48	249
49 50 51	250
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230 Test and Retest Reliability:

231 It has excellent test and re-test reliability, with ICC values of 0.959 for the constant pain score 232 and 0.924 for the intermittent score. The SEM and MDC of the tChICOAP total score were 3.71 233 and 10.28, respectively. (Table 5)

236 **Discussion:**

238 The translation and cultural adaptation process were not challenging and produced an accurate 239 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", 240 241 "appropriateness" and "relevance" all achieved the standard of good content validity with CVI of 80% or above²⁵. In order to ensure we would evaluate and measure the impact of KOA as in 242 other multinational trials, we followed the translation steps as recommended by the 243 244 OARSI/OMERACT¹³.

The internal consistency of the tChICOAP total score is excellent, with high Cronbach's alpha 246 and corrected item-total subscale correlation. It is comparable to the original version, 247 (Cronbach's alpha 0.93), the simplified Chinese version (Cronbach's alpha 0.94), and other 248 language versions (Cronbach's alpha 0.82-0.95)⁵ ¹² ²⁶. The performance of the test and re-retest 249 reliability is the best among the original version (ICC 0.85), the simplified Chinese version (ICC 250 0.932) and other language versions such as Turkish (ICC 0.942), Portuguese (ICC 0.92), and 251 Greek (ICC 0.88)^{5 8 9 11 12}. 252

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253	
254	Like other language versions, the tChICOAP correlated strongly with the WOMAC pain
255	subscale, as both were constructed to measure osteoarthritic pain ⁵ ¹² ²⁶ . As expected, the
256	tChICOAP's intermittent and total scores have a strong correlation with SF-12v2 PCS, and only
257	moderate correlation with SF-12v2 MCS. This indicates that the measures are evaluating similar
258	constructs, and the intermittent pain may be the major contributor of reduced physical activity in
259	KOA. The tChICOAP constant pain score correlates moderately with both SF-12v2 PCS and
260	MCS. This can be explained by the complex heterogeneity of pain in KOA. Nociceptive pain,
261	neuropathic pain, central pain sensitization, pain catastrophizing, and the underlying biological
262	activity of joint destruction all contribute to the level of constant pain in KOA, making it difficult
263	to be constructed by SF-12v 2^{27} .
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265	One limitation of this study is that responsiveness of the tChICOAP was not tested, and a future
266	prospective study will be needed to address this.
267	
268	In summary, the tChICOAP is a reliable and valid instrument to measure the pain experience of
269	Chinese patients with KOA.
270	
271	Declarations
272	
273	Ethics approval and consent to participate:
274	The study complies with the Declaration of Helsinki and has been approved by the Joint Chinese
275	University of Hong Kong - New Territories East Cluster Clinical Research Ethics Committee.

1 ว					
2 3 4	276	(Reference No.: 2016-601). Written inform consent was obtained from all participants.			
5 6	277				
7 8 9	278	Consent to publish:			
) 10 11	279	Not applicable			
12 13	280				
14 15 16	281	Availability of data and material:			
17 18	282	All data generated or analyzed in this study are included in this published article.			
19 20	283				
21 22 23	284	Conflict of interest:			
23 24 25	285	The authors declare no completing interest.			
26 27	286				
28 29	287	Role of the funding source:			
30 31 32	288	The study is funded by the Chinese University of Hong Kong Direct Grant for Research 2017			
33 34	289	(HKD 56,084). The funding body has no role in the study other than providing funding.			
35 36	290				
37 38 30	291	Author Contributions:			
40 41	292	The following authors had made substantial contributions to the following: the concept and			
42 43	293	design of the study (RS and WW), collection and assembly of data (RS and LC), analysis and			
44 45 46	294	interpretation of data (RS, DC and BY), drafting the article (RS and SW), revising critical			
40 47 48	295	important intellectual content (RS, DC, WW, BY and SW). All the authors approved final			
49 50	296	version of the manuscript.			
51 52	297				
53 54 55 56	298	Data sharing statement:			
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3 4	299	All data in this study are available upon request
5 6	300	
/ 8 9	301	Acknowledgement:
10 11	302	We would like to thank Dr. George KH Leung, the orthopedic surgeon and associate consultant
12 13	303	from the Department of Orthopedic and Traumatology of Tuen Mun Hospital, the Hong Kong
14 15 16	304	Special Administrative Region, for the forward translation of ICOAP. We would like to thank all
10 17 18	305	the participants in the study.
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7 8 9	395	Table 1. Characteristics of the parti	cipants	
9 10 11		Characteristics	Total sample ($N = 110$)	
12 13		Age (years)	62.2 ± 5.7	
14 15 16		Gender		
10 17 18		Male	28 (25.5%)	
19 20		Female	82 (74.5%)	
21 22 22		BMI [^]	24.68 ± 3.68	
23 24 25		WOMAC pain score, mean (SD)	169.70 (124.37)	
26 27		SF-12v2 (PCS), mean (SD)	39.22 (9.50)	
28 29 20		SF-12v2 (MCS), mean (SD)	48.79 (9.29)	
30 31 32		Duration of knee pain [^]	8.76 ± 6.70	
33 34		Kellgren and Lawrence Grading [#]		
35 36 27		Grade 1	17 (16.5%)	
37 38 39		Grade 2	42 (40.8%)	
40 41		Grade 3	36 (35%)	
42 43		Grade 4	8 (7.7%)	
44 45 46 47 48 49 50 51 52 53	396	[^] Missing 6 sets of data, [#] Missing 7 sets of data		
	397	BMI= Body Mass Index, WOMAC= Western Ontario McMaster University Osteoarthritis Index,		
	398	SF-12= Short form of Health Survey-12, PCS= physical component score, MCS= mental		
	399	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)
	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 <u>持續性</u> <u>膝痛</u> 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 <u>持續性膝痛</u> 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%
甲) 持續性痛症 (Constant Pain)	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 <u>持續性膝痛</u> 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 <u>持續性膝痛</u> 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 <u>間歇性膝痛</u> 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	90%	90%	100%
	severe knee pain that comes and			
	goes been?)			
	二、過去一週,這類 <u>間歇性膝痛</u>			
	發作得有多頻密?(In the past	100%	100%	100%
	week, how frequently has this knee	10070	10070	10070
	pain that comes and goes occurred?)			
	三、在過去一周中,您的 <u>間歇性</u>			
	膝痛對您的睡眠有多大影響?(In	1000/	1000/	1000/
	the past week, how much has your	100%	100%	100%
	knee pain that comes and goes			
	affected your sleep?)			
	四、住蛔云一同中,心的间歇住			
	<u> 脸</u> 拥 到 心 り 全 腹 生 活 貝 糸 月 多 人 長 郷 り (In the next week how much			
	影響? (In the past week, now much	90%	100%	100%
	has your knee pain that comes and			
	life?)			
	五、過去一调,您的問歇性膝痛			
	$\Delta你有多泪雲或恒擾?(In the past$			
	week how frustrated or annoved	90%	100%	100%
	have you been by your knee pain			
	that comes and goes?)			
	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	100%	80%	90%
	you been by your knee pain that			
	comes and goes?)		•	
03				
.04				
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08				
.09				

11						
11						
12	Tab	ble 3. Internal consistency of the tChICOAP (N	V=110)			
-	ICC	DAP items	Corrected	Corrected	Cronbach's	Cronback
			item-total	item-total	α if item	α if item
			coefficients ¹	coefficients ²	deleted ¹	deleted ²
-	Cor	nstant pain subscale				
	1.	In the past week, how intense has your	.853	.802	.913	.941
		constant knee pain been?				
	2.	In the past week, how much has your	.697	.698	.940	.945
		constant knee pain affected your sleep?				
	3.	In the past week, how much has your	.869	.833	.910	.940
		constant knee pain affected your overall				
		quality of life?				
	4.	In the past week, how frustrated or	.855	.847	.912	.940
		annoyed have you been by your constant				
		knee pain?				
	5.	In the past week, how upset or worried	.852	.850	.914	.940
		have you been by your constant knee pain?				
	Inte	ermittent pain subscale				
	6.	In the past week, how intense has your	.716	.728	.887	.944
		most severe knee pain that comes and goes				

.948

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.620

.623

.900

2 3 4			been?
5 6			
7 8		7.	In the past week, how frequent has this
9 10			knee pain that comes and goes occurred
11 12		8.	In the past week, how much has your k
13 14 15			pain that comes and goes affected your
16 17			sleep?
18 19		9.	In the past week, how much has your k
20 21			pain that comes and goes affected your
22 23			overall quality of life?
24 25 26		10.	In the past week, how frustrated or
20 27 28			annoved have you been by your knee p
29 30			that comes and goes?
31 32		11	In the past week, how upset or warried
33 34		11.	have been been been been been as in the t
35 36			nave you been by your knee pain that
37 38			comes and goes?
39 40 41	414	¹ ger	nerated from constant and intermittent pa
42 43	415	² ger	nerated from the total pain score of ICOA
44 45	416		
46 47	417		
48 49	418		
50 51	419		
52 53	420		
54 55 56	421		
57 58			
59 60			For peer review only - http://bmj

	knee pain that comes and goes occurred?				
8.	In the past week, how much has your knee	.680	.739	.892	.944
	pain that comes and goes affected your				
	sleep?				
9.	In the past week, how much has your knee	.841	.803	.869	.942
	pain that comes and goes affected your				
	overall quality of life?				
10.	In the past week, how frustrated or	.787	.794	.876	.942
	annoyed have you been by your knee pain				
	that comes and goes?				
11.	In the past week, how upset or worried	.755	.711	.882	.945
	have you been by your knee pain that				
	comes and goes?				
¹ ger	nerated from constant and intermittent pain su	bscales of	ICOAP		
² ger	nerated from the total pain score of ICOAP				

1 2								
2 3 4	422							
5 6	423							
7 8	424							
9 10	425	Table 4. Construct valid	lity of the tChICOAP (N	=110)				
11 12			SF12 Physical	SF12 Mental	WOMAC			
13 14 15			Component Summary	Component Summary	Pain Subscale			
15 16			Component Summary	Component Summary				
17 18		ICOAP						
19 20		Constant	$487 (p < 0.001)^2$	398 (p < 0.001) ²	.671 (p < 0.001) ¹			
21 22 23		Intermittent	590 (p < 0.001) ¹	418 $(p < 0.001)^2$.678 (p < 0.001) ¹			
23 24 25		Total	558 (p < 0.001) ¹	431 (p < 0.001) ²	.707 (p < 0.001) ¹			
26 27	426	Spearman's correlation	coefficients, p < 0.001					
28 29	427	¹ Strong correlation (r =	> 0.5)					
30 31 32	428	² Moderate correlation (1	² Moderate correlation (r = $0.35-0.50$)					
33 34	429							
35 36	430							
37 38 39	431							
40 41	432							
42 43	433							
44 45 46	434							
40 47 48	435							
49 50	436							
51 52	437							
53 54 55 56	438							
57 58 59					23			
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439							
440							
441							
442	Table 5. Tes	st and retest relia	bility of the tCh	ICOAP (N=100)			
	<u> </u>				0 1 12	CEM	
	Scale	Weall score (SI	D)	ICC (95% CI)		SEM	MD
				_	coefficient		
		First	Second				
	Constant	30.23 (21.11)	31.18 (20.62)	0.959 (0.940-0.972)	.934*	4.27	11.8
	Intermittent	38.11 (18.12)	36.74 (18.56)	0.924 (0.889-0.948)	.902*	5.00	13.8
	Total	34.52 (18.54)	34.21 (18.77)	0.960 (0.941-0.972)		3.71	10.2
443	*Excellent r	eliability >0.75		-			
444	SD= Standa	rd Deviation					
445	CI=Confide	nt Interval					
446	ICC=Intracl	ass correlation					
447	SEM=Stand	ard Error of Mea	asurement				
448	MDC= Mini	imal Detectable	Change				
449							
450							
451							
452							
453							
454							
455							

1 2 3 456 4 5 457 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30		
31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	25

參加者編號:				參加者語	簽署:
日期:					
	間歇性利	口持續性骨關節	炎疼痛的測量	(ICOAP):膝關領	節版本
我們知道	道,很多人都曾經歷站	日本同類刑的陈	痛(句括疄痛武	「不谪」,為了更好	F地瞭解不同類刑的膝
我們想	分別詢問您有關「持續	賣性疼痛」(時刻	刻都感受到疼痛	i)及「間歇性疼	痛」(不定時感到膝痛
情況。」	以下問題是關於您在這	過去一周中感至]膝痛的情況。	請回答所有問題	0
甲)持續	續性痛症				
請就以	下每條問題,選擇最低	能形容您過去	一週持續性膝痛的	的平均情况的答答	安
1. 在	過去一周中,您的持续	濟性膝 痛有多強	<i>运</i> 列?		
14.7			9711 ·		
	完全沒有/沒	輕微	中等	嚴重	極度
	有持續性膝痛				
2. 過	去一週,您的持續性	膝痛有多影響您	3的睡眠?		
	完全沒有/沒	輕微	中等	嚴重	極度
	有持續性膝痛				
3. 在法	過去一周中,您的持续	賣性膝痛對您的	D整體生活質素	有多大影響?	
	完全没有/没	輕微	甲等	嚴重	極度
	月村績性脉捕				
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	輕微	中等	嚴重	極度
	有持續性滕涌				
5. 過	去一週,您的持續性	膝痛令您有多擔	š心?		
		_			
	元主没月/没	輕微	甲等	嚴里	極度

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Page 27 of 29				BMJ Open				
1 2 3	乙) 請家	間题 就以下名	歇性疼痛 辱條問題, 選擇最	最能形容您過去	云一週間歇性膝痛	平均情況的答案		
4 5 6	6.	在過去	去一周中,您最嚴	重的間歇性膝	痛有多強烈?			
7 8 9 10 11 12			口 完全沒有/沒 有間歇性膝痛	□ 輕微	口中等	□ 嚴重	□ 極度	
13 14 15	7.	過去一	一週,這類間歇性	膝痛發作得有	多頻密?			
16 17 18 19 20 21			口 完全沒有/沒 有間歇性膝痛	很少	□ 有時	□常常	□ 經常	
22 23 24	8.	在過去	去一周中,您的間	歇性膝痛對您	的睡眠有多大影響	響?		
25 26 27 28 29 30			口 完全沒有/沒 有間歇性膝痛	回輕微	中等	□ 嚴重	□ 極度	
31 32 33	9.	在過去	去一周中,您的間	歇性膝痛對您	的整體生活質素有	有多大影響?		
34 35 36 37 38 39			口 完全沒有/沒 有間歇性膝痛	□ 輕微	口中等	□ 嚴重	□ 極度	
40 41 42	10.	過去-	一週,您的間歇性	膝痛令您有多	沮喪或煩擾?			
43 44 45 46 47 48			口 完全沒有/沒 有間歇性膝痛	□ 輕微	口中等	□ 嚴重	□ 極度	
49 50 51	11.	過去一	一週,您的間歇性	膝痛令您有多	擔心?			
52 53 54 55 56 57 58 59 60			口 完全沒有/沒 有間歇性膝痛	□ 輕微	口中等	□ 嚴重	□ 極度	

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31 32 33 34 35 36 37 38 40 41 42 43 445 46 47 48 90 51 52 53 54 55 57

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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
Participants	6	(<i>a</i>) 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/	8*	For each variable of interest, give sources of data and details of methods of
measurement		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	(<i>a</i>) 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)
		(<u>e</u>) 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

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		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.

Translation, Cross-Cultural Adaptation and Validation of the Traditional Chinese Intermittent and Constant Osteoarthritis Pain (ICOAP) Questionnaire for Knee Osteoarthritis

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Primary Subject Heading :	Rheumatology
Secondary Subject Heading:	Research methods
Keywords:	ICOAP, Traditional Chinese, Knee Osteoarthritis, Pain

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Translation, Cross-Cultural Adaptation and Validation of the Traditional Chinese 1 2 Intermittent and Constant Osteoarthritis Pain (ICOAP) Questionnaire for Knee 3 **Osteoarthritis** 4 Regina WS Sit*1MBBS, Dicken CC Chan MSc¹, Wendy Wong PhD², Benjamin HK Yip PhD¹, 5 6 Lyan LY Chow BSc¹, Samuel YS Wong MD¹ 7 ¹The Jockey Club School of Public Health and Primary Care, The Chinese University of Hong 8 9 Kong, Hong Kong ² The School of Chinese Medicine, The Chinese University of Hong Kong, Hong Kong 10 11 12 Regina WS Sit: reginasit@cuhk.edu.hk Dicken CC Chan: dicken@cuhk.edu.hk 13 14 Wendy Wong: wendy.wong@cuhk.edu.hk Benjamin HK Yip: benyip@cuhk.edu.hk 15 Lyan LY Chow: chowlyan@cuhk.edu.hk 16 17 Samuel YS Wong: yeungshanwong@cuhk.edu.hk 18 19 *Corresponding author: 20 Regina WS Sit Address: 4/F School of Public Health Building, Prince of Wales Hospital, Shatin, Hong Kong 21 22 Special Administrative Region 23 Tel: (852) 2503-9406, Email: reginasit@cuhk.edu.hk

24 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).

46 Conclusions: The tChICOAP is a reliable and valid instrument to measure the pain experience of

1		
2 3 4	47	Chinese patients with KOA.
5 6	48	
7 8	49	Keywords: ICOAP, Traditional Chinese, Knee Osteoarthritis, Pain
9 10 11	50	
12 13	51	
14 15 16	52	
17 18	53	Strengths and Limitations:
19 20	54	• This is the first study to validate the Traditional Chinese version of the ICOAP questionnaire.
21 22	55	• The translation and validation of the tChICOAP followed a robust methodology
23 24 25	56	• The content validity index of the ICOAP was first reported in this study
25 26 27	57	Responsiveness of the tChICOAP was not tested.
28 29	58	
30 31 32	59	
33 34	60	
35 36	61	
37 38 20	62	
40 41	63	
42 43	64	
44 45 46	65	
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58 59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

73 Introduction

Knee osteoarthritis (KOA) is a major cause of pain and disability contributing to the health-care service burden worldwide¹. 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 pain². 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 draining³. 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 Greek⁸⁻¹¹. 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.

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A simplified Chinese version of ICOAP has been published by Zhang et al¹². 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 tChICOAP¹³. 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

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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 months¹⁴. Participants were excluded if they were not Cantonese speaking, they had other disease of the bones and joints of the lower limbs, or

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they had neurological disease, back problems or widespread pain, or an inability or unwillingnessto complete the questionnaire.

142 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 life⁵. Previous study
has supported the use of constant and intermittent subscales as one-dimensional measures of pain¹⁵.
Each score is rated from 0 to 4, and the sum is further standardized to a range of values from 0100.

The Chinese WOMAC: The WOMAC is a disease-specific questionnaire recommended to be used during osteoarthritis clinical trials¹⁶. 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 subscale¹⁷. The WOMAC pain subscale is recommended by the developer of ICOAP to test on the construct validity⁵. The total score will be determined by adding corresponding items for each dimension. We use the validated Chinese WOMAC in this study¹⁸.

5 157

> 158 The Chinese Short form of Health Survey (SF-12v2): This consists of 12 items measuring eight 159 subscales on physical functioning, role physical, bodily pain, general health, vitality, social 160 functioning, and emotional and mental health¹⁹. The sub-scale scores can be summarized into 161 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 0.3²⁰. We hypothesized that the ICOAP total and subscales would correlate strongly with
the SF-12v2 PCS.

169 ICOAP, WOMAC pain subscale and SF-12v2 are self –reported questionnaires. Participants 170 completed the questionnaires with the help of a research assistant at the study site. The interviews 171 were repeated by the same research assistant 5 days later at the same study site. An interval of 5 172 days was chosen after considering the possible change in pain score with time; we believe the 173 memory effect should be minimal given that our participants were mostly older people with KOA. 174 Age, sex, body mass index, duration of knee pain and Kellgren-Lawrence grading of the knees 175 were collected.

177 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 process¹³. 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 subjects²¹.

Statistical Analysis:

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186	Content validity was evaluated with content validity index (CVI). Construct validity was evaluated
187	using the correlation coefficients between the domain scores and total scores of tChICOAP,
188	WOMAC pain subscale and SF-12v2; with > 0.5 , 0.35-0.50, and < 0.35 considered as strong,
189	moderate and weak, respectively ¹⁸ . Internal consistency was assessed using the Cronbach's alpha
190	and corrected item-total scale correlations. Cronbach's alpha ≥ 0.7 is generally regarded as
191	acceptable for group comparison ²² . Corrected item-total scale correlation between domains and
192	their constituent item with ≥ 0.4 was considered as acceptable ²³ . Test and re-test reliability was
193	assessed with an interval of 5 days in between using intra-class correlation (ICC; two-way mixed
194	effects model); an ICC >0.75 is considered as excellent, 0.59–0.75 as good, 0.40–0.58 as fair,
195	and <0.4 as showing poor reliability ²⁴ . The standard error of measurement (SEM) is estimated
196	from the standard deviation of a sample of scores at baseline and a test-retest reliability index of
197	the measurement instrument. Minimal detectable change (MDC) was estimated from SEM and a
198	degree of confidence. The data were entered and analyzed using the statistical package for Social
199	Sciences (SPSS) software (version 21.0). P-value < 0.05 was considered as statically significant.
200	
201	Results:
202	
203	The demographics of 110 participants are summarized in Table 1.
204	
205	Cross-cultural adaptation and content validity:
206	Slight differences were identified in the structure of the sentences between the original and
207	translated versions and minor adjustments were made. Two participants found it difficult to

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understand the difference between "frustrated or annoved" 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

p < 0.001), and the constant pain score correlated moderately with SF12 PCS (r=-0.487, p < 0.001). 229 Moderate correlations were found for constant, intermittent and total pain score with the SF12

230 MCS score (r=-0.398, -0.418 and -0.431 respectively, p < 0.001). (Table 5)

score and total pain score correlated strongly with the SF12 PCS (r = -0.590 and -0.558 respectively,

1 2		
2 3 4	231	
5 6	232	
7 8 9 10 11 12 13 14 15	233	Discussion:
	234	
	235	The translation and cultural adaptation process were not challenging and produced an accurate
	236	tChICOAP. The Chinese wordings in all the question and response items are easily understandable,
16 17	237	and the questionnaire is simple to complete. The items' CVIs on "clarity", "appropriateness" and
18 19 20	238	"relevance" all achieved the standard of good content validity with CVI of 80% or above ²⁵ . In
21 22	239	order to ensure we would evaluate and measure the impact of KOA as in other multinational trials,
23 24 25	240	we followed the translation steps as recommended by the OARSI/OMERACT ¹³ .
25 26 27	241	
28 29 30 31 32 33 34 35 36 37 38 39 40	242	The internal consistency of the tChICOAP total score is excellent, with high Cronbach's alpha and
	243	corrected item-total subscale correlation. It is comparable to the original version, (Cronbach's
	244	alpha 0.93), the simplified Chinese version (Cronbach's alpha 0.94), and other language versions
	245	(Cronbach's alpha 0.82-0.95) ^{5,12,26} . The performance of the test and re-retest reliability is the best
	246	among the original version (ICC 0.85), the simplified Chinese version (ICC 0.932) and other
	247	language versions such as Turkish (ICC 0.942), Portuguese (ICC 0.92), and Greek (ICC
42 43	248	$(0.88)^{5,8,9,11,12}$.
44 45	249	
46 47 48	250	Like other language versions, the tChICOAP correlated strongly with the WOMAC pain subscale,
49 50	251	as both were constructed to measure osteoarthritic pain ^{5,12,26} . As expected, the tChICOAP's
51 52 53 54 55 56	252	intermittent and total scores have a strong correlation with SF-12v2 PCS, and only moderate
	253	correlation with SF-12v2 MCS. This indicates that the measures are evaluating similar constructs,
57 58 59		11
60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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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-12v2²⁷. 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.

1 2		
2 3 4	277	(Reference No.: 2016-601). Written inform consent was obtained from all participants.
5 6 7	278	
7 8 9	279	Consent to publish:
10 11	280	Not applicable
12 13 14	281	
15 16	282	Availability of data and material:
17 18	283	All data generated or analyzed in this study are included in this published article.
19 20 21	284	
21 22 23	285	Conflict of interest:
24 25	286	The authors declare no completing interest.
26 27 28	287	
28 29 30	288	Role of the funding source:
31 32	289	The study is funded by the Chinese University of Hong Kong Direct Grant for Research 2017
33 34 25	290	(HKD 56,084). The funding body has no role in the study other than providing funding.
35 36 37	291	
38 39	292	Author Contributions:
40 41	293	The following authors had made substantial contributions to the following: the concept and design
42 43 44	294	of the study (RS and WW), collection and assembly of data (RS and LC), analysis and
45 46	295	interpretation of data (RS, DC and BY), drafting the article (RS and SW), revising critical
47 48	296	important intellectual content (RS, DC, WW, BY and SW). All the authors approved final version
49 50 51	297	of the manuscript.
52 53	298	Data sharing statement:
54 55 56 57 58	299 300 301	Extra data can be accessed via the Dryad data repository at http://datadryad.org/ with the doi:10.5061/dryad.30r34f7
59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
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Speci	al Administrative Region, for the forward translation of ICOAP. We would like to thank all	hed as Pro
the pa	articipants in the study.	10.113 tected
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40 41 42	399			1
43	400	Table I. Cr	haracteristics of the part	icipants
44 45 46		Character	istics	Total sample $(N = 110)$
47 48		Age (year	s)	62.2 ± 5.7
49 50 51		Gender		
52 53		Male		28 (25.5%)
54 55 56 57 58		Female	;	82 (74.5%)
59 60			For peer review only -	http://bmjopen.bmj.com/site/about/guidelines.xhtml

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2 3		\mathbf{BMI}^{\wedge}		24.68 ± 3.68			
4 5 6		WOMAC pain s	score, mean (SD)	169.70 (124.3	7)		
7 8 9		SF-12v2 (PCS),	mean (SD)	39.22 (9.50)			
9 10 11		SF-12v2 (MCS)	, mean (SD)	48.79 (9.29)			
12 13		Duration of kne	e pain [^]	8.76 ± 6.70			
15 16		Kellgren and La	wrence Grading [#]				
17 18		Grade 1		17 (16.5%)			
19 20 21		Grade 2		42 (40.8%)			
22 23		Grade 3		36 (35%)			
24 25 26		Grade 4		8 (7.7%)			
20 27 28	401	[^] Missing 6 sets o	f data,#Missing 7 sets	s of data		_	
29 30	402	BMI= Body Mas	s Index, WOMAC=	Western Ontario M	IcMaster Universit	y Osteoarthritis Ir	ıde
31 32	403	SF-12= Short for	m of Health Survey-	12, PCS= physical	component score,	MCS= mental	
33 34 25	404	component score	S				
36 37	405						
38 39	406						
40 41	407						
42 43 44		Table 2 間歇性 (A Measure of I	上和持續性骨關節炎 ntermittent and Cons	疼痛的測量(ICC stant Osteoarthritis	OAP):膝關節版 Pain, ICOAP: KN	本 EE Version)	
45 46 47 48 49 50 51		Facet	Item of ICOAP: KI	NEE Version	No. of patients (%) rated item as appropriate (N=10)	No. of patients (%) rated items as clear (N=10)	
52 53 54 55		甲) 持續性痛症 (Constant	↓ 請就以下每條問題 容您過去一週持續 情況的答案	夏,選擇最能形 資性膝痛的平均			
56 57 58							_

Pain)	一、在過去一周中,您的 <u>持續性</u>			
	<u>膝痛</u> 有多強烈?(In the past week,	100%	100%	100%
	how intense has your constant knee	10070	10070	10070
	pain been?)			
	二、過去一週,您的 <u>持續性膝痛</u>			
	有多影響您的睡眠?(In the past	100%	100%	100% "
	week, how much has your constant	10070	10070	rote
	knee pain affected your sleep?)			Čte
	二、 社 過 去 一 周 中 , 您 的 持 續 性 時 京 幣 / な / お 時 / 、 ぶ 時 売 ま れ /			d by
	滕痛對您的整體生活質素有多大	1000/	1000/	1000/ 00
	影響?(In the past week, how much	100%	100%	100% PY
	has your constant knee pain affected			ght
	your overall quality of life?)			,
	四、迥云一迥,心的 <u>仔續任脉痛</u>			lua
	症令恐有多沮喪或煩擾?(In the	1009/	1009/	1000/ 5
	past week, now irustrated or	10070	10070	100%
	constant knee pain?)			use
	五、過去一週,您的持續性膝痛			s re
	今您有多不安或擔憂?(In the past			late
	week how upset or worried have	100%	100%	90% 8
	vou been by your constant knee			tex
	pain?)			lan
	請就以下每條問題, 選擇最能形			ata I
	容您過去一週間歇性膝痛平均情	4		nin n
	況的答案			ing,
	一、在過去一周中,您最嚴重的			A
	<u>間歇性膝痛</u> 有多強烈?(In the past			rain
	week, how intense has your most	90%	90%	100% Ing
乙) 間歇性	severe knee pain that comes and			an an
医病 (Pain that	goes been?)			ds
Comes and	二、過去一週,這類 <u>間歇性膝痛</u>			mia
Goes)	發作得有多頻密?(In the past	100%	100%	100% 6
)	week, how frequently has this knee	10070	10070	l ioo, o chn
	pain that comes and goes occurred?)			0
	二、在過去一周中,您的 <u>間歇性</u>			gies
	<u>膝痛</u> 對您的睡眠有多大影響?(In	1009/	1000/	1000/
	the past week, how much has your	100%	100%	100%
	knee pain that comes and goes			

GEZ-LTA

	Sourc		100 (3370 0.	αco	efficient		.D
	Scale	Mean score (SD)	ICC (05% C	[) (ro	mbach's	SEM M	<u>س</u>
419	Pain (ICO)	AP) subscales and total pain					
418	Table 3. In	iternal consistency and reliab	oility of the Intermitte	nt and Constar	nt Osteoarthritis a	and	
417							
416							
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400		comes and goes?)					
		week, how upset or you been by your kr	worried have	100%	80%	90%)
		令您有多不安或擔	國國沿線通 憂?(In the past				
		that comes and goes					
		week, how frustrated have you been by you	d or annoyed our knee pain	90%	100%	100%	0
		令您有多沮喪或煩	擾?(In the past				
		life?) 五、過去一调,你	的問歇性膝痛				
		has your knee pain t goes affected your o	by that comes and overall quality of				
		影響?(In the past v	week, how much	90%	100%	100%	6
		日之组80(1,1)	1 1 1				

		First	Second	-			
	Constant	30.23 (21.11)	31.18 (20.62)	0.959 (0.940-0.97	2) .934*	4.2	27 11.
	Intermittent	38.11 (18.12)	36.74 (18.56)	0.924 (0.889-0.94	8) .902*	5.0	00 13.
	Total	34.52 (18.54)	34.21 (18.77)	0.960 (0.941-0.97	2)	3.7	71 10.
420	*Excellent re	liability >0.75					
421							
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435	Table 4. Corr	elation of each i	tem and total Int	ermittent and Const	ant Osteoarth	ritis and Pain	
436	(ICOAP) scor	res (N=110)					
	ICOAP item	18		Corrected	Corrected	Cronbach's	Cronbac
				item-total	item-total	α if item	α if iten

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

1								
2 3			aloom 9					
4			sleep?					
5								
6 7		9.	In the past week, how much has your knee	.841	.803	.869	.942	
8			1 , 5					
9			pain that comes and goes affected your					
10 11								
12			overall quality of life?					
13		10	In the past weak, how frustrated or	707	704	976	042	
14 15		10.	In the past week, now indstrated of	./0/	./94	.870	.942	
16			annoved have you been by your knee pain					
17								
18			that comes and goes?					
20								
21		11.	In the past week, how upset or worried	.755	.711	.882	.945	
22			have you been by your knee pain that					
25 24			have you been by your knee pain that					
25			comes and goes?					
26 27								
27 28	437	¹ gene	erated from constant and intermittent pain sub	scales of I	COAP			
29		2						
30 21	438	² gene	erated from the total pain score of ICOAP					
32	439							
33	433							
34 25	440							
36								
37	441							
38 20	440							
39 40	442							
41	443							
42 43	0							
44	444							
45								
46 47	445							
47 48	116							
49	440							
50 51	447	Table	e 5. Criterion and Construct validity of Interm	nittent and	Constant Osteoa	rthritis and Pain	l	
51 52								
53	448	(ICO	AP)subscales and total pain $(N=110)$					
54								
ээ 56								
57								
58								
59 60			For peer review only - http://bmjopen.b	mj.com/site/	/about/guidelines.>	khtml	22	

		SF12 Physical	SF12 Mental	WOMAC
		Component Summary	Component Summary	Pain Subscale
	ICOAP			
	Constant	487 (p < 0.001) ²	398 (p < 0.001) ²	.671 (p < 0.001)
	Intermittent	590 (p < 0.001) ¹	418 (p < 0.001) ²	.678 (p < 0.001)
	Total	$558 (p < 0.001)^1$	431 $(p < 0.001)^2$.707 (p < 0.001)
449	Spearman's correlati	on coefficients, p < 0.001		
450	¹ Strong correlation (1	r = > 0.5)		
451	² Moderate correlation	n (r = $0.35 - 0.50$)		

				2 775 117	
日期:_					
	間歇性利	口持續性骨關節	i炎疼痛的測量	(ICOAP):膝關領	節版本
我們知	道,很多人都曾經歷述	局不同類型的膝	痛(包括酸痛或	不適),為了更好	出瞭解不同類型的關
我們想 情況。	分別詢問您有關「持約」	賣性疼痛」(時 過去一周中咸至	刻都感受到疼痛)及「間歇性疼;	痛」(不定時感到膝約 。
IH VL					
甲)持	續性痛症				
請就以	下每條問題,選擇最高	能形容您過去-	一週持續性膝痛的	的平均情況的答案	
1. 在	過去一周中,您的持续	賣性膝痛有多 帶	前 ?		
	完全沒有/沒	輕微	中等	嚴重	極度
	月持續性膝痛				
2. 過	去一週,您的持續性	膝痛有多影響您	[5]的睡眠?		
	完全沒有/沒	輕微	中等	嚴重	極度
	月持續性膝痛				
3. 在	過去一周中,您的持續	賣性膝痛對您的	的整體生活質素	有多大影響?	
	_	_		0	_
		上一			
	元王没有/ 没 右结嬉性膝痛		甲寺	敢 里	極度
	日前领江冰阳				
4. 過	去一週,您的持續性	膝痛症令您有多	6沮喪或煩擾?		
	_	_	_	_	_
	□ □ □ □	「「「」	山	□□□	板底底
	元王/2/月//2/ 右持續性膝痛	¥空17以	十寺	取里	心心反
5. 過	去一週,您的持續性	膝痛令您有多擔	雪心?		
	完全沒有/沒	輕微	中等	嚴重	極度
	有持續性膝痛				

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Page	25 of	27			BMJ Open		
1 2 3	乙) 請就	間题 就以下4	歇性疼痛 导條問題, 選擇最	能形容您過去-	一週間歇性膝痛	平均情況的答案	
4 5 6	6.	在過去	去一周中,您最嚴重	重的間歇性膝痛	有多強烈?		
7 8 9 10 11 12			口 完全沒有/沒 有間歇性膝痛	□ 輕微	口中等	□ 嚴重	□ 極度
13 14 15	7.	過去一	一週,這類間歇性朋	漆痛發作得有多	頻密?		
16 17 18 19 20 21			口 完全沒有/沒 有間歇性膝痛	旧役	口有時	□常常	□ 經常
22 23 24	8.	在過去	去一周中,您的間题	飲性膝痛對您的	睡眠有多大影響	鄂?	
25 26 27 28 29 30			口 完全沒有/沒 有間歇性膝痛	回 輕微	口中等	□ 嚴重	□ 極度
31 32 33	9.	在過去	去一周中,您的間题	次性膝痛對您的	整體生活質素有	 	
34 35 36 37 38 39			口 完全沒有/沒 有間歇性膝痛	□ 輕微	口中等	日産	□ 極度
40 41 42	10.	過去-	一週,您的間歇性朋	漆痛令您有多沮	喪或煩擾?		
43 44 45 46 47 48			口 完全沒有/沒 有間歇性膝痛	□ 輕微	口中等	□ 嚴重	□ 極度
49 50 51	11.	過去一	一週,您的間歇性腳	漆痛令您有多擔	心?		
52 53 54 55 56 57 58 59 60			口 完全沒有/沒 有間歇性膝痛	□ 輕微	口中等	□ 嚴重	□ 極度

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

	Item No	Recommendation
Title and abstract	1	(<i>a</i>) 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
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participantsP.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
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	(<i>a</i>) 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)
		(<i>d</i>) 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)
D		(c) Consider use of a flow diagram (NA)
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and

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		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.