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Cultural adaptation and validation of the knee injury and osteoarthritis outcome score into Sinhala language in patients with primary knee osteoarthritis: a cross-sectional study

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Abstract

Background Knee Injury and Osteoarthritis Outcome Score (KOOS) scale is a patient-reported outcome measurement tool. It evaluates both short- and long-term consequences of knee injury and primary osteoarthritis. This study aims to translate and validate the KOOS scale for a Sinhala-speaking Sri Lankan population.

Methods A cross sectional **s**tudy was conducted in three hospitals. Four hundred and fifteen patients comprising 185 males and 227 females (3 subjects did not reveal their gender) with knee osteoarthritis (KOA) participated in the study. Seventy nine participants without KOA were recruited as controls. The functionality and quality of life level in patients and healthy participants were assessed using translated versions of the KOOS and Short Form-36 (SF-36) scales. Internal consistency of the instrument was assessed by Cronbach alpha. Construct validity and test-retest reliability were examined using the Intraclass Correlation Coefficient (ICC). Confirmatory Factor Analysis (CFA) was used to assess factorial validity.

Results The mean age (± sd) of the KOA subjects was 54.9 (± 9.2) years and for the control group was 49.2 (± 8.0) years. Majority of the respondents were female and Sinhalese in both groups. Internal consistency reliability was high (Cronbach's alpha values ≥ 0.70). The test–retest reliability was excellent with the intraclass correlation coefficient for all subscales being above 0.90. Construct validity was assessed by the magnitude of the correlation coefficient between KOOS and SF-36 subscale scores. KOOS Pain scale moderately correlated with SF-36 bodily pain (Pearson's $r = 0.41$). SF-36 physical function scores had a weak positive correlation with all KOOS subscales and SF-36 emotional wellbeing was not significantly correlated with KOOS Quality of Life (QoL) subscale. A five-factor Confirmatory Factor Analysis (CFA) model yielded a Comparative Fit Index (CFI) = 0.950, Tucker Lewis Index (TLI) = 0.946, Root Mean Square Error of Approximation (RMSEA) = 0.082 and Standardised Root Mean squared Residual (SRMR) = 0.072.

Conclusion The Sinhala translation of the KOOS scale is a reliable and valid instrument to assess KOA in a Sinhala-speaking Sri Lankan population. Studies to assess its use as a scale to evaluate responsiveness are recommended.

Keywords KOOS, Osteoarthritis, Knee Joint, Validation, Sinhala-speaking, Sri Lanka

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Introduction

Knee osteoarthritis (KOA), characterised by degeneration of the articular cartilage in the knee joints causing crepitus and the growth of osteophytes in addition to stiffness and pain in the joint, eventually results in impairment of movement [1]. Age, sex and obesity are the most important risk factors for KOA; other factors such as lack of exercise, genetic predisposition, bone density, occupational injury, previous trauma and activities involving repeated knee bending can also contribute to the development of this condition [2]. The prevalence of KOA is increasing due to improved life expectancy and increase in obesity [3, 4].

The prevalence of KOA is higher than that of hip osteoarthritis (OA) [3]. In 2017, there were approximately 303.1 million people estimated to have hip and knee OA globally [5]). The prevalence rate was 3,754.2 of cases per 100,000 people. This represents a 9.3% increase from 1990 to 2017 [5]. The prevalence of KOA is increasing globally as well as in Sri Lanka. In Sri Lanka, the age-standardized prevalence of clinical KOA among females, estimated based on population statistics of the 2012 census, was 21.8% (95% CI: 21.7–21.9%) [6].

Because of the high prevalence of the condition and possible movement impairments the disease can result in, it is important to identify, assess and monitor the progress of the condition. Internationally, several tools are available for assessing the condition of a patient with KOA such as the Knee Injury and Osteoarthritis Outcome Score (KOOS) [7]. Among them, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Intermittent and Constant Osteoarthritis Pain measure (ICOAP) are commonly used by orthopaedic doctors and therapists [8]. However, in Sri Lanka, no validated disease-specific instrument is available. Sri Lanka has a rapidly ageing population [9], and age-related musculoskeletal conditions and their subsequent health burden due to complications are expected to rise. In such a context, instruments that can assess the condition and its functional impairments within a relatively short time, and that do not require special training to administer and interpret are beneficial.

KOOS evaluates both short- and long-term consequences of knee injury and consequences of primary OA. It assesses the patient's opinion about their knee and associated problems subjectively. The scale is available in about 49 languages [10] and has been validated for several orthopaedic interventions [11, 12].

This study aimed to validate KOOS among a Sinhala-speaking Sri Lankan population which will enable researchers and clinicians to obtain a reliable assessment of orthopaedic conditions and monitor response to treatment.

Methods

This study was carried out in two phases. Phase I consisted of translation of the scale from English to Sinhala. Phase II consisted of field testing the Sinhala version for reliability and validity.

Translation and cultural adaptation procedure

The English KOOS scale was translated into Sinhala as per the guidelines laid down by American Academy of Orthopaedic Surgeons (AAOS) [13]. The original English version was translated into Sinhala by two independent translators. One of them was familiar with the concepts aiming for clinical equivalence, whereas the other, a naive translator, was unaware of the concepts to ensure linguistic accuracy. The Sinhala version was synthesized by reconciling differences between the two translations, resulting in a common version. The synthesized version was back translated to English by two independent translators who were fluent in both English and Sinhala and who were unaware of the original scale. The back translation was compared with the original for consistency. An expert committee, consisting of medical professionals, a methodologist and translators, reviewed all translations and resolved discrepancies, producing a pre-final version. Four items in the scale were deemed not acceptable during reviewing as the activities indicated were not culturally relevant. These items were: item A7 - getting in and out of a car; item A9- putting on socks/stockings; item A11 - taking off socks/stockings; and item A13 - getting in and out of a bath tub. The items were replaced with functionally similar items that were relevant to the Sri Lankan culture. For example, "putting on socks/stockings" was changed to "wearing a trouser/skirt by bending the knee"; "taking off socks/stockings" was changed to "removing a trouser/skirt by bending the knee" "Getting in and out of a car" was replaced by "getting in and out of a vehicle/car"; and "having bath in a bathtub" was changed to "having a bath by getting water from a bucket". The pre-final version was pretested on 30 individuals. No further issues were observed during the back translation and pre-testing.

Study design, setting and participants

A cross-sectional study was conducted at outpatient clinics and in-patient units of the Departments of Physical Medicine at the National Hospital, Kandy; Rheumatology and Rehabilitation Hospital, Ragama: and District General Hospital, Ampara in Sri Lanka.

A convenient sample of individuals aged 30 to 70 years with KOA, who had been referred for physiotherapy, were invited for the study. All KOA patients referred for physiotherapy were diagnosed by physicians using clinical and/or radiologic confirmation. Those who had undergone knee surgery, including arthroscopy, within

the past 12 months, received intra-articular steroid injections within the past six months, who were diagnosed with other types of arthritis, fibromyalgia, congenital deformities of the lower limb, those who were not conversant in Sinhala and unable to give consent were excluded. A second group of participants aged 30 to 70 years receiving curative and/or rehabilitative services for conditions other than KOA was also administered the scale as a control group. These participants were selected through a screening procedure that involved answering questions about their medical history, including any prior history of osteoarthritis, joint issues, or knee pain. Both groups consisted of male and female Sinhala-speaking participants.

Sample size

KOOS scale has 42 items. Therefore, for a 10:1 ratio, a sample size of 420 was required [14]. Assuming a non-response rate of 10%, 467 participants were required for the validation of the scale. A further 100 participants without KOA were recruited as a control group. Debates regarding the ideal sample size for factor analysis are abound in the field. According to Guliford and Cattell, a minimum sample size for confirmatory factor analysis (CFA) is 200 and 250, respectively [15]. Based on that, a sample size of 467 was deemed adequate.

Study instruments

Socio-demographic characteristics and anthropometric data were obtained through a questionnaire and measurements.

KOOS scale

The KOOS-Sinhala scale had 42 items divided into five subscales: KOOS pain, KOOS symptoms, activities of daily living (KOOS ADL), function in sport and recreation (KOOS Sport/Rec), and knee–related quality of life (KOOS QoL). All items were scored on a five-point Likert scale ranging from 0 to 4; zero indicating no problem and four indicating extreme problems. Scores were converted to a scale from 0 to 100, with zero for extreme knee problems and 100 for no knee problems as per the guidelines for scoring given for the original English version.

Short form – 36 health survey questionnaire (SF-36)

The validated Sinhala SF-36 questionnaire was used to assess Health-Related Quality of Life [16]. It measures eight aspects of quality of life across eight subscales: physical functioning, role limitations due to physical health, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, and mental health. Each item is scored on a 0 to 100 scale where the lowest and highest possible scores are 0 and 100, respectively. The items in the relevant scale were averaged to obtain the scale scores. A high score denotes a better health state.

Data collection

The paper-based scales and questionnaires were distributed among the consenting participants who were able to read and write in Sinhala in the participating hospitals after details of the study were explained to them. The researchers interfered minimally in the completion of the questionnaires but were available to answer any queries the participants had. Data were coded and stored in password protected electronic formats.

A subsample of 50 individuals from the KOA patient group who visited the rehabilitation clinic after 2 weeks were randomly selected and re-administered the KOOS and SF-36 under the same conditions to assess test-retest reliability.

Data analysis

Summary statistics of socio-demographic characteristics are presented using means, frequencies and percentages. It was hypothesized that KOA patients will score significantly lower for KOOS and SF-36 subscales compared to participants without KOA. A p-value <0.05 was considered significant. Reliability and validity of the instrument was assessed using the indices given below.

Floor and ceiling effects

Floor and ceiling values were considered acceptable if $<15\%$ of the participants scored either the lowest score or the highest possible score, respectively [17].

Internal consistency reliability

Internal consistency of individual subscales was measured using Cronbach's alpha. A Cronbach's alpha value of 0.7–0.9 is indicative of a good internal consistency of the instrument [18].

Test-retest reliability

ICC was calculated by using a two-way mixed effects model to assess absolute agreement between the two measures. Based on the 95% confidence interval of the ICC estimate, values less than 0.5, between 0.5 and 0.75, between 0.75 and 0.9, and greater than 0.90 are indicative of poor, moderate, good, and excellent reliability, respectively [19].

Standard error of measurement (SEM)

SEM has been defined as the amount of variation or spread in measurement errors for a test [20]. It is a parameter for the amount of measurement error present in an instrument and is an indicator of the reliability of the instrument [21]. The SEM is calculated by the following formula.

$$SEM \equiv SD\sqrt{1 - ICC}$$

Minimum detectable change (MDC)

MDC is the change in the instrument's score beyond measurement error [22]. It provides a value for the minimum change that needs to be observed to be confident that the observed change is real and not a product of measurement error [21]. The MDC was calculated using the following formula [22].

$$\mathrm{MDC} = 1.96 * \sqrt{2} * \mathrm{SEM}$$

Validity

Construct validity

Construct validity of the instrument was assessed by testing *a priori* set of hypotheses about the correlation between the KOOS subscales and the SF-36 scale using the Pearson correlation coefficient. It was expected that the scales that measured similar constructs will demonstrate strong correlations. A correlation coefficient ≥ |0.68| was considered strong, between |0.36| and |0.67| as moderate, and <|0.35| as weak [23]. We hypothesized a strong convergence between KOOS pain score and SF-36 bodily pain score; and a moderate convergence between all other subscales of KOOS and SF-36 Physical Function score.

For divergent relations, we hypothesized that all subscales of the KOOS scale except KOOS QoL subscale will poorly or negatively correlate with SF- 36 emotional wellbeing scale and a weak positive correlation between KOOS QoL subscale and SF-36 emotional well-being scale.

Table 1 Sociodemographic characteristics of the study population

Sociodemographic Characteristics	KOA Present (*n* = 415) *n* (%)	KOA Absent (*n* = 79) *n* (%)
Gender[1]		
Male (*n* = 202)	185 (44.9)	17 (21.5)
Female (*n* = 289)	227 (55.1)	62 (78.5)
Age Category (years)[1]		
Less than 45 (*n* = 88)	62 (15.1)	26 (32.9)
45–54 (*n* = 178)	139 (33.9)	39 (49.4)
55–64 (*n* = 163)	152 (37.1)	11 (13.9)
above 65 (*n* = 60)	57 (13.9)	03 (3.8)
BMI Category[2]		
Underweight (*n* = 3)	03 (0.9)	0 (0.0)
Normal weight (*n* = 49)	44 (13.0)	5 (6.6)
Risk to overweight (*n* = 83)	65 (19.2)	18 (23.7)
Overweight (*n* = 230)	188 (55.6)	42 (55.3)
Obesity (*n* = 49)	38(11.2)	11 (14.5)
Educational level[1]		
No Schooling (*n* = 3)	03 (0.7)	0 (0.0)
up to grade 5 (*n* = 66)	44 (10.6)	22 (28.2)
GCE O/L (*n* = 119)	119 (28.7)	0 (0.0)
GCE A/L (*n* = 166)	143 (34.5)	23 (29.5)
Diploma (*n* = 45)	29 (7.0)	16 (20.5)
Graduate (*n* = 86)	73 (17.6)	13 (16.7)
Postgraduate (*n* = 4)	0 (0.0)	04 (5.1)

[1] Sample sizes do not add up to the column totals due to missing data as some participants did not reveal some demographic details

[2] BMI category (Underweight = < 18.5 kg/m^2, Normal weight = 18.5 kg/m^2 – 22.9 kg/m^2, Risk to overweight = 23 kg/m^2 – 24.9 kg/m^2, Overweight = 25 kg/m^2 – 29.9 kg/m^2, Obesity = BMI ≥ 30 kg/m^2) [27]

Factorial Validity

Factorial validity was tested for a five-factor model using confirmatory factor analysis (CFA). The model fit was evaluated with several goodness-of-fit indices: Comparative Fit Index (CFI), Tucker Lewis Index (TLI), Standardized Root Mean Squared Residual (SRMR) and Root Mean Squared Error of Approximation (RMSEA). The standardized factor loading (standardized regression weight), modification indices (MI), and squared multiple correlation (R^2) were used as indicators to select items to be retained in the CFA model. A value of more than 0.90 for CFI and TLI, Chi-square/degrees of freedom of less than 3 and a RMSEA value of <0.08, and a SRMR < 0.08 were considered to indicate a good model fit [24, 25].

All analyses were performed using SPSS version 22 and CFA done using Lavaan package in R software [26].

Results

A total of 462 patients with KOA completed the scale. Forty-seven patients with incomplete responses were excluded. Thus, data from 415 patients were included in the study. The second group consisted of 100 participants without KOA. Of these participants, 79 were included in the study and the rest were excluded due to incomplete responses.

Missing baseline data

Seventy two of 17,430 items (0.41%) were missing for the KOOS data and 125 of 14,940 items (0.83%) were missing for the SF-36 data among the KOA patients (first group). Thirteen of 3,318 items were missing for the KOOS data and 0 of 2,844 items (0.83%) were missing for the SF-36 data among the participants without KOA (second group). Values were missing at random. A subsample of data without missing values was used for the CFA.

Sociodemographic characteristics of participants

Table 1 presents the characteristics of the two participant groups. The mean age (±sd) of the KOA subjects was 54.9 (±9.2) years. Majority of the respondents were female (55.1%) and Sinhalese (88.1%). The mean (±sd) BMI was 26.3 (±3.3) and the mean (±sd) duration of KOA was 3.0

Table 2 Comparison of mean scores of KOOS between participants with and without KOA

KOOS Subscales	Mean (SD)		t-value (*p*-value)
	KOA Present (*n* = 415) *n* (%)	KOA Absent (*N* = 79) *n* (%)	
KOOS Symptoms	60.2 (14.5)	84.3 (5.1)	-14.6 ($p < 0.001$)
KOOS Pain	46.3 (13.4)	85.1 (5.1)	-25.4 ($p < 0.001$)
KOOS Activities of Daily Living	45.8 (14.2)	90.7 (7.2)	-27.4 ($p < 0.001$)
KOOS Sport/ Recreation	28.5 (19.7)	87.9 (11.4)	-25.9 ($p < 0.001$)
KOOS Quality of Life	35.7 (14.5)	87.3 (5.6)	-31.1 ($p < 0.001$)
SF-36 Subscales			
Physical functioning	53.0 (20.6)	63.6 (23.7)	-4.0 ($p < 0.001$)
Role limitations due to physical health	34.7 (28.9)	97.1 (8.9)	-19.0 ($p < 0.001$)
Role limitations due to emotional problems	38.3 (33.9)	81.6 (30.2)	-10.5 ($p < 0.001$)
Energy/fatigue	59.6 (13.2)	67.5 (6.3)	-5.3 ($p < 0.001$)
Emotional wellbeing	73.6 (16.5)	77.8 (12.5)	-2.1 ($p < 0.001$)
Social functioning	64.9 (23.4)	86.1 (10.2)	-7.9 ($p < 0.001$)
Bodily Pain	52.2 (17.0)	72.3 (15.8)	-9.8 ($p < 0.001$)
General health	62.3 (20.8)	91.2 (6.5)	-12.3 ($p < 0.001$)

Table 3 Reliability coefficients for the KOOS subscales

KOOS Subscales	Overall Cronbach's alpha
KOOS Symptoms	0.73
KOOS Pain	0.88
KOOS Activities of Daily Living	0.96
KOOS Sports	0.93
KOOS Quality of Life	0.83

(±1.6) years. Majority of the participants were homemakers (31.9%).

The mean (±sd) age of the control group was 49.2 (±8.0) years. Majority of the participants were female (78.5%) and Sinhalese (87.3%). Less than one third (30.4%) of the participants were homemakers and 30.4% were retired. The mean (±sd) BMI was 26.9 (±2.7).

The mean KOOS and SF-36 scores of KOA patients were significantly lower than those of participants without KOA across all subscales (Table 2).

Floor and ceiling effects

There were no floor/ceiling effects for any of the KOOS subscales among participants with KOA. For participants with no KOA, there were no floor effects in any of the KOOS subscales; ceiling effects were reported in ADL Function (20.3%), and Sports/Recreation Function (29.1%) subscales.

Reliability

Internal consistency reliability

The Cronbach's alpha values for all five subscales ranged from 0.73 to 0.96 which suggests acceptable internal consistency. In KOOS QoL subscale, the overall alpha increases to 0.88 if Q2 (have you modified your lifestyle to avoid potentially damaging activities to your knee?) was deleted (Table 3). Other subscales had optimum internal consistency and could not be further improved.

Test-retest reliability

A subsample of 50 KOA patients completed the KOOS-Sinhala again within 10 to 14 days. The ICC for all subscales were above 0.90 demonstrating excellent temporal stability. The SEM ranged between 1.07 and 2.26 and the MDC ranged between 2.96 and 6.26 (Table 4).

Construct validity

KOOS Pain subscale moderately correlated with SF-36 bodily pain scores (r=0.41) (Table 5). The correlation between all KOOS subscales and SF-36 physical function

Table 4 Test-retest reliability of KOOS subscales

KOOS Subscales	Intra Class Correlation Coefficient (ICC) [95% confidence interval of ICC]	Standard error of measurement (SEM)	Minimum Detectable Change (MDC)
KOOS Symptoms	0.95 [0.92–0.97]	1.99	5.51
KOOS Pain	0.94 [0.89–0.96]	2.26	6.26
KOOS Activities of Daily Living	0.98 [0.97–0.99]	1.15	3.18
KOOS Sports	0.99 [0.98–0.99]	1.07	2.96
KOOS Quality of Life	0.96 [0.93–0.98]	1.86	5.15

scores had a weak positive correlation; there was no correlation between SF-36 emotional wellbeing score and KOOS QoL subscale (Table 5).

Factorial Validity

The CFA supported a five-factor model (CFI 0.95, TLI 0.95, RMSEA 0.08, SRMR 0.07). All factor loadings were significant except for item S4 which was negative (Fig. 1).

Discussion

The validation and adaptation of the Sinhala KOOS scale has demonstrated good psychometric properties. The reliability of the instrument, tested in terms of internal consistency, test-retest reliability, SEM and MDC was good. The internal consistency assessed using Cronbach's alpha was above 0.7 for all subscales of KOOS indicating excellent reliability of the scale. Test-retest reliability was high which indicates stability of scores over short time periods (14 days); the SEM was low for all sub scales. SF-36 questionnaire was used to assess construct validity which had small but yet positive correlations among corresponding subscales of Sinhala KOOS. Structural validity, assessed using a five-factor CFA model, showed good model-fit.

High Cronbach's alpha coefficients obtained for all subscales confirmed that the KOOS subscales are internally consistent, and items within a subscale correlate with each other. The internal consistency of the QoL subscale is within acceptable range but could be improved from 0.83 to 0.88 by removing item Q2. Cronbach's alpha coefficients were comparable to the coefficients obtained in the validation of the Swedish (0.71–0.95) [28], Singapore English (0.70–0.92) [29], French (0.76–0.93) [30], Portuguese (0.77–0.95) [31], Indonesian (0.84–0.97) [32], Finnish (0.79–0.96) [33], and Malaysian (0.78–0.95) [34] versions. The Dutch version was validated in several different groups of patients, the Cronbach's alpha values for mild OA ranged from 0.71 to 0.94, for moderate OA from 0.83–0.97, for severe OA from 0.56 to 0.98, six months after a total knee replacement (TKA) from 0.74 to 0.94 and for patients who had undergone a revision of the primary TKA from 0.78 to 0.95. Among those Cronbach's alpha values, the symptoms subscale for severe KOA was 0.56 [35]. Xie et al., and Salavati et al., reported Cronbach's alpha values less than 0.70 for the pain subscale and QoL among KOA patients and patients with knee injuries [29, 36].

The test–retest reliability was excellent with the intraclass correlation coefficients being >0.9 for all subscales indicating satisfactory temporal stability of the KOOS Sinhala version. This is similar to other cultural adaptations of the KOOS: the Urdu version had an ICC ranging from 0.967 to 0.986 [37]; the Arabic version an ICC ranging from 0.875 to 0.957 [38]; and the Portuguese version had an ICC ranging from 0.82 to 0.94 [31].

The SEM (range 1.07 and 2.26) and the MDC (range 2.96 and 6.26) of the Sinhala KOOS scale are small showing the scale's ability to detect even small changes not due to random errors with time. These values indicate a high level of measurement precision and a relatively small detectable change threshold. The SEM for the mild and moderate OA groups in de Groot et al.'s study ranged from 5.2 to 9.0 and from 5.8 to 11.6, respectively; the SEM values for post-revision total knee replacement patients ranged from 7.2 to 24.6 [35]. The French KOOS showed good to excellent reproducibility with ICC values ranging from 0.755 to 0.914 [30]. The Persian version in patients with isolated meniscus injury had SEM values between 5.68 and 9.24 and a MDC value of 25.61 [11]. The SEM values reported for the Finnish version of the KOOS ranged from 6.0 to 12.2, the lowest being for the symptom subscale and the highest for the sport and recreation function subscale; the individual level MDC ranged between 2.2 and 3.4, the lowest (16.6) being for the symptom subscale and highest (33.8) for the sport and recreation function subscale, while at the group level, the MDC ranged between 2.2 and 4.4 [33].

Item-subscale correlation was satisfactory. Similar findings have been reported in the Portuguese KOOS validation [31]. Xie et al., (2006) reported correlations

Table 5 Correlation between KOOS subscales and SF-36 scores

SF-36 Subscales	Sample size (*n*) [1]	KOOS Pain	KOOS Symptoms	KOOS Activities of Daily Living	KOOS Sports	KOOS Quality of Life
Physical functioning	465	0.21**	0.22**	0.18**	0.29**	0.20**
Role limitations due to physical health	486	0.47**	0.44**	0.61**	0.53**	0.62**
Role limitations due to emotional problems	480	0.35**	0.35**	0.36**	0.34**	0.42**
Energy/Fatigue	489	0.14**	0.23**	0.16**	0.17**	0.26**
Emotional wellbeing	483	0.04	0.14**	0.08	0.03	0.07
Social functioning	489	0.26**	0.28**	0.23**	0.27**	0.34**
Bodily pain	494	0.41**	0.40**	0.41**	0.39**	0.47**
General Health	479	0.30**	0.30**	0.28**	0.31**	0.44**

**Correlation coefficient is significant at the 0.01 level (2-tailed)

[1] Sample sizes are based on both KOA patients and controls and are different for each variable due to missing data

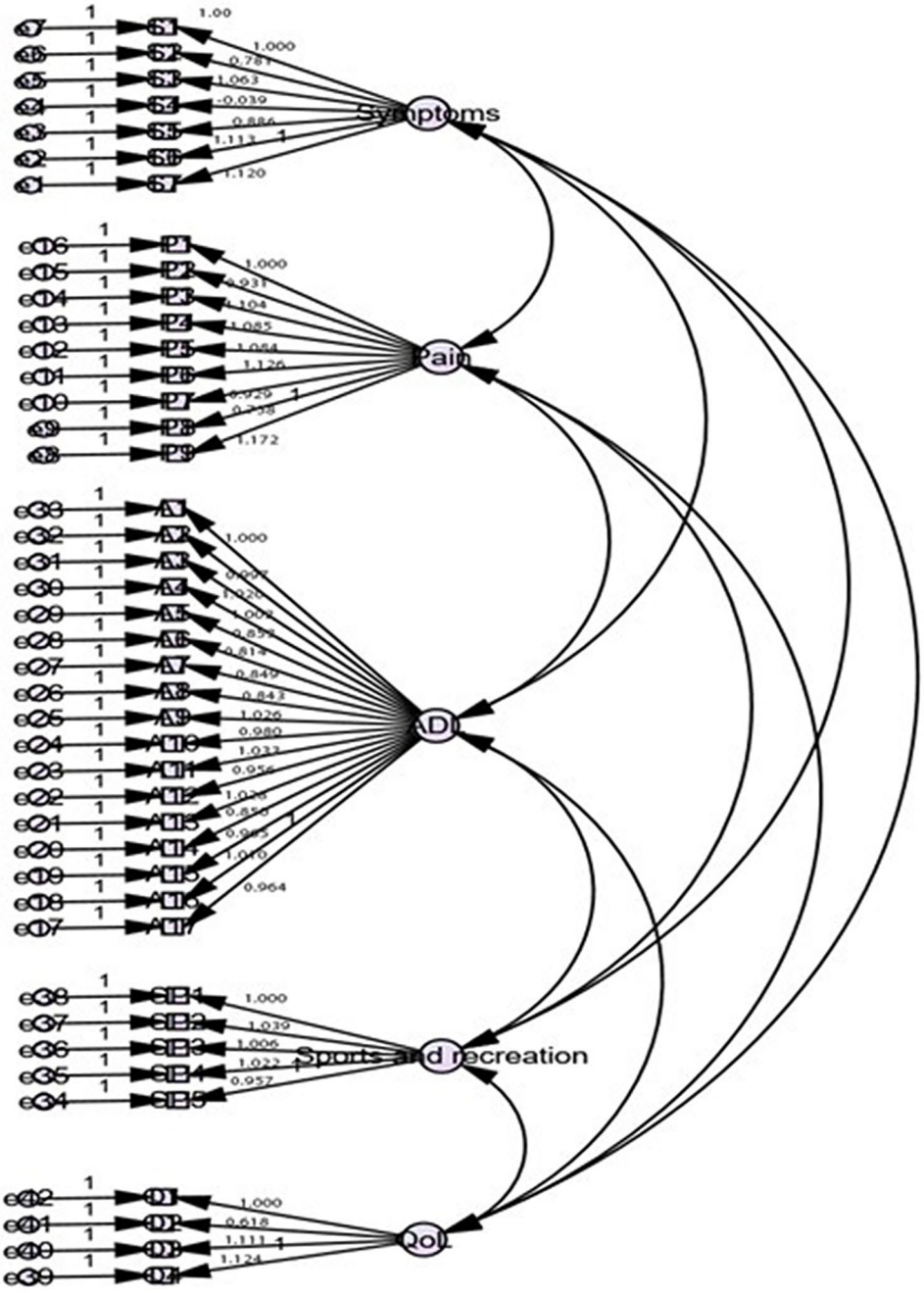

Fig. 1 KOOS 42 items: CFA model; $n = 404$

exceeding 0.40 for all 42 items in the KOOS subscales in the Singapore English and Chinese versions with the exception of 4 items and 13 items, respectively [29]. In the Persian KOOS, Spearman's correlation coefficient exceeded 0.40 for all subscales except all items of the symptom subscale and one item of the QoL subscale [36].

Many studies have reported a moderate correlation between the KOOS subscales and SF-36 subscales measuring similar constructs [30, 31, 39]. In our study, KOOS pain scores moderately correlated with SF-36 bodily pain and physical health scores. The correlation between KOOS pain scores and other SF-36 subscale scores were statistically significant but poor. Similarly, moderate correlations were observed between KOOS symptoms scores and SF-36 physical health and bodily pain scores; KOOS ADL scores and SF-36 bodily pain scores; and KOOS sports scores and SF-36 physical health scores. Difference in the time periods considered in SF-36 (4 weeks) and KOOS (1 week) could be a reason for the poor correlation between the subscales. It is likely that

the hospitalized patients may have experienced a certain level of difficulty evaluating their ability to do certain knee-related functions like jumping, climbing stairs etc.

The SF-36 emotional wellbeing subscale poorly correlated with KOOS symptoms subscale; it did not correlate with other KOOS subscales including KOOS QoL. SF-36 emotional wellbeing scale assesses mental health and KOOS QoL assesses knee-specific quality of life; this difference may have been responsible for the poor correlation between the two scales.

Results of CFA showed that the KOOS Sinhala version with all items retained the original five-factor model. The Malaysian KOOS was the first validation which used CFA to test factor structure [34]. The goodness-of-fit indices of the final model of the Malaysian KOOS with only 26 items were CFI=0.93, TLI=0.92, IFI=0.93 and chi- square/degree of freedom=2.18 and RMSEA=0.07. Items s2, s4, s5, p1, p2, p4, p6, a1, a2, a3, a5, a9, a10, a11, a16 and q1 were eliminated from the Malaysian KOOS.

We acknowledge several limitations of this study. We did not compare Sinhala KOOS with other scales such as Western Ontario and McMaster Universities Arthritis Index (WOMAC), Pain numeric scale or Visual Analog Scale. Lack of a validated, specific knee scale in Sinhala is a limitation of this study; poor correlations between subscales of the Sinhala KOOS scale and the Sinhala SF-36 subscales suggests that SF-36 may not have been the best tool to use to assess construct validity. The selection of KOA patients was based on a physician diagnosis which probably was based on a radiologic diagnosis; even if it was not, clinical diagnoses of experienced physicians is unlikely to have affected the performance of the scale. As most of the study participants were in an advanced stage of the disease, this study possibly may not represent the entire disease spectrum of KOA. Radiography which is considered the gold standard for diagnosing osteoarthritis was not used when recruiting patients. The lack of radiologic confirmation is a limitation as it may have led to misclassification of participants.

Conclusions

The Sinhala version of the KOOS scale is a reliable and valid instrument to measure the outcomes of KOA progression. The Sinhala version of the KOOS scale can be used as a valid, self-reporting, disease-specific instrument in a Sinhala speaking population. Further research is suggested to assess its usefulness in monitoring progression of disease.

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Author contributions
JG and RW designed the study. JG collected data. JG, RP and RW analysed the data and wrote the manuscript. RW did the final editing and overall supervision. All authors reviewed and approved the manuscript.

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Data availability
Data are available upon reasonable request. Please contact the corresponding author and the Ethics Review Committee of the Faculty of Medicine, University of Kelaniya, Sri Lanka. Contact details are as follows: Ethics Review Committee, Faculty of Medicine, University of Kelaniya, P.O. Box 6, Thalagolla Road, Ragama 11010, Sri Lanka. Tel: +94 11 296 1267 Email: ercmed@kln.ac.lk.

Declarations

Ethics approval and consent to participate
Ethics clearance was obtained from the Ethics Review Committee of the Faculty of Medicine, University of Kelaniya, Sri Lanka (P/25/04/2022). For the translation, written permission was obtained from the KOOS web manager. Permission from the Directors of relevant hospitals and physical medicine departments in each hospital was obtained to gain access to the knee osteoarthritis patients and controls. Informed consent was obtained from all participants prior to data collection. Written informed consent was obtained from all participants after explaining the purpose of the study.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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References

1. Arden N, Blanco F, Cooper C, Guermazi A, Hayashi D, Hunter D, et al. Atlas of Osteoarthritis. Tarporley: Springer Healthcare Ltd.; 2014.
2. Symmons D, Mathers C, Pfleger Bruce. & (2003). Global burden of osteoarthritis in the year 2000. WHO global burden of disease. World health report. 2002;5:Version 2.
3. Cross M, Smith E, Hoy D, Nolte S, Ackerman I, Fransen M, et al. The global burden of hip and knee osteoarthritis: estimates from the global burden of disease 2010 study. Ann Rheum Dis. 2014;73:1323–30.
4. Tong L, Yu H, Huang X, Shen J, Xiao G, Chen L, et al. Current understanding of osteoarthritis pathogenesis and relevant new approaches. Bone Res. 2022;10:60.
5. Safiri S, Kolahi AA, Smith E, Hill C, Bettampadi D, Mansournia MA et al. Global, regional and national burden of osteoarthritis 1990–2017: A systematic analysis of the Global Burden of Disease Study 2017. Annals of the Rheumatic Diseases. 2020. https://doi.org/10.1136/annrheumdis-2019-216515
6. Prashansanie Hettihewa A, Gunawardena NS, Atukorala I, Hassan F, Lekamge IN, Hunter DJ. Prevalence of knee osteoarthritis in a suburban, Srilankan, adult female population: a population-based study. Int J Rheum Dis. 2018;21:394–401.
7. Roos EM, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee Injury and Osteoarthritis Outcome score (KOOS)—Development of a self-administered outcome measure. J Orthop Sports Phys Ther. 1998;28:88–96.
8. Bond M, Davis A, Lohmander S, Hawker G. Responsiveness of the OARSI-OMERACT osteoarthritis pain and function measures. Osteoarthr Cartil. 2012;20:541–7.
9. Perera ELSJ. Ageing population of Sri Lanka: emerging issues, needs and policy implications: thematic report based on census of population and housing 2012. United Nations Population Fund, Sri Lanka; 2017.
10. Official, KOOS | Knee injury and Osteoarthritis Outcome Score distributed by Mapi Research Trust | ePROVIDE. 2024. https://eprovide.mapi-trust.org/instruments/knee-injury-and-osteoarthritis-outcome-score. Accessed 27 Jul 2024.

11. Ebrahimi N, Jalaie S, Salsabili N, Ansari NN, Naghdi S. Knee Injury and osteoarthritis outcome score in patients with isolated meniscus injury; validity and reliability. J Res Med Sciences: Official J Isfahan Univ Med Sci. 2017;22.
12. Mazaheri M, Khorrami M, Salavati M, Akhbari B, Mohammadi F. Knee injury and osteoarthritis outcome score (KOOS); reliability and validity in competitive athletes after anterior cruciate ligament reconstruction. Osteoarthr Cartil. 2011;19:406–10.
13. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine. 2000;25:3186–91.
14. Tsang S, Royse CF, Terkawi AS. Guidelines for developing, translating, and validating a questionnaire in perioperative and pain medicine. Saudi J Anaesth. 2017;11:S80–9.
15. MacCallum RC, Widaman KF, Zhang S, Hong S. Sample size in factor analysis. Psychol Methods. 1999;4:84–99.
16. Gunawardena NS, Seneviratne SR, de Atauda A. An approach to validation of a multi-dimensional tool. J Coll Community Physicians Sri Lanka. 2003;8:18–26.
17. McHorney CA, Tarlov AR. Individual-patient monitoring in clinical practice: are available health status surveys adequate? Qual Life Res. 1995;4:293–307.
18. Streiner DL. Starting at the beginning: an introduction to coefficient alpha and internal consistency. J Pers Assess. 2003;80:99–103.
19. Koo TK, Li MY. A Guideline of selecting and reporting Intraclass correlation coefficients for Reliability Research. J Chiropr Med. 2016;15:155–63.
20. Palta M, Chen H-Y, Kaplan RM, Feeny D, Cherepanov D, Fryback DG. Standard Error of Measurement of 5 Health Utility Indexes across the range of Health for Use in estimating reliability and responsiveness. Med Decis Mak. 2011;31:260–9.
21. Geerinck A, Alekna V, Beaudart C, Bautmans I, Cooper C, De Souza Orlandi F, et al. Standard error of measurement and smallest detectable change of the Sarcopenia Quality of Life (SarQoL) questionnaire: an analysis of subjects from 9 validation studies. PLoS ONE. 2019;14:e0216065.
22. De Vet HCW, Terwee CB, Mokkink LB, Knol DL. Measurement in medicine: A practical guide. Measurement in Medicine: A Practical Guide. 2011;:1–338.
23. Taylor R. Interpretation of the correlation coefficient: a Basic Review. J Diagn Med Sonography. 1990;6:35–9.
24. Hu LT. Cutoff criteria for fit indexes in covariance structure analysis: conventional criteria versus new alternatives. Struct Equ Model. 1999;6:1–55.
25. Fabrigar LR, Wegener DT, MacCallum RC, Strahan EJ. Evaluating the use of exploratory factor analysis in psychological research. Psychol Methods. 1999;4:272–99.
26. Rosseel Y. Lavaan: an R Package for Structural equation modeling. J Stat Softw. 2012;48:1–36.
27. Ministry of Health SL. Body mass index (BMI) – Nutrition Division. https://nutrition.health.gov.lk/english/body-mass-index-bmi/. Accessed 4 May 2023.
28. Roos EM, Roos HP, Ekdahl C, Lohmander LS. Knee injury and osteoarthritis outcome score (KOOS) - validation of a Swedish version. Scand J Med Sci Sports. 1998;8:439–48.
29. Xie F, Li SC, Roos EM, Fong KY, Lo NN, Yeo SJ, et al. Cross-cultural adaptation and validation of Singapore English and Chinese versions of the knee injury and osteoarthritis outcome score (KOOS) in asians with knee osteoarthritis in Singapore. Osteoarthr Cartil. 2006;14:1098–103.
30. Ornetti P, Parratte S, Gossec L, Tavernier C, Argenson J-N, Roos EM, et al. Cross-cultural adaptation and validation of the French version of the knee injury and osteoarthritis outcome score (KOOS) in knee osteoarthritis patients. Osteoarthr Cartil. 2008;16:423–8.
31. Gonçalves RS, Cabri J, Pinheiro JP, Ferreira PL. Cross-cultural adaptation and validation of the Portuguese version of the knee injury and osteoarthritis outcome score (KOOS). Osteoarthr Cartil. 2009;17:1156–62.
32. Phatama KY, Aziz A, Bimadi MH, Oktafandi IGNAA, Cendikiawan F, Mustamsir E. Knee Injury and Osteoarthritis Outcome score: validity and reliability of an Indonesian version. Ochsner J. 2021;21:63–7.
33. Multanen J, Honkanen M, Häkkinen A, Kiviranta I. Construct validity and reliability of the Finnish version of the knee Injury and Osteoarthritis Outcome score. BMC Musculoskelet Disord. 2018;19:1–10.
34. Zulkifli MM, Kadir AA, Elias A, Bea KC, Sadagatullah AN. Psychometric properties of the malay Language Version of knee Injury and Osteoarthritis Outcome score (KOOS) questionnaire among knee osteoarthritis patients: a confirmatory factor analysis. Malaysian Orthop J. 2017;11:7.
35. de Groot IB, Favejee MM, Reijman M, Verhaar JAN, Terwee CB. The Dutch version of the knee injury and osteoarthritis outcome score: a validation study. Health Qual Life Outcomes. 2008;6:1–11.
36. Salavati M, Mazaheri M, Negahban H, Sohani SM, Ebrahimian MR, Ebrahimi I, et al. Validation of a persian-version of knee injury and osteoarthritis outcome score (KOOS) in iranians with knee injuries. Osteoarthr Cartil. 2008;16:1178–82.
37. Ateef M, Kulandaivelan S, Alqahtani M. Cross-cultural validation of Urdu Version KOOS in Indian Population with primary knee osteoarthritis. Int J Rheumatol. 2017;2017:1–4.
38. Peter M, Fayers DM. Cross-cultural adaptation, reliability, internal consistency and validation of the arabic version of the knee injury and osteoarthritis outcome score (KOOS) for Egyptian people with knee injuries. W.B. Saunders; 2013.
39. Cheung RTH, Ngai SPC, Ho KKW. Chinese adaptation and validation of the knee Injury and Osteoarthritis Outcome score (KOOS) in patients with knee osteoarthritis. Rheumatol Int. 2016;36:1449–54.

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