



Responsiveness and the Minimal Important Change of Knee Injury and Osteoarthritis Outcome Score Following Physiotherapy Intervention in Iraqi People with Knee Osteoarthritis

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Abstract

Background: The Knee Injury Osteoarthritis Outcome Score (KOOS) is a widely used patient-reported questionnaire to evaluate individuals with knee osteoarthritis or a history of knee injuries.

Objectives: The aim of this study was to evaluate the responsiveness and establish the minimal important change (MIC) for the Arabic version of KOOS in Iraqi individuals with knee osteoarthritis following physiotherapy intervention.

Methods: Fifty volunteers (13 male and 37 female, mean age: 59.3 ± 9.6 years old) with an orthopedic diagnosis of knee osteoarthritis participated in this study. The Arabic KOOS was completed by the participants once before the intervention and once after completing a 4-week physiotherapy treatment program. A seven-item global rating of change scale was used as an external anchor to assess the participants' opinion about the treatment and its possible changes. Responsiveness was evaluated by calculating the receiver operating characteristic (ROC) curve, and the MIC was established by identifying an optimal cut-off on the ROC curve.

Results: All subscales of the Arabic KOOS showed an area under the curve > 0.70. The MICs reflecting the values required by the participants to feel the improvement were 15.5, 14.5, 11, 11.5, and 12.5 for the pain, symptoms, activities of daily living, sports and recreation, and quality of life subscales, respectively.

Conclusions: All subscales of the Arabic KOOS are responsive to physiotherapy treatment. Therapists and researchers can use the MIC values to evaluate whether their prescribed treatment was satisfactory and effective from their patients' point of view.

Keywords: KOOS, Psychometric Properties, Minimal Important Changes, Knee Osteoarthritis, Physiotherapy

1. Background

Knee osteoarthritis (OA) is one of the most common chronic diseases that has caused several problems in the daily life of millions of people around the world (1). Knee OA may cause inability to perform activities of daily living (ADL) and ultimately lead to a decrease in their quality of life (QoL) (2-4). Based on prior studies the global incidence of knee OA is 203 per 10,000 person-years in people aged 20 and over. Also, there are more than 86 million individuals (20 years and older) annually with knee OA in 2020 worldwide (5).

Based on prior studies, for preventing knee OA progression and subsequent disability, use of accurate outcome measurement tools for diagnostic and therapeutic goals is imperative (6, 7). Accurate measures are helpful in determining level of pain, stiffness, and

QoL. Based on the identified impairments, clinicians can design an individualized treatment plan and track the effectiveness of the prescribed intervention (6-8).

Patient-reported questionnaires are the main outcome measurement tools for determining and monitoring the effectiveness of therapeutic exercise interventions in clinical and research settings (9). It is essential that the psychometric properties of these measurement tools including validity, reliability, and the ability to detect change following interventions should be at an acceptable level, so that clinicians and researchers can use them to improve the diagnostic and clinical decision-making processes (10, 11).

Knee injury Osteoarthritis Outcome Score (KOOS) is one of the widely used patient-reported questionnaires to evaluate people with knee OA or with a history of knee

injuries (9, 11). This questionnaire examine secondary complications of knee OA, including pain and stiffness, and their effects on ADL and aspects of QoL (12, 13). The original version of this questionnaire has acceptable validity, reliability, and responsiveness (14) and has been translated into different languages (15-22). The Arabic version of this questionnaire is also cross-culturally translated and adapted for all Arab-speaking countries and recorded acceptable internal validity and reliability (23). However, the responsiveness of this version has not been examined. Responsiveness which measures through minimal important change (MIC) is an essential property of a diagnostic and clinical measurement tool (8). According to the Consensus-based Standards for the development of Measurement Instruments (COSMIN), responsiveness refers to the ability of a measurement tool to record changes in a specific aspect that is designed to assess; like the ability to detect changes in individual performance over time (24, 25).

2. Objectives

Since the responsiveness and the MIC for the Arabic-KOOS have not been investigated, the purpose of this study was to investigate the responsiveness and the MIC for Arabic-KOOS among Iraqi people with knee OA following physiotherapy interventions.

3. Methods

This study had an observational and cohort design. Iraqi people with OA referring to physiotherapy clinics of Basra recruited to this study based on the following Inclusion criteria: People with a definitive orthopedist diagnosis of knee OA, age over 50 years, presence of radiological signs of OA and presence of clinical symptoms of OA. Exclusion criteria were as follows: History of knee arthroplasty, history of intra-articular injection, presence of neurological problems such as low back pain originating from pressure on the nerve roots and radicular symptoms, presence of neuromuscular diseases such as Parkinson's, presence of systemic diseases such as rheumatoid arthritis, cognitive problems, and/or the inability to understand the instructions and conditions of performing tests and Inability to write and speak in Arabic. During the data collection period, 57 people with symptoms of knee OA referred to the targeted physiotherapy clinics in Basra. Of these, 2 people did not want to participate in the study, 3 had a history of intra-articular injection, and 2 reported low back pain. Therefore, this study was conducted on 50 volunteers who met the inclusion and exclusion criteria.

After getting the ethics committee's confirmation, data collection started. After explaining the purposes and procedures of the study to the recruited people with OA, if they volunteered, signed the consent form and entered the study.

Demographic and baseline clinical characteristics of the participants, including gender, age, height, weight, body mass index, cognitive status, years of education, and the affected knee were recorded in the first session by a physical therapist (MA). The Arabic KOOS questionnaire was completed by the participants before and after the physiotherapy program. The physiotherapy program was 4 weeks (3 sessions per week; each session 45 minutes) and contained routine physical interventions for people with OA including electrotherapy (26), thermal modalities (27), and strengthening and stretching exercises (28). The interventions were done by a physical therapist (MA).

Also, after the final session of the treatment, the participants completed a 7-point global rating of change scale. In this scale, they were asked about the perceived changes in their condition compared to before the start of the treatment by choosing one of the following seven answers: I have become very much better (score 7), I have become much better, I have little improvements, I have not changed, I have become worse, I have become much worse and I have become very much worse (score 1). This scale exhibits the external anchor of the participant's opinion on the amount of change that he/she perceived. It is worth to note that the 7-point global rating scale is a validated tool commonly used as an external reference standard in rehabilitation literature to show the individual's opinion about recovery (29). Based on the response to the global rating scale of change, the participants were divided into two groups: Improved (those who answered that I have improved very much or that I have improved a lot) and not improved (the rest of the answers except the previous two).

3.1. Outcome Measure

The KOOS contains 42 items that are categorized into five subscales of pain, symptoms, ADL, sport and recreation (Sport/Rec), and knee-related QoL. Each item is scored from 0 (no problems) to 4 (severe problems). The score achieved from each subscale is normalized from 0 to 100 such that the higher scores reflect better health conditions while lower scores represent worse health conditions (12). The Arabic version of this tool has acceptable reliability and validity (23).

3.2. Sample Size Calculation

Since the minimum number of participants for responsiveness studies is 50 (24), this number of volunteers was included in the present study. Sampling

was done in a simple non-probability way among the available Arabic-speaking population with knee OA who were referred to physiotherapy clinics.

3.3. Statistics

SPSS version 22.0 (SPSS Inc., Chicago, IL) was used for statistical analysis. In all analyses, the significance level was set at 0.05. Descriptive statistics were used to assess the demographic and clinical characteristics of the participants. Normality of the data was checked using Kolmogorov-Smirnov test. Paired *t*-test (for normal data) or Wilcoxon's signed-rank test (for non-normal data) were used to compare the KOOS subscales scores before and after the intervention program.

The changes in the KOOS subscales after the treatment were calculated as the change in scores. The change scores were calculated for all participants (improved and not-improved subgroups). The correlations between the change scores and the score of external reference standard were checked using Gamma correlation. Correlation coefficients were interpreted as follows: Less than 0.25 was considered as little or no correlation, 0.25 - 0.50 fair correlation, 0.51 - 0.75 moderate to good correlation, and > 0.75 good to excellent correlation (8, 24).

The ROC curve analysis (95% confidence interval) was also used to evaluate the ability of the Arabic KOOS subscales to correctly distinguish improved individuals from not-improved (24). For this purpose, the global rating of change scale was used as an external anchor to define a dichotomous variable named improved versus not-improved (30). Then, based on the answer to the external anchor question, participants were divided into two groups: Improved (scores 6 and 7) and non-improved (scores 1, 2, 3, 4, and 5) (10). By using the subscales change scores of KOOS as cut-off points on the plotted curve, the area under the curve (AUC) was calculated. An AUC of more than 0.70 is an indicator of acceptable responsiveness (25).

4. Results

Table 1 shows the demographic information of the participants. All fifty participants finished their physiotherapy sessions as planned for 4 weeks.

Table 2 shows the pre-intervention, post-intervention, and change scores of the KOOS subscales for the total sample and improved/not-improved subgroups. There were statistically significant differences for all the subscales following the treatment (P-values: < 0.001).

According to the global rating of change scale, from 50 people participating in the study, 29 (58%) sensed improvement following the treatment program and 21 (42%) did not experience this feeling. The number of

Table 1. Demographic and Clinical Characteristics of Participants (n = 50)^a

Variables	Participants
Age, y	59.37 ± 9.65
Height, cm	164.25 ± 8.03
Weight, kg	78.94 ± 14.31
Body mass index, kg/m ²	29.72 ± 4.51
Sex	
Men	13 (26)
Women	37 (74)
Year of education, y	13.54 ± 3.03
MMSE score	29.06 ± 1.33
Affected limb side	
One side	19.84 (5.18)
Two side	50.78 (4.39)

Abbreviations: BMI, body mass index; MMSE, mini-mental state examination.

^a Values are expressed as mean ± SD or No. (%).

people reporting "very much better" was 11 (22%), "much better" 18 (36%), "slightly better" 13 (26%), "no change" 7 (14%), "slightly worse" 1 (2%), "much worse" 0 (0%), and "very much worse" was 0 (0%).

Table 3 shows the correlations coefficients between the change scores of KOOS subscales and the global rating of change score. The AUC was 0.83 for pain subscale, 0.77 For symptoms, 0.82 For ADL, 0.78 For Sport/Rec, and 0.86 For QoL. Also, the MIC values was 15.5 for pain subscale, 14.5 For symptoms, 11 For ADL, 11.5 For Sport/Rec, and 12.5 For QoL.

5. Discussion

In general, the results of this study indicated that all subscales of the Arabic KOOS have acceptable responsiveness. This result means that Iraqi clinicians and researchers can use this measure to evaluate changes after their prescribed intervention and be sure that this outcome measure is responsive to the changes.

In line with the results of this study, similar results have been reported in the study by Mostafaei et al. that all subscales of the Persian KOOS were responsive to changes following physiotherapy intervention among persians with knee OA (30). In that study, the subscales of pain (AUC: 0.87) and ADL (AUC: 0.91) recorded the highest responsiveness among the other subscales (30). It means that these two subscales showed better the changes following treatment than the three other subscales (30). Also stated that since the QoL requires long term interventions, its responsiveness is in third place among the five subscales (AUC: 0.74) (30).

Table 2. Mean \pm SD of Pre-intervention, Post-intervention and Change Scores of the Arabic KOOS (n = 50) ^a

Variables	Pre-intervention	Post-intervention	Change	F	P-Value
Pain					
Total (n = 50)	42.38 \pm 10.45	58.74 \pm 12.68	16.36 \pm 7.17	0.113	< 0.001 ^b
Improved (n = 29)	39.17 \pm 9.19	58.61 \pm 11.78	19.43 \pm 6.32	0.192	< 0.001 ^b
Not improved (n = 21)	47.01 \pm 10.68	58.94 \pm 14.29	11.94 \pm 6.03	0.253	< 0.001 ^b
Symptoms					
Total (n = 50)	52.67 \pm 9.89	67.79 \pm 11.34	15.13 \pm 5.28	0.484	< 0.001 ^b
Improved (n = 29)	53.09 \pm 10.29	70.2 \pm 10.69	17.13 \pm 4.54	0.549	< 0.001 ^b
Not improved (n = 21)	52.06 \pm 9.58	64.31 \pm 11.66	12.25 \pm 5.05	0.770	< 0.001 ^b
Activities of daily living					
Total (n = 50)	50.23 \pm 10.57	61.56 \pm 11.38	11.33 \pm 4.29	0.782	< 0.001 ^b
Improved (n = 29)	50.31 \pm 10.02	63.52 \pm 10.57	13.22 \pm 3.77	0.758	< 0.001 ^b
Not improved (n = 21)	50.13 \pm 11.65	58.75 \pm 12.24	8.63 \pm 3.56	0.774	< 0.001 ^b
Sport/recreational					
Total (n = 50)	18.28 \pm 11.76	28.92 \pm 12.75	10.64 \pm 6.1	0.004	< 0.001 ^b
Improved (n = 29)	16.17 \pm 11.53	29.09 \pm 11.28	12.91 \pm 5.24	0.172	< 0.001 ^b
Not improved (n = 21)	21.31 \pm 11.79	28.69 \pm 15.01	7.38 \pm 5.89	0.917	< 0.001 ^b
Quality of life					
Total (n = 50)	33.85 \pm 12.91	47.72 \pm 12.53	13.87 \pm 5.35	< 0.001 ^b	< 0.001 ^b
Improved (n = 29)	33.39 \pm 11.68	49.82 \pm 10.82	16.43 \pm 4.97	< 0.001 ^b	< 0.001 ^b
Not improved (n = 21)	34.51 \pm 14.87	44.69 \pm 14.47	10.19 \pm 3.41	< 0.001 ^b	< 0.001 ^b

Abbreviations: SD, standard deviation; KOOS, knee injury and osteoarthritis outcome score.

^a Values are expressed as mean \pm SD.

^b Significant

Table 3. Gamma Correlation Coefficient and Area under the Receiver Operating Characteristic (AUC) Curve for the Arabic KOOS According to External, Dichotomized Measure of Global Rating Scale (Improved Versus Unimproved) (n = 50)

Questionnaires	Gamma Coefficient (P-Value)	AUC (95% CI)	P-Value	Optimal Cut-off Value	Sensitivity (95% CI)	Specificity (95% CI)
Pain	0.88 (< 0.001)	0.83 (0.69 - 0.96)	0.001	15.5	0.78 (0.56 - 0.93)	0.81 (0.54 - 0.96)
Symptoms	0.72 (0.004)	0.77 (0.62 - 0.93)	0.004	14.5	0.74 (0.52 - 0.90)	0.69 (0.41 - 0.89)
ADL	0.75 (0.002)	0.82 (0.68 - 0.95)	0.001	11	0.70 (0.47 - 0.87)	0.75 (0.48 - 0.93)
Sport	0.61 (0.027)	0.78 (0.63 - 0.92)	0.003	11.5	0.65 (0.43 - 0.84)	0.69 (0.41 - 0.89)
QoL	0.78 (0.001)	0.86 (0.74 - 0.98)	< 0.001	12.5	0.65 (0.43 - 0.84)	0.81 (0.54 - 0.96)

Abbreviations: AUC, area under the curve; CI, confidence interval; ADL, activities of daily living; QoL, quality of life.

In our study the pain (AUC: 0.83) and ADL (AUC: 0.82) subscales were more responsive than symptoms (AUC: 0.77) and sports/Recreational (AUC: 0.78) subscales. But in our study, the QoL subscale (AUC: 0.86) is ranked higher than the pain and the ADL. This may be due to cultural differences and participants' satisfaction with the treatment they received. There is a possibility that Iraqi people had been more satisfied than Iranian people from receiving therapeutic interventions and this satisfaction along with the improvements resulting from

the treatment had created a tangible change in their QoL.

The MIC value is used to evaluate within-group improvements in a specific patient group. Although the method of calculating these values is determined by considering the maximum sensitivity and specificity, there are still some degrees of misclassification in this regard (10). In other words, by using MIC cut-off, we will have an estimate of patients' feeling after completing the treatment, but the main priority in clinical decision-making should be the patients' actual feeling

about the treatment (regardless of the MIC). Therefore, MIC should not be replaced by the patients' feeling and judgment regarding improvement or not-improvement after treatment.

Another point is that the MIC should be larger than the minimal detectable change (MDC) calculated from reliability methods (31). With this precondition, it is concluded with 95% confidence so that the change the patient feels is not due to chance and be a real feeling that shows the improvement following treatment (32).

Alfadhel et al. reported the reliability, validity and also the MDCs for the Arabic KOOS in people with knee OA (23). The results of this study helped us in interpreting the obtained MIC values. In our study, MIC values for the Pain (15.5), symptoms (14.5) and QoL (12.5) subscales were greater than MDC values reported by Alfadhel et al. (23). Regarding the subscales of ADL and sports, the obtained MIC values were lower than the reported MDC by Alfadhel et al. Hence, if Iraqi individuals improved their scores of the ADL by 11 points and the sport by 11.5 points, it cannot be interpreted as satisfaction with their treatment. This is because the minimum value of a real change (not by chance) should be 13.5 and 14.5 points for the ADL and sport, respectively (23).

The present study had some limitations. First, there is a possibility that through using the global rating of change scale to determine the participants' feeling of the improvement, the recall bias had affected the results. To reduce this possibility, the duration of the treatment period was planned as short as possible so that the individuals did not forget their pre-intervention or baseline conditions. Second, the majority of people referring to physiotherapy clinics were women, which also was a limitation in previous studies in people with knee OA (23, 30). This issue makes the results more generalizable to women with knee OA. For this reason, it is recommended that future studies consider the percentage of male and female participants for designing their studies.

5.1. Conclusions

All the subscales of the Arabic KOOS are responsive to physiotherapy treatment. Also, therapists and researchers can use the MIC values (especially the values of pain, symptoms and QOL subscales) to evaluate whether their prescribed treatment was satisfactory and effective from their patients' point of view.

Footnotes

Authors' Contribution: A. B. designed the study and drafted the manuscript. M.A. participated in designing the evaluation, collected the clinical data, performed parts of

the statistical analysis and helped to draft the manuscript. S. G. re-evaluated the clinical data, performed the statistical analysis and revised the manuscript. N.P. interpreted data and revised the manuscript. All authors read and approved the final manuscript.

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