

# Development and Initial Validation of the Ibadan Knee/Hip Osteoarthritis Outcome Measure

**ABSTRACT:** *Background and Aim:* Development of outcome measures remains a focus of health research in the 21st century. Outcome measures originally developed for the Nigerian environment are very rare. The aims of this study were to develop an outcome measure for management of hip and knee arthritic conditions, and to investigate the validity and responsiveness of it.

*Methods:* The Ibadan Knee/Hip Osteoarthritis Measure (IKHOAM) was developed from other measures found in literature, as well as complaints of attending patients. Forty nine patients with pain from knee and/or hip osteoarthritis, the OA group (OAG) and 49 individuals without knee or hip pain, the pain-free group (PFG) were assessed, using the IKHOAM. The OAG was assessed on IKHOAM and the Visual Analogue Scale (VAS) before and after a 6-week physiotherapy programme.

*Results:* Significant differences between IKHOAM scores of the OAG and PFG and between IKHOAM scores of OAG pre and post 6-week physiotherapy programme, as well as the significant negative correlations between changes in IKHOAM and VAS scores of OAG before and after the 6-week physiotherapy programme were demonstrated.

*Conclusion:* IKHOAM demonstrated initial criteria towards validity and responsiveness and may be used in a Nigerian population of OA knee/hip individuals and similar environments.

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## INTRODUCTION

Osteoarthritis is a common chronic joint disease and a leading cause of disability in the elderly (Swedberg and Steinbauer, 1992). It affects 60-70% of the Western adult population older than 60 years (Lane, 1997). It is also common in the Black African population (Eti et al, 1998). In Nigeria, the most frequently affected joint is the knee, followed by the hip (Alonge, 2002).

Outcomes measurement in clinical practice provides the means by which the health care provider, the patient, the public and the payer are able to assess the end results of care and its effects on the health of the patient and the society (Yeomans, 2000). The health care delivery system has been in the 'era of accountability' since the mid 1980s (Yeomans, 2000). Health care providers, especially those in the developed countries of the world have been challenged to account for their interventions more rigorously than before due to health policy changes and the demands of the third party payers (Ducksworth, 1999; Buton et al,

2000). Consequently, many generic and disease-specific outcome measures have been developed. Many of these clinical instruments measure what matters most to patients and the payers, that is, the change in the functional health status (Yeomans, 2000). Many outcome measures specific to osteoarthritis are available in literature (Fries et al, 1980; Meenan et al, 1980; Kellen et al, 1999; Roos et al, 1998). Outcome measures often reflect the environment and culture of the people they were originally developed for. We observed that some of the existing osteoarthritis outcome measures include few items such as "turning faucets off and on" and "walking several blocks" which may not be readily understood by Nigerians, especially those with low educational attainments (faucets are better known as taps in Nigeria; the average Nigerian is not familiar with the concept of a block being equal to 100 meters). Almost all existing OA outcome measures exclude activities that are important to many patients we see in our clinic. Such

activities include assuming the Islamic praying posture (sitting on the heels) and incomplete kneeling (by females) or prostrating (by males) to show courtesy to elders while greeting them. Besides, many of the instruments focus disproportionately on joints of the upper extremity, which are not often affected by osteoarthritis in Nigerians. In addition, some of these scales are rated by the patient alone and do not include items that are measured by the clinician. Outcome measures that consist of both self/patient- and clinician/observer-measured items have been recommended over patient-administered ones, so as to

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minimize belief mismatch, a problem that has been associated with patient-administered tools (McDowell and Newel, 1996). On the basis of all these, we embarked on developing an outcome measure for knee and hip osteoarthritis that would be both patient- and clinician-administered and would be appropriate for the Nigerian environment. The present paper reports on the development of IKHOAM and initial scientific evidence for the responsiveness, criterion and construct validity of the IKHOAM. The responsiveness of a clinical instrument is its sensitivity to slightest changes in patients' conditions over time while validity is the extent to which an instrument measures what it is intended to measure (McDowell and Newell, 1996).

## MATERIALS AND METHODS

### Development of IKHOAM

The conceptual basis of IKHOAM was that in osteoarthritis of the knee and/or hip, certain functional limitations occur. It was therefore developed noting key areas of difficulty and changes in the physical functioning of patients with knee and hip osteoarthritis. We considered some activities that are important to many patients who attend our clinic. To develop the content of the outcome measure, we interviewed some patients with knee and hip OA that were referred to our clinic (Physiotherapy Out-patient clinic, University College Hospital, Ibadan) to determine the common activities of daily living they had difficulty with. Following this, the measuring tool was given the name "Ibadan Knee/Hip Osteo-Arthritis Outcome Measure" (IKHOAM). It was made specific to osteoarthritis of the knee and hip because these are the two joints most frequently involved in Nigerians (Alonge, 2002).

### Description of the IKHOAM

The IKHOAM (see addendum) is a three part instrument and it takes about fifteen minutes to complete. Parts 1 and 2 are patient-report, which may be completed by the patient (self) or through interview. Part 1 measures disability in activities of daily living and part 2 assesses participation restrictions (handicap) due to knee/hip osteoarthritis. The component questions for these parts of IKHOAM

were compiled from interviews of Nigerian OA patients, as well as items from some outcome measures available in literature. These were the Arthritis Impact Measurement Scales (Meenan et al, 1980), Stanford Health Assessment Questionnaire (Fries et al, 1980), and the Functional Status Questionnaire (Jette, 1986). Only questions or items that are relevant to the knee and hip joints and those that Nigerians are familiar with were selected. Part 1 of IKHOAM comprises 25 items of functional activities and part 2 included 3 items of restriction. Part 3 of IKHOAM comprises 5 physical performance tests that are rated by the clinician. The ratings of these tests were determined using data collected during a pilot study involving 10 patients with knee or hip OA and 10 age-matched apparently healthy individuals without knee or hip pain. The data served as a guide to possible limits of performance on each test by individuals with and without knee/hip pain. The tests are as follows:

a) **Walk Test:** Subjects were asked to walk to and fro on a long corridor (pre-marked at 5m intervals) at their own pace until they were tired to proceed. The distance covered by the subjects ranged from 46m to 257m. The walk test was thereafter rated 0 to 5 with ability to walk 250m or more distance graded 5 and the ability to walk 50m or less distance graded 0 (see addendum).

b) **Squat Test:** In standing position, with both hands on the waist, each subject was asked to squat as far as possible, looking straight forward and keeping the back straight. The range of motion and the degree of difficulty with which squatting was performed were observed and graded as shown in the addendum.

c) **One Leg Stance Test:** Subjects were asked to stand on their preferred (apparently healthy subjects), affected leg (subjects with joint pain on one leg) or more painful leg (subjects with joint pain both legs) with the eyes opened for as long as they could and timed using a stop watch. Subjects were allowed to practice standing on one leg 6 times before the actual test. Three trials were allowed and the best performance was recorded for each subject. The time recorded for the subjects varied between

35 seconds and 4 minutes 7 seconds. Subsequently, ability to maintain balance for 4 minutes or more was graded 5, ability to maintain balance for less than 1 minute was graded 1 and inability to balance on one leg at all was graded 0 (see addendum).

d) **Stairs Climbing Test:** Each subject was asked to climb an 8-step staircase with fixed banisters at a comfortable pace. Each step was 15cm high. Performance was graded according to the amount of assistance required by subjects as shown in the addendum.

e) **Balance Test:** Each subject was asked to balance on a wooden wobble board and was timed using a stop watch. Three trials were allowed and the best performance was recorded for the subject. The time recorded for the subjects was between 8 seconds and 49 seconds and the ability to maintain balance for 45 seconds or more was graded 5 and ability to maintain balance for less than 10 seconds was graded 1 (see addendum).

### Content Validity

In order to improve content validity of the instrument (IKHOAM), contributions were received from 8 Physiotherapists with over 10 years of working experience and 3 Consultant Orthopaedic Surgeons from the University College hospital (UCH), Ibadan, Nigeria. After taking their comments and suggestions, a second draft was produced and it was assessed by 24 physiotherapists from 6 other tertiary health institutions and 6 secondary health institutions in Southwestern geopolitical zone of Nigeria during a focus group discussion. Using their comments and suggestions, a third draft was produced and then pre-tested on 15 patients with osteoarthritis of knee, and or hip (these subjects did not participate in the main study). The frequency of endorsement of all items was found to be satisfactory. The final draft of the IKHOAM is as shown in the addendum.

### Score calculation

Part 1 of IKHOAM rates 25 disability attributes on a 5-point ordinal scale (0-4) for each of the degree of difficulty experienced and nature of assistance required

in carrying out the activities. Part 2 contains 3 attributes of participation restrictions on a 4-point ordinal scale (0-3) for the extent of restriction in participation. Part 3 includes 5 physical performance tests.

Scores were computed as follows:

- a) The degree of difficulty and the nature of assistance required to carry out each of 25 items in part 1 was scored between 0 and 4 each. This gave a maximum obtainable score of 200 (4 x 25 for degree of difficulty and 4 x 25 for nature of assistance).
- ii) The extent of participation restriction in performing the 3 items in part 2 were scored between 0 and 3, giving a maximum obtainable score of 9 (3 x 3 for extent of restriction).
- iii) Part 3 contains 5 items with a maximum obtainable score of 23 (5 for 250 walk test, 4 for squat test, 5 for one leg stance test, 4 for stairs climbing test and 5 for balance test). The maximum obtainable score on IKHOAM is 232 (200+9+23). The score for a subject was calculated in percentage as:

$$\frac{\text{Subject's Score}}{\text{Total Possible Score}} \times 100$$

Low score on IKHOAM implies low level of physical functioning ability and high score means high level of physical functioning.

### Investigation on Validity and Responsiveness of IKHOAM

Fifty five male and female patients already diagnosed as having osteoarthritis (OA) of one or both knees and/or hips were recruited into the study but only 49 completed the study. They were patients attending physiotherapy and orthopaedic outpatient clinics of the University College Hospital (UCH), Ibadan and they were recruited as they became available. They formed the OA group (OAG). Forty nine apparently healthy age and sex-matched individuals without pain or other symptoms of knee or hip osteoarthritis (pain free group or PFG) also participated in the study. The subjects in the PFG were workers and retirees of the UCH.

Approval of the Joint University of Ibadan and University College Hospital Institutional Review Committee on human subject research was granted and informed consent from each patient was obtained. The subjects in the PFG were assessed on IKHOAM during only one visit while the patients with osteoarthritis were assessed on IKHOAM before and after a 6-week treatment programme. In addition, the pain intensity score of the OAG was measured using the Visual Analogue Scale which has been shown to be useful in the Nigerian clinical setting (Akinpelu and Olowe, 2002). Parts 1 and 2 of IKHOAM were administered through an interview and the physical performance tests (part 3) were conducted by one of the authors (ACO).

### Data Analysis

Data were summarized by calculating the mean and standard deviation. Data were also subjected to the following statistical analyses:

- 1) Independent t test was used to compare IKHOAM scores of the OAG and the PFG to provide initial evidence of construct validity. Correlation between IKHOAM and VAS scores of the OAG before and after the 6 week physiotherapy programme was analysed using the Spearman Rank Order Correlation to demonstrate initial criterion-related validity of IKHOAM (McDowell and Newell, 1996).
- 2) For the OAG, IKHOAM scores before and after the 6 week physiotherapy programme was compared using paired t-test and correlation between changes in IKHOAM and VAS scores following the 6 week physiotherapy programme was analysed using Spearman Rank Order Correlation to demonstrate responsiveness of IKHOAM (McDowell and Newell, 1996).

### RESULTS

Forty nine osteoarthritis patients (20 males, 29 females) with a mean age of 58.3 ±13.0 years and 49 apparently healthy individuals (19 males, 30 females) with a mean age of 55.1±13.2 years participated in the study.

The mean IKHOAM score of the PFG (98.1±2.9) was significantly higher

**Table 1: t-test for IKHOAM and VAS scores.**

		OAG		PFG		t-value	P-value
		Mean	S.D.	Mean	S.D.		
<b>IKHOAM Score (%)</b>	Pre-Rx	78.9	9.2	98.1	2.9	13.84*	0.000
	Post-Rx	86.0	7.8				
	t-value	4.1**					
	P-value	0.000					
<b>VAS Score (%)</b>	Pre-Rx	5.4	2.0				
	Post-Rx	2.7	1.9				
	t-value	6.9**					
	p-value	0.000					

\* = Independent t-test (Critical t-value at p = 0.05, df = 47 equals 2.021)

\*\* = Paired t-test (Critical t-value at p = 0.05, df = 48 equals 2.021)

Rx = Treatment, OAG = Osteoarthritis Group, PFG = Pain Free Group

**Table 2: Spearman's Correlation Coefficient between IKHOAM and VAS Scores of OAG.**

	Pre-Rx VAS Score	Post-Rx VAS Score	Post-Rx change in VAS score
Pre-Rx IKHOAM Score	-0.347 (p = 0.002)		
Post-Rx IKHOAM Score		-0.461 (p = 0.000)	
Post-Rx change in IKHOAM score			-0.319 (p = 0.000)

Critical r-value at p = 0.05, df = 48 equals 0.288 Rx = Treatment

(p = 0.00) than the pre-treatment score of the OAG (78.9±9.2) (Table 1). After the treatment programme, the mean IKHOAM score of the OAG increased significantly (P = 0.00) to 86.02±7.83 (giving a mean increase of 7.2) (Table 1). The mean VAS score of the subjects in the OAG decreased significantly (p=0.00) from a pre-treatment value of 5.4±2.0 to a post-treatment value of 2.7 ±1.9, (giving a mean decrease of 2.70).

Significant negative correlation coefficients were observed between IKHOAM and VAS scores before (r = -0.35) and after (r = -0.46) the 6 weeks treatment programme (Table 2). There was a significant negative correlation (r = -0.32) between changes in IKHOAM scores and changes in VAS scores following the 6 week treatment programme (Table 2).

**DISCUSSION**

The Ibadan Knee/Hip Osteo-Arthritis Measure (IKHOAM) was developed for evaluating the outcome of therapeutic interventions in patients with knee and/or hip osteoarthritis in the Nigeria clinical settings. The final objective of this study was to determine the validity and responsiveness of the IKHOAM. The mean age of subjects in the OA group (58.3±13 years) supports the fact that osteoarthritis is a disease of middle and old age and the gender distribution of the OA group (20 males and 29 females) indicated a slight female bias (3:2).

The finding that the IKHOAM score of the Pain-Free Group (PFG) was significantly higher than that of the OA group indicates that IKHOAM is able to differentiate between individuals with and without painful knee and/or hip conditions. It also shows that individuals with knee and/or hip OA were lower in physical functioning than those without knee or hip joint pain. The significant negative correlation between the IKHOAM and VAS (pain intensity) scores of the OA group before and after the 6 week treatment programme indicates that subjects who had higher levels

of pain were lower in physical function and vice versa. This finding demonstrates that pain is a major factor contributing to reduced level of physical functioning in individuals with osteoarthritis. The hypotheses that there would be significant correlation between the IKHOAM scores and VAS scores of subjects before the 6 week treatment programme and after the 6 week treatment programme are accepted. These findings provide initial evidence that IKHOAM possesses criterion-related validity, (VAS being the criterion measure) and that it assesses the effect of knee and/or hip OA on physical function and performance of patients.

The ability of IKHOAM to detect changes in patients' status over time was demonstrated by the significant difference between IKHOAM scores before and after 6 weeks of physiotherapy and the significant negative correlation between changes in IKHOAM scores and changes in VAS scores following the 6 week programme. This suggests that IKHOAM can be used to evaluate outcomes of therapeutic interventions for patients with painful knee/hip osteoarthritis. This attribute contributes to the value of IKHOAM as an outcome measure.

**CONCLUSION AND RECOMMENDATION**

From the findings of this study, it was concluded that IKHOAM demonstrates initial qualities of responsiveness and validity, and may be used for measuring outcomes of interventions in patients with painful knee and/or hip osteoarthritis in the Nigerian and similar clinical settings.

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**ADDENDUM: IBADAN KNEE/HIP OSTEOARTHRITIS OUTCOME MEASURE (IKHOAM)**

**PART I: INDICATE THE EXTENT OF LIMITATIONS YOU EXPERIENCE IN CARRYING OUT THE FOLLOWING ACTIVITIES USING THESE SCALES:**

**Degree of difficulty:** 4 = no difficulty; 3 = mild difficulty; 2 = moderate difficulty; 1 = severe difficulty; 0 = inability to carry out the activity.

**Nature of Assistance:** 4 = requires no assistance; 3 = requires use of aid(s)/device(s) only; 2 = requires assistance of one person only; 1 = requires assistance of one person and the use of aid(s); 0 - unable to perform the activity.

	Difficulty	Assistance
1. Washing all body parts during shower.		
2. Walking within the house		
3. Sweeping with a short broom		
4. Walking outside the house for 15-20 minutes		
5. Putting on under clothes		
6. Getting in and out of a saloon car		
7. Hand washing of clothes at floor/low level		
8. Rising from bed/mat		
9. Rising from high chair (dining/office chair)		
10. Putting on/lacing shoes or buckling sandals		
11. Rising from an easy chair or sofa		
12. Sweeping with a long brush/broom or using mop stick		
13. Participating in coitus		
14. Incomplete kneeling/prostrating to show courtesy/greet elders		
15. Getting on/off water closet toilet		
16. Getting in and out of a bus/high vehicle		
17. Standing for at least 15 minutes (waiting at bus stop/working in a modern kitchen with high cooker)		
18. Manual grass cutting/hoeing/gardening		
19. Sitting on the heels (Islamic praying posture)		
20. Climbing stairs		
21. Picking things from floor/low level (kitchen cabinet)		
22. Kneeling (Christian praying posture)		
23. Sitting on a very low stool (e.g. when cooking on a low stove or firewood at floor level)		
24. Descending stairs		
25. Using pit/Asiatic toilet		

**PART II: INDICATE THE EXTENT OF RESTRICTION YOU EXPERIENCE PARTICIPATING IN THE FOLLOWING LIFE SITUATIONS USING THE SCALE BELOW:**

**Extent of restriction:** 3-full participation, 2- at risk full participation, 1-participation with restriction, 0-no participation

	Extent
1. Performing duties at work (office or at home.	
2. Travelling for one hour or more	
3. Participation in social gatherings (e.g. wedding, naming, funeral, birthday parties)	

### PART III: PHYSICAL PERFORMANCE TESTS

#### 250m Walk Test

- 5 - able to walk 250m or more at one stretch
- 4 - able to walk 200-<250m at one stretch
- 3 - able to walk 150-<250m at one stretch
- 2 - able to walk 100-<150m at one stretch
- 1 - able to walk 50-<100m at one stretch
- 0 - able to walk <50m at one stretch

#### Squat Test

- 4 -  $\geq 100^\circ$  knee flexion
- 3 - 70-99° knee flexion
- 2 - 40-69° knee flexion
- 1 - 10-39° knee flexion
- 0 - < 100° knee flexion

#### One leg Stance Test

- 5 - can be maintained for 4 minutes or more
- 4 - can be maintained for 3-<4 minutes
- 3 - can be maintained for 2-<3 minutes
- 2 - can be maintained for 1-<2 minutes
- 1 - can be maintained for <1 minute
- 0 - unable to perform the test

#### Stairs Climbing Test

- 4 - can climb with no difficulty and no assistance
- 3 - can climb with mild difficulty (one railing)
- 2 - can climb with moderate difficulty (two railings)
- 1 - can climb with severe difficulty (two railings and help)
- 0 - unable to climb.

#### Balance Test on a Balance Board

- 5 - can balance for 45 seconds or more
- 4 - can balance for 30-<45 seconds
- 3 - can balance for 20-<30 seconds
- 2 - can balance for 10-<20 seconds
- 1 - can balance for <10 second
- 0 - unable to balance at all.

#### SCORING:

Minimum score each part = 0

Maximum obtainable score for part 1 = 200

Maximum obtainable score for part 2 = 9

Maximum obtainable score for part 3 = 23

Total maximum obtainable score on IKHOAM = 232

**The score for each patient is calculated as:**

**Patient's score / Total possible score x 100**

(Wright et al, 1998)