Original Article

Item generation and content validation of domains with item pool for the individual with knee osteoarthritis: a mixed-method study

Geração de itens e validação de conteúdo de domínios e de itens para o indivíduo com osteoartrite do joelho: um estudo de método misto

Asir John Samuel[1]
Durairaj Kanimozhi[2]

[1]Corresponding author. Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Maharishi Markandeshwar (Deemed to be University), Mullana-133207, Ambala District, Haryana. India. asirjohnsamuel@mmumullana.org
[2]Department of Physiotherapy, Faculty of Medicine, Punjabi University, Patiala-147002, Punjab, India. kaninarkeesh1976@gmail.com

ABSTRACT | INTRODUCTION: There are several scales to evaluate subjective perceptions and individual components in individuals with knee osteoarthritis (IKOA). Till date, no scale is available to measure the combined balance, mobility, ADL and QoL in IKOA based on the International Classification of Functioning, Disability and Health (ICF). **OBJECTIVE:** The purpose of the study was to generate items and domains related to problems faced by IKOA and to validate the content by experts. **METHODS:** The domains and items were generated through extensive literature search (ELS) to extract items related to symptoms, balance, mobility, ADL and QoL in IKOA based on the International Classification of Functioning, Disability and Health (ICF) and through in-depth direct interview (IDDI) from 13 IKOA and three experts. The content validation of domains and items generated were validated by 10 experts through online Delphi survey. Minimum item-level content validation index (I-CVI) of 0.80 was considered to validate the identified items and the overall scale-level content validation index (S-CVI) of 0.90 was fixed to validate the generated items to use in scale development process. **RESULTS:** 117 items generated by IDDI and ELS were grouped under 18 domains initially. Content validation by Delphi method resulted in reduction with 56 item pool being grouped under the 14 domains with SCVI is 0.93. **CONCLUSION:** The comprehensive impairment, activity limitation and participation restriction item pool for IKOA under the proposed domains, have been developed and content validated. These items are recommended for their use in development of new comprehensive knee osteoarthritis index scale (CKOAI).

KEYWORDS: Construct validity. Criterion-related validity. Domains. Factor analysis. Inter rater reliability. Item development. Osteoarthritis. Scale formulation. Test retest reliability.

RESUMO | INTRODUÇÃO: Existem várias escalas para avaliar as percepções subjetivas e os componentes individuais em indivíduos com osteoartrite (OA) de joelho. Até o momento, não há escalas disponíveis conhecidas para medir o equilíbrio combinado entre mobilidade, AVD e QV em OA de joelho com base na Classificação Internacional de Funcionalidade, Incapacidade e Saúde (CIF). **OBJETIVO:** Gerar itens e domínios relacionados aos problemas enfrentados pelos indivíduos com OA de joelhos e validar o conteúdo por especialistas. **MÉTODOS:** Os domínios e itens foram gerados através de pesquisa bibliográfica extensa (ELS) para extrair itens relacionados a equilíbrio, mobilidade, ADL e QV em indivíduos com OA em joelhos baseados na CIF e através de entrevista aprofundada direta (EAD) em 13 pessoas com OA de joelhos e três especialistas. A validação de conteúdo dos domínios e itens gerados foi validada por 10 especialistas por meio da pesquisa Delphi online. O índice mínimo de validação de conteúdo em nível de item (I-CVI) de 0,80 foi considerado para validar os itens identificados e o índice de validação de conteúdo em nível de escala geral (S-CVI) de 0,90 foi fixado para validar os itens gerados para uso no processo de desenvolvimento da escala. **RESULTADOS:** Os 117 itens gerados por EAD na ELS foram inicialmente agrupados em 18 domínios. A validação de conteúdo pelo método Delphi resultou em uma diminuição para 56 itens agrupados em 14 domínios com SCVI de 0, 93. **CONCLUSÃO:** O conjunto abrangente de itens de deficiência, limitação de atividade e restrição de participação para indivíduos com OA de joelhos nos domínios propostos foi desenvolvido e o conteúdo validado. Esses itens são recomendados para uso no desenvolvimento de uma nova escala abrangente de índice de osteoartrite do joelho (CKOAI).

PALAVRAS-CHAVE: Validade de construto. Validade relacionada ao critério. Análise fatorial. Osteoartrite. Formulação de escala.

Submitted 09/24/2020, Accepted 11/27/2020, Published 01/11/2021
J. Physiother. Res., Salvador, 2021 February;11(1):11-31
http://dx.doi.org/10.17267/2238-2704rpf.v11i1.3304 | ISSN: 2238-2704
Designated editors: Cristiane Dias, Katia Sá

How to cite this article: Samuel AJ, Kanimozhi D. Item generation and content validation of domains with item pool for the individual with knee osteoarthritis: a mixed-method study. J Physiother Res. 2021;11(1):11-31. http://dx.doi.org/10.17267/2238-2704rpf.v11i1.3304

Introduction

One of the worldwide leading causes of disability and pain is osteoarthritis[1]. 22% to 39% of the 1.252 billion population suffer from osteoarthritis (OA). Hip and knee OA are the most prevalent forms of OA with the overall prevalence of knee OA, 28.7%[2]. This will increase by 33.5% in 2030 due to the alarming increase in the aging population[3]. Individuals with knee OA (IKOA) are seen with deficits in static and dynamic balance which comprises impaired proprioception, muscle strength, disturbed postural control, and decreased range of motion at knee joint[4]. Furthermore, IKOA has pain and increase physical limitation and functional limitation[5,6]. Eventually decreasing their quality of life (QoL)[7].

Static balance in IKOA is assessed using several outcome measures such as timed single-leg stance[8], functional reach test[9], and variation of postural sway in unipedal or bipedal stance[10]. For more than two decades, the Berg Balance Scale and Tinetti Performance-Oriented Mobility Assessment (balance subscale) were used to assess dynamic balance[11,12]. Recently, the Community Balance and Mobility Scale (CB&M) have been validated for the purpose[13]. The isokinetic dynamometer has been in use to estimate muscle strength[14,15]. Proprioception was measured by joint repositioning test[16,17]. Several researchers explored QoL in IKOA[7,18–20] and combined it with functional independence[21].

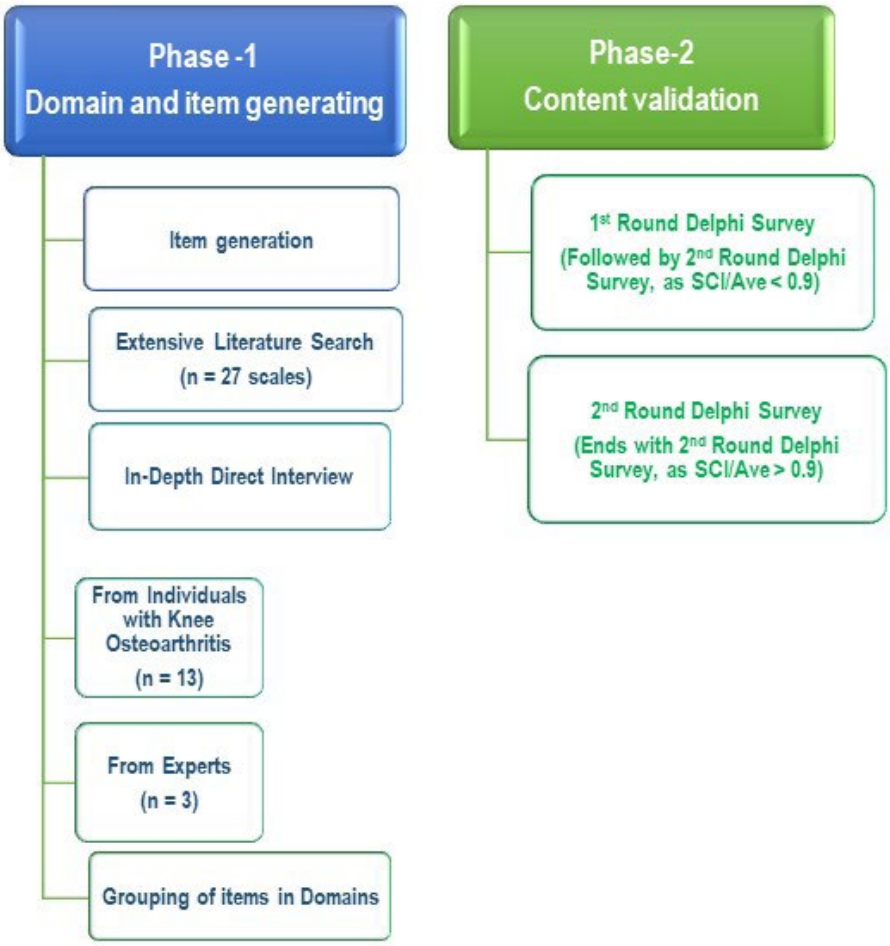
Various measures of knee function adopted by International Knee Documentation Committee (IKDC) 22 such as Knee Injury and Osteoarthritis Outcome Score (KOOS), Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS-PS), Knee Outcome Survey Activities of Daily Living Scale (KOS-ADL), Lysholm Knee Scoring Scale, Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Activity Rating Scale (ARS), and Tegner Activity Score (TAS) are subjective in nature. The patient reported a problem-based rating scale in IKOA with objective scoring is still lacking. This way, the purpose of this research project is to develop items for the rating scale that combines the assessment of balance, mobility, ADL, and QoL in IKOA.

Materials and methods

Protocol approval

The study protocol was approved by the institutional research committee (IRC) on 28th February 2017 (MMIPT/2017/5180) and then submitted and approved by the Institutional Ethics Committee (IEC) of Maharishi Markandeshwar Deemed-to-be University on 8th December 2017 (MMU/IEC/1021). After obtaining the approval from the Research Advisory Committee (RAC) and Institutional Ethics Committee (IEC), the study protocol was registered in the open-access public domain, ClinicalTrials.gov, on 5th April 2018 (NCT03498833). The study is composed of two main phases. First, item generation related to comprehensive impairment, activity limitation, and participation restriction in IKOA and grouping of item pool to relevant domains, and second, validation of generated item pool for the content validity. The first phase is composed of three sub-phases, item pool generation through extensive literature search (ELS), item pool generation through the in-depth direct interview (IDDI) method, and grouping of identified item pool under relevant domain related to impairment, activity limitation, and participation restriction domain. The first phase of the study was qualitative in nature, while the second phase used the Delphi survey method to validate the identified item pool. Hence, overall, the study was a mixed-method study. The details of the study phases were displayed in Figure 1.

Figure 1. Phases of the study



The study strictly adhered to the ethical principles for medical research involving human subjects, Helsinki declaration, 2013 adopted by the World Medical Association, the International ethical guidelines for health-related research involving humans (Revised, 2016) adopted by the Council for International Organizations of Medical Sciences (CIOMS) and also adopted the National ethical guidelines for biomedical and health research involving human participants by Indian Council of Medical Research (ICMR), 2017. Before the recruitment, all IKOA signed an informed consent form for their participation in an in-depth direct interview. The online informed consent form was obtained before the expert begins scale validation through the Delphi process.

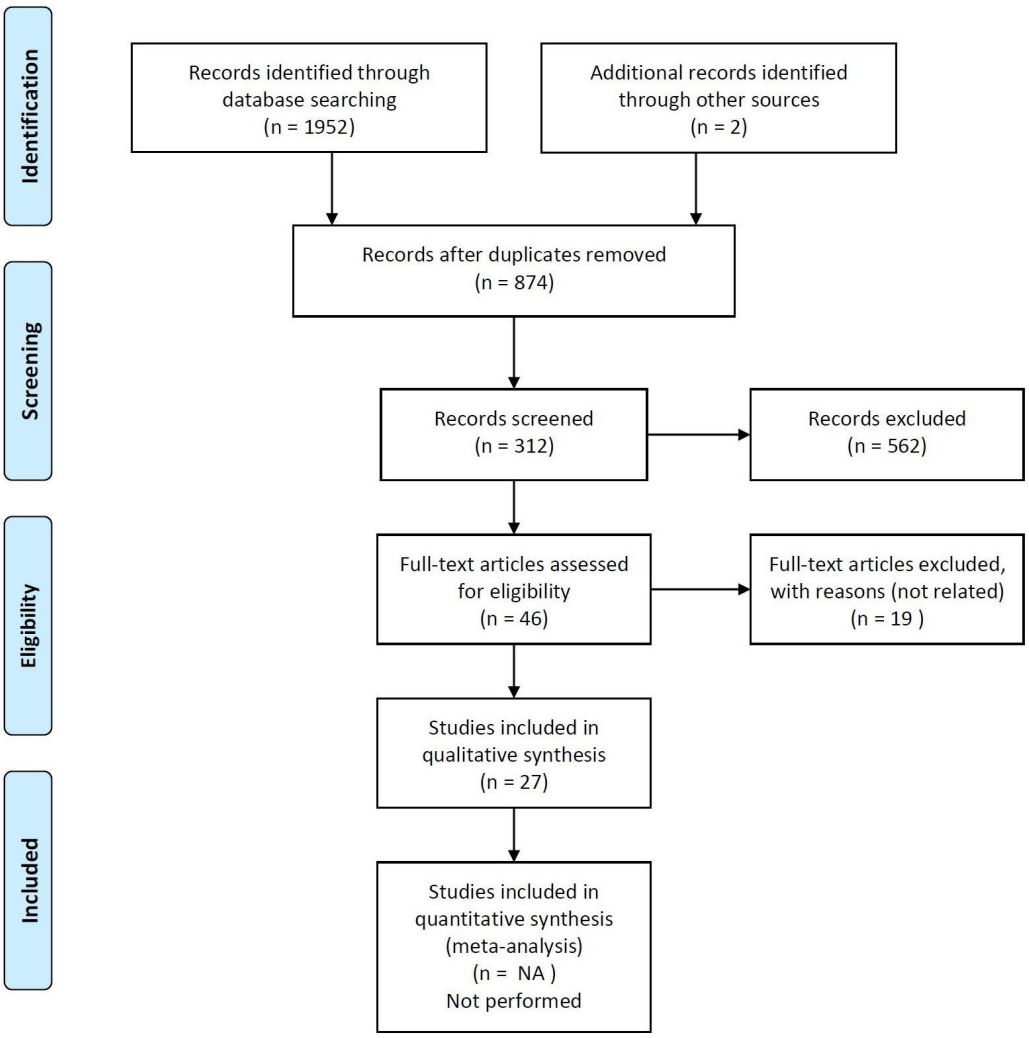
Phase 1: Domain and item generating

This phase of the study was aimed at generating the item pool related to impairment, activity limitation, and participation restriction in IKOA using ELS and IDDI.

Sub-phase 1: Literature search

Extensive literature (ELS) in the English language were searched in PubMed, ProQuest, MD Consult, SCOPUS, Cochrane Library, and EbscoHost databases in the time frame between January 1980 and February 2018. Also, the reference part of the filtered articles was searched manually to confirm that no articles would be missed by any error in the electronic search. The primary author conducted the electronic search using the following medical subject headings (MeSH) terms: "knee", "knee joint", "knee osteoarthritis", "osteoarthritis", "outcome", "outcome assessment", "outcome studies", "outcome research", "pain", "Physical therapy modalities", "Physical therapy techniques", "physiotherapy", and "exercise". These MeSH terms were used in association with Boolean operators such as "AND", "OR" and "NOT". From a total of 1954 articles, 874 duplicates were removed, 312 screened, 562 excluded, and 46 full-text articles were assessed for eligibility. After the removal of 19 non-relevant articles, only 27 scales were included in the qualitative analysis. The flowchart describing the details of the study included was displayed in Figure 2.

Figure 2. Flowchart describing details of studies included in scale validation



Sub-phase 2a: In-depth direct interview from IKOA

For IDDI, thirteen IKOA who comprised all four grades of on knee radiograph (Kellgren and Lawrence) grading system were approached in person at home or at the outpatient department (OPD) by the principal investigator to collect the data. We have recruited thirteen patients that were asked to generate the items that are relevant to assess their impairment, activity limitation, and participation restriction. First, the patients were asked to mention different items related to impairment that they feel important to be included in the pool. Second, they were asked to report items related to activity limitation Patients, and third, items related to participation restriction. Fourth, they were motivated to fill a maximum number of items which they feel appropriate based on their experience concerning functional activity in daily life. Fifth, the patients were given the item pool identified from the literature and were asked to add more items that were not mentioned in the literature. This procedure was chosen to yield the maximum number of items the patients felt that needed to be on the scale. After the generation of items from the literature and interviews, the items were pooled together and corrected for duplicates.

Sub-phase 2b: In-depth direct interview from experts

Three physiotherapists who had a minimum clinical experience of 10 years (experts) in the field of physiotherapy were approached to report about the functional activities, which IKOA reported to be difficult to perform. This approach was considered to obtain the maximum number of items to be included under the functional task, which is unique to this scale.

Sub-phase 3: Grouping item in domain

After generating items by ELS and IDDI, the items were grouped under the domains identified. First, the items that were closely related in function were identified and grouped. This was followed by placing the grouped items under the relevant domain generated. It was ensured that all the items were included under any of the domains identified.

Phase 2: Content validation by Delphi methodology

The content validation of identified items was executed by the online Delphi method. The two round Delphi survey was carried out to achieve a consensus of 80% agreement among the identified panel of 10 experts. These experts were physiotherapists with at least 10 years of clinical experience in treating IKOA from different geographical locations within India, to identify the needs for IKOA in each round of Delphi survey. As more than 10 experts were deemed to be unnecessary, we have included not more than a panel of 10 experts in each Delphi survey. The panel of experts who participated in the first round Delphi survey was not selected in the second round. The identified items were added to the Google Forms with each item bearing three options, “agree”, “disagree”, and “neutral”. As acknowledged and advised by the early writers[23–25], we have used a 3-point rating scale for the item validation. The experts were asked to exercise their opinion about each item with the above options. The “neutral” option was included to avoid skipping the items.

Eighty percent of agreement between the experts was fixed in a recommendation by Lynn to yield the item-level content validation index (I-CVI) of 0.80. According to Lynn’s (1986) criteria, a minimum I-CVI of 0.78 for 6 to 10 experts is required to validate each item on a scale[24,25]. The item pool was selected by the experts based on the relevance to impairment, activity limitation and participation restriction, simplicity, and clarity. Feedback and comments provided by the experts regarding the inclusion of additional items which was not included earlier in scale validation were also considered. The grouping of items under the domains was sent to the panel of experts (sample of 10). The first round Delphi method of scale validation resulted in scale-level content validation index (SCVI) less than the recommended level (SCVI/Ave = 0.90)26, hence the second round Delphi method of scale validation was carried out after the elimination of individual item less than 0.78 (I-CVI)[25]. Each round of Delphi method of scale validation was executed by

emailing the Google Forms to the identified panel of experts (n=10 in each round). Twenty experts (2n) who are expert in treating IKOA were identified created Google Form link were emailed. That were sent email reminders, phone calls, and messages on WhatsApp® to the non-responded experts after five working days, and the Google Form link was closed once the required response was obtained. The filled online content validation forms received from the experts were analyzed.

Data analysis

Description of the articles screened, excluded, and included were reported in the whole number. Demographic dimensions of IKOA, along with the grade of OA, were tabulated. Item pool generated through ELS and IDDI were also tabulated. The duplicate item generated was highlighted and retained under the tabulated items of either ELS or IDDI. Each generated item was validated and reported in terms of I-CVI. The overall validation of the proposed scale with item pool was reported with S-CVI after the end of each Delphi method of scale validation. S-CVI was computed by both approaches, the universal agreement calculation method (S-CVI/UA) and the averaging calculation method (S-CVI/Ave)[24]. Lynn recommended that minimum I-CVI of .78, in case of 6 to 10 experts, and overall, the scale should an SCVI/Ave of .90 or higher for considered to have excellent content validity[25].

Results

Extensive literature search resulted in total of 19856 articles. After the removal of duplicates (18742), screening (1114), excluded (962), assessed for eligibility (152) and non-relevant articles (125). 27 studies were included in qualitative synthesis. From 27 studies, 13 articles were included in the item pool development. From 13 articles, seven scales' (AIMS - Arthritis Impact Measurement Scales; KOOS - Knee Injury and Osteoarthritis Outcome Score; KSKSS - Knee Society Knee Scoring System; LISOHK - Lequesne Indexes of Severity for Osteoarthritis of the Hip and Knee; NKSKSS – The New Knee Society Knee Scoring System; OKS - Oxford Knee Score; TLKSS – Tegner Lysholm Knee Scoring Scale) were used in generating item pool and domain. Total 51 items were identified by ELS, 48 items by IDDI. After removing two duplicates with ELS, IDDI resulted in 46 items. The details of item pool generated by extensive literature search with source of literature was displayed in Chart 1. The demographic characteristic of IKOA included in-depth review with their qualitative report related to their problem due to knee osteoarthritis were reported in Chart 2 and the combined 97 items pool generated by both ELS and IDDI were tabulated in Chart 3.

Ten performance-based functional tasks developed through ELS and IDDI are displayed in Chart 4. That way, 117 identified item pool were grouped under 18 domains according to their relevance was displayed in Chart 5. The first round Delphi survey results in the removal of 43 items and yields a total of 64 items (in Chart 6) with SCVI/Ave is 0.77 and mean expert proportion is also 0.77. Hence, the item pool entered the second round Delphi survey. At the end of the second round, the Delphi survey resulted in 56 items with SCVI/Ave is 0.93, and mean expert proportion is 0.93. As SCVI /Ave of 0.90 or higher is considered to have excellent content validity, the third round of the Delphi survey was not performed. Thus, the content validation by a panel of experts resulted in 56 item pool being grouped under the 14 domains. The I-CVI for each item and domain are tabulated in Chart 7.

Chart 1. List of items generated and its source through extensive literature search based on the International Classification of Functioning, Disability, and Health (ICF)

S. No	Items	Source	Scale
1.	Walking outside the house for 15-20 minutes	Literature	IKHOAM
2.	Walking with one stick	Literature	LISOHK
3.	Constant swelling	Literature	TLKSS
4.	Walking in uneven surfaces	Literature	LISOHK
5.	Swelling after ordinary activities	Literature	TLKSS
6.	Swelling after moderate activities	Literature	TLKSS
7.	Swelling after vigorous activities	Literature	TLKSS
8.	Swelling on severe exertion	Literature	TLKSS
9.	Stand up from a chair after meal	Literature	OKS
10.	Getting up from squatting/toilet chair	Literature	KOOS
11.	Squatting	Literature	KOOS
12.	Get up from kneel down	Literature	OKS
13.	Sitting on the heels (praying posture)	Literature	IKHOAM
14.	Incomplete kneeling to show courtesy to greet elders	Literature	IKHOAM
15.	Kneeling	Literature	IKHOAM/KOOS
16.	Gardening	Literature	IKHOAM
17.	Hoeing	Literature	IKHOAM
18.	Washing all body parts during shower	Literature	IKHOAM
19.	Hand washing of clothes at floor/low level	Literature	IKHOAM
20.	Taking off socks/lower pant	Literature	WOMAC/KOOS
21.	Putting on under clothes	Literature	IKHOAM
22.	Turning in bed	Literature	KOOS
23.	Pain interference with usual daily work	Literature	OKS
24.	Limping when walking, because of knee pain	Literature	OKS
25.	Remaining standing for 30 min increases pain	Literature	LISOHK
26.	Picking up any objects from floor/ground	Literature	KOOS
27.	Bucking sandals/lacing shoes	Literature	IKHOAM
28.	Pain in sitting position for 2 h	Literature	LISOHK
29.	Available knee flexion	Literature	NKSKSS
30.	Sit to stand from easy-chair	Literature	IKHOAM
31.	Getting up from bed	Literature	KOOS
32.	Knee catch or hung up during walking	Literature	KOOS
33.	Knee extension lag	Literature	KSKSS
34.	Knee varus/valgus	Literature	NKSKSS
35.	Knee flexion deformity	Literature	NKSKSS
36.	Morning stiffness	Literature	WOMAC/AIMS
37.	Knee straightening	Literature	KOOS
38.	Knee bending/stiff knee	Literature	KOOS
39.	Going shopping	Literature	KOOS/ WOMAC
40.	Discomfort in sitting position for minimum 2 h continuously	Literature	LISOHK
41.	Walking with two Canes/sticks	Literature	LISOHK
42.	Walking with walker/frame or crutches	Literature	AIMS/KSKSS
43.	Rising from high chair (dining/office chair)	Literature	IKHOAM
44.	Lifting or carrying groceries	Literature	AIMS
45.	Public transport difficult	Literature	AIMS
46.	Household shopping	Literature	OKS
47.	Mopping the floor	Literature	IKHOAM
48.	Sweeping with broom	Literature	IKHOAM
49.	Climbing stairs*	Literature	IKHOAM/ WOMAC
50.	Descending stairs*	Literature	IKHOAM/ WOMAC
51.	Getting in and out of car	Literature	OKS/ LISOHK

Abbreviations: AIMS - Arthritis Impact Measurement Scales; IKHOAM-Ibadan Knee/Hip Osteoarthritis Outcome Measure; KOOS - Knee Injury and Osteoarthritis Outcome Score; KSKSS - Knee Society Knee Scoring System; LISOHK - Lequesne Indexes of Severity for Osteoarthritis of the Hip and Knee; NKSKSS – The New Knee Society Knee Scoring System; OKS - Oxford Knee Score; TLKSS – Tegner Lysholm Knee Scoring Scale

Chart 2. Individuals with knee OA reported problems related to ADL recorded through the in-depth direct interview (IDDI) (to be continued)

S.No	Patient Name	Age/Sex	Condition	Stage of OA	Reported problems
1.	Patient 1	65/M	B/L OA	2	1. Difficulty in climbing stairs 2. Pain increases during Sit to stand from chair and floor 3. Pain level increases in night 4. Difficult in toileting and bathing 5. Dressing difficult 6. Loss balance during walking 7. Walking within house painful 8. Rising from bed difficult without support 9. Sleep disturbed
2.	Patient 2	40/F	Lt knee OA	2	1. Difficulty in climbing stairs 2. Pain increases during walking 3. Difficulty and pain during squatting 4. Cannot bend the knee completely 5. Pain increased during cold season 6. Difficult during harvesting, cutting paddy 7. Watering crops/plants 8. Cattle rearing and milk taking from cow 9. Bending and picking water from bucket
3.	Patient 3	60/F	B/L OA with genu varum	2	1. Difficulty in descending stairs 2. Difficulty in squatting and getting up 3. Difficulty in bending and picking up any object from floor 4. Pain during rest while sitting and lying 5. Difficult in cross-sitting 6. Painful during walking within and outside the house 7. Not able to walk fast 8. Difficult to turn while walking 9. Car travel difficult 10. Taking holy water dip in temple premises 11. Sitting long time in car 12. Getting in and out of car
4.	Patient 4	46/M	B/L OA	2	1. Difficulty in climbing and descending stairs 2. Cannot bend the knee completely 3. Sit to stand difficult and painful 4. Feel grinding sound during walking 5. Not even able to climb the stairs 6. Travel in two-wheelers difficult 7. Riding bicycle difficult 8. Loss balance during wearing socks and footwear 9. Sitting in movie theatre difficult 10. Attending party or get together with friends 11. Work difficult due to long time sitting and standing 12. Bike transport 13. Morning walk/brisk walking
5.	Patient 5	55/F	B/L OA	2	1. Difficulty in climbing stairs 2. Cross-sitting not possible 3. Prolong standing painful 4. Sweeping with broom difficult 5. Mopping the floor difficult 6. Washing clothes difficult 7. Loss balance during stair climbing 8. Bowing down difficult 9. Kneeling down difficult during prayer 10. Getting in and out of car difficult 11. Performing pooja

Chart 2. Individuals with knee OA reported problems related to ADL recorded through the in-depth direct interview (IDDI) (continuation)

S.No	Patient Name	Age/Sex	Condition	Stage of OA	Reported problems
6.	Patient 6	65/M	B/L OA R>L	3	1. Climbing upstairs painful 2. Walking in uneven surfaces painful 3. Pain increased during cold season 4. Sit to stand painful 5. Difficulty in getting up from squatting position 6. Travel in car difficult 7. Difficult in rising from low chair/stool 8. Standing in queue during train ticket booking/temple 9. Turning difficult
7.	Patient 7	58/F	B/L OA	3	1. Morning stiffness 2. Night pain 3. Pain increased during cold season 4. Pain in inner (medial) aspect of knee joint 5. Not able to bend the knee completely 6. Knee catch or hung up during walking 7. Not able to straighten the knee completely 8. Difficulty in squatting and getting up 9. Difficulty in bending and picking up any object from floor 10. Pain during rest while sitting and lying 11. Standing painful 12. Difficult in rising from easy-chair 13. Sitting on sofa and getting up difficult 14. Disturbed sleep 15. Sitting and singing bajana (religious song) in temple and house
8.	Patient 8	55/Y	L - OA	3	1. Climbing upstairs painful 2. Walking in uneven surfaces painful 3. Pain increased during cold season 4. Sit to stand painful 5. Cutting paddy/wheat during harvesting difficult 6. Getting up from toilet painful and difficult 7. Public transport difficult 8. Sweeping with broom difficult 9. Mopping the floor difficult 10. Washing clothes difficult 11. Praying position difficult 12. Sitting on floor in temple difficult 13. Attending marriage difficult
9.	Patient 9	50/F	B/L OA		1. Pain after activity 2. Difficulty and pain during squatting 3. Cannot bend the knee completely 4. Sit to stand difficult and painful 5. Feel grinding sound during walking 6. Not even able to climb the stairs 7. Pain in anterio-inferior aspect of knee 8. Train and bus travel difficult 9. Taking more time to walk 10. Not able to sit and gossip for long time
10.	Patient 10	70/M	B/L OA		1. Pain during bending knee 2. Able to bend and straighten the knee completely. But bending painful 3. Walking in uneven surfaces painful 4. Pain in anterio-inferior aspect of knee 5. Bathing and toileting difficult
11.	Patient 11	72/M	B/L OA		1. Climbing upstairs painful 2. Pain increased during cold season 3. Sit to stand painful 4. Difficulty in getting up from squatting position

Chart 2. Individuals with knee OA reported problems related to ADL recorded through the in-depth direct interview (IDDI) (conclusion)

S.No	Patient Name	Age/Sex	Condition	Stage of OA	Reported problems
					5. Descending stairs difficult, sometimes loses control
12.	Patient 12	73/M	B/L OA with genu varum		1. Pain in inner (medial) aspect of knee joint 2. Not able to bend the knee completely 3. Knee catch or hung up during walking 4. Not able to straighten the knee completely 5. Walking possible only with stick 6. Taking rest in between during walking 7. Difficulty in squatting and getting up 8. Morning stiffness 9. Night pain 10. Walking inside house difficult 11. Pain during rest while sitting and lying 12. Standing painful 13. Difficulty in bending and picking up any object from floor 14. Bowing down difficult 15. Eating langar difficult 16. Difficult during prayer
13.	Patient 13	75/M	B/L OA		1. Walking painful 2. Knee bending painful 3. Squatting not possible 4. Side lying difficult 5. Sit to stand difficult 6. Using stick for confidence 7. Difficult in kneeling 8. Farming difficult

Chart 3. List of items generated through extensive literature search and in-depth direct interview based on the International Classification of Functioning, Disability, and Health (ICF) (to be continued)

S. No	Items	Source
1.	Climbing stairs	IDDI/ELS
2.	Descending stairs	IDDI/ELS
3.	Walking in uneven surfaces	IDDI
4.	Walking outside the house for 15-20 minutes	ELS
5.	Walking over ramp	IDDI
6.	Not able to walk fast	IDDI
7.	Picking up any objects from floor/ground	IDDI
8.	Walking inside house	IDDI
9.	Walking with wall support	IDDI
10.	Walking with one stick	ELS
11.	Constant swelling	ELS
12.	After ordinary activities	ELS
13.	After moderate activities	ELS
14.	After vigorous activities	ELS
15.	Swelling on severe exertion	ELS
16.	Sit to stand from chair	IDDI
17.	Sit to stand from floor	IDDI
18.	Sit to stand from easy-chair	IDDI
19.	Sit to stand from sofa	IDDI
20.	Stand up from a chair after meal	ELS
21.	Squatting	IDDI
22.	Getting up from squatting/toilet chair	IDDI
23.	Kneeling down	IDDI
24.	Get up from kneel down	ELS
25.	Sitting on the heels (praying posture)	ELS
26.	Bowing down by touching head on floor	IDDI
27.	Incomplete kneeling to show courtesy to greet elders	ELS
28.	Morning walk	IDDI
29.	Brisk walking	IDDI
30.	Knee bending/stiff knee	IDDI
31.	Knee catch or hung up during walking	IDDI
32.	Knee straightening	IDDI
33.	Cutting paddy/wheat	IDDI
34.	Gardening	ELS
35.	Hoeing	ELS
36.	Watering plant/crops	IDDI
37.	Sitting during toilet use	IDDI
38.	Standing and Bathing	IDDI
39.	Bending and picking water from bucket	IDDI
40.	Applying soap	IDDI
41.	Washing all body parts during shower	ELS
42.	Washing cloths	IDDI
43.	Hand washing of clothes at floor/low level	ELS
44.	Drying cloths	IDDI
45.	Wearing socks/footwear	IDDI
46.	Taking off socks/lower pant	ELS
47.	Bucking sandals/lacing shoes	IDDI
48.	Getting up from bed	IDDI
49.	Turning in bed	IDDI
50.	Side lying in bed	IDDI
51.	Overall dressing	IDDI
52.	Putting on under clothes	ELS
53.	Wearing lower pant	IDDI
54.	Cross-sitting on floor in temple	IDDI
55.	Cross-sitting during eating/langar	IDDI
56.	Cross leg sitting on chair	IDDI
57.	Morning stiffness	IDDI

Chart 3. List of items generated through extensive literature search and in-depth direct interview based on the International Classification of Functioning, Disability, and Health (ICF) (conclusion)

S. No	Items	Source
58.	Pain interference with usual daily work	ELS
59.	Night pain	IDDI
60.	Limping when walking, because of knee pain	ELS
61.	Night stiffness	IDDI
62.	Pain during cold season	IDDI
63.	Stiffness during cold season	IDDI
64.	Remaining standing for 30 min increases pain	ELS
65.	Pain in sitting position for 2 h	ELS
66.	Available knee flexion	ELS
67.	Knee extension lag	ELS
68.	Knee varus/valgus	ELS
69.	Knee flexion deformity	ELS
70.	Train and bus travel difficult	IDDI
71.	Public transport difficult	IDDI
72.	Car travel – sitting prolong	IDDI
73.	Getting in and out of car	IDDI
74.	Travelling in Bike	IDDI
75.	Travelling in Bicycle	IDDI
76.	Attending party or get together with friends	IDDI
77.	Attending marriage function	IDDI
78.	Going shopping	ELS
79.	Discomfort in sitting position for minimum 2 h continuously	IDDI
80.	Walking with two Canes/sticks	ELS
81.	Walking with walker/frame or crutches	ELS
82.	Sitting in movie theatre difficult	IDDI
83.	Rising from high chair (dining/office chair)	ELS
84.	Lifting or carrying groceries	ELS
85.	Mopping the floor	IDDI
86.	Sweeping with broom	IDDI
87.	Standing in queue during train ticket booking/temple	IDDI
88.	Washing vessels	IDDI
89.	Cooking	IDDI
90.	Household shopping	ELS
91.	Sleep disturbed	IDDI
92.	Milking cows	IDDI
93.	Cutting vegetable for cooking	IDDI
94.	Not able to sit/stand and gossip for long time	IDDI
95.	Sitting and singing bajana (religious song) in temple/house	IDDI
96.	Performing pooja	IDDI
97.	Taking holy water dip in temple premises	IDDI

Chart 4. List of performance-based items generated and its source through extensive literature search (ELS) and in-depth direct interview (IDDI)

S. No	Items	Source	Scale
1.	Squatting	ELS/ IDDI	IKHOAM/ NKSKSS
2.	Standing on one foot over firm surface	ELS	IKHOAM
3.	Turn 90°	ELS	NKSKSS
4.	Turn 180°	ELS	NKSKSS
5.	Stair climbing (12-step/nine step/four step)	ELS	OARSI
6.	Gait speed (Self-paced 13 m)	ELS	OARSI
7.	Chair sit to stand (30-s chair-stand test/5R)	ELS	OARSI
8.	Floor sit to stand	IDDI	Therapist 1,3
9.	Standing on one foot over foam surface	IDDI	Therapist 2,3
10.	Standing on one foot over narrow surface	IDDI	Therapist 1,2

Abbreviations: ELS - Extensive literature search; IDDI - in-depth direct interview; IKHOAM-Ibadan Knee/Hip Osteoarthritis Outcome Measure; KOOS - Knee Injury and Osteoarthritis Outcome Score; NKSKSS – The New Knee Society Knee Scoring System; OARSI - Osteoarthritis Research Society International recommended Performance based-test

Chart 5. Items generated and domains after grouping (to be continued)

a. Body structure and function (Impairment)	
Items	**Pain**
1.	Morning
2.	Night
3.	During activity
4.	Cold season
5.	Remaining standing for 30 min increases pain
6.	Pain in sitting position for 2 h
7.	Limping when walking, because of knee pain
8.	Interference with usual daily work
Items	**Stiffness**
1.	Morning walk
2.	Knee bending/stiff knee
3.	Knee catch or hung up during walking
4.	Knee straightening
5.	Stiffness during cold season
6.	Night stiffness
Items	**Swelling**
1.	Constant
2.	After ordinary activities
3.	After moderate activities
4.	After vigorous activities
5.	On severe exertion
Items	**Alignment**
1.	Available knee flexion
2.	Knee extension lag
3.	Knee varus/valgus
4.	Knee flexion deformity
b. Activity limitation	
Items	**Stairs**
1.	Climbing stairs
2.	Descending stairs
Items	**Walking**
1.	Walking over uneven surfaces
2.	Walking over ramp
3.	Not able to walk fast
4.	Walking inside house
5.	Brisk walk
6.	Walking with wall support
7.	Walking with one stick
8.	Walking with two Canes/sticks
9.	Walking with walker/frame or crutches
10.	Walking outside the house for 15-20 minutes
Items	**Bathing**
1.	Standing and Bathing
2.	Bending and picking water from bucket
3.	Washing all body parts during shower
4.	Applying soap
Items	**Toilet use**
1.	Squatting
2.	Getting up from squatting
3.	Sitting during toilet use
Items	**Dressing**
1.	Overall dressing
2.	Putting on under clothes
3.	Wearing lower pant
4.	Wearing socks/footwear
5.	Taking off socks/lower pant
6.	Bucking sandals/lacing shoes

Chart 5. Items generated and domains after grouping (continuation)

Items	**Household work**
1.	Washing cloths
2.	Hand washing of clothes at floor/low level
3.	Picking up any objects from floor/ground
4.	Drying cloths
5.	Mopping the floor
6.	Lifting or carrying groceries
7.	Shopping
8.	Sweeping with broom
9.	Washing vessels
10.	Cooking
Items	**Transport**
1.	Train and bus travel difficult
2.	Public transport difficult
3.	Car travel – sitting prolong
4.	Getting in and out of car
5.	Bike transport
6.	Travelling in Bicycle
Items	**Sit to stand**
1.	Sit to stand from chair
2.	Sit (cross leg) to stand from floor
3.	Sit to stand from easy-chair
4.	Sit to stand from sofa
5.	Stand up from a chair after meal
Items	**Lying in bed**
1.	Getting up from bed
2.	Turning in bed
3.	Side lying in bed
	c. Participation restriction
Items	**Job performance**
1.	Discomfort in sitting position for minimum 2 h continuously
2.	Rising from high chair (dining/office chair)
3.	Cross leg sitting on chair
4.	Standing during working hours
5.	Walking during working hours
6.	Cutting paddy/wheat
7.	Hoeing/digging
8.	Watering plant/crops
9.	Milking cows
10.	Standing in queue during train ticket booking
Items	**Recreational activities**
1.	Not able to sit/stand and gossip for long time
2.	Gardening
3.	Sitting in movie theatre difficult
Items	**Social gatherings**
1.	Attending party or get together with friends
2.	Attending marriage function
3.	Incomplete kneeling to show courtesy to greet elders
Items	**Religious activities**
4.	Sitting and singing bajana (religious song) in temple/house
5.	Cross-sitting on floor in temple
6.	Performing pooja
7.	Sitting on the heels (praying posture)
8.	Kneeling down
9.	Get up from kneel down
10.	Taking holy water dip in temple premises
11.	Bowing down by touching head on floor
12.	Standing in queue in temple

Chart 5. Items generated and domains after grouping (conclusion)

d. Performance based-test	
Items	**Performance based functional task**
1.	Squatting
2.	Standing on one foot over firm surface
3.	Standing on one foot over foam surface
4.	Standing with narrow base of support
5.	Turn 90°
6.	Turn 180°
7.	Stair climbing (12-step/nine step/four step)
8.	Gait speed
9.	Chair sit to stand (Five-repetition chair-stand test)
10.	Floor sit to stand

Chart 6. Items generated, domains and percentage level of agreement between experts in terms of item-level content validation index after first round Delphi survey (to be continued)

Comprehensive Knee Osteoarthritis Index (CKOAI): Body structure and function (Impairment)		
Items	**Pain**	**I-CVI**
1.	Morning	0.50
2.	Night	0.80
3.	During activity	1.00
4.	Cold season	0.60
5.	Remaining standing for 30 min increases pain	0.90
6.	Pain in sitting position for 2 h	0.60
7.	Limping when walking, because of knee pain	0.90
8.	Interference with usual daily work	0.80
Items	**Stiffness**	**I-CVI**
1.	Morning walk	0.90
2.	Knee bending/stiff knee	0.90
3.	Knee catch or hung up during walking	0.50
4.	Knee straightening	0.80
5.	Stiffness during cold season	0.90
6.	Night stiffness	0.60
Items	**Swelling**	**I-CVI**
1.	Constant	0.40
2.	After ordinary activities	0.40
3.	After moderate activities	0.70
4.	After vigorous activities	1.00
5.	On severe exertion	1.00
Items	**Alignment**	**I-CVI**
1.	Available knee flexion	0.50
2.	Knee extension lag	0.90
3.	Knee varus/valgus	1.00
4.	Knee flexion deformity	0.80

Chart 6. Items generated, domains and percentage level of agreement between experts in terms of item-level content validation index after first round Delphi survey (continuation)

Comprehensive Knee Osteoarthritis Index (CKOAI): Activity limitation		
Items	**Stairs**	**I-CVI**
1.	Climbing stairs	1.00
2.	Descending stairs	1.00
Items	**Walking**	**I-CVI**
1.	Walking over uneven surfaces	1.00
2.	Walking over ramp	0.70
3.	Not able to walk fast	0.90
4.	Walking inside house	0.40
5.	Brisk walk	0.80
6.	Walking with wall support	0.60
7.	Walking with one stick	0.90
8.	Walking with two Canes/sticks	0.60
9.	Walking with walker/frame or crutches	0.80
10.	Walking outside the house for 15-20 minutes	0.80
Items	**Bathing**	**I-CVI**
1.	Standing and Bathing	0.60
2.	Bending and picking water from bucket	0.70
3.	Washing all body parts during shower	0.70
4.	Applying soap	0.60
Items	**Toilet use**	**I-CVI**
1.	Squatting	0.80
2.	Getting up from squatting	0.90
3.	Sitting during toilet use	0.90
Items	**Dressing**	**I-CVI**
1.	Overall dressing	0.50
2.	Putting on under clothes	0.70
3.	Wearing lower pant	0.80
4.	Wearing socks/footwear	0.90
5.	Taking off socks/lower pant	0.90
6.	Bucking sandals/lacing shoes	0.70
Items	**Household work**	**I-CVI**
1.	Washing cloths	0.60
2.	Hand washing of clothes at floor/low level	0.70
3.	Picking up any objects from floor/ground	1.00
4.	Drying cloths	0.60
5.	Mopping the floor	0.90
6.	Lifting or carrying groceries	0.90
7.	Shopping	0.70
8.	Sweeping with broom	0.90
9.	Washing vessels	0.80
10.	Cooking	0.90
Items	**Transport**	**I-CVI**
1.	Train and bus travel difficult	0.90
2.	Public transport difficult	0.90
3.	Car travel – sitting prolong	0.60
4.	Getting in and out of car	0.90
5.	Bike transport	0.70
6.	Travelling in Bicycle	0.60
Items	**Sit to stand**	**I-CVI**
1.	Sit to stand from chair	1.00
2.	Sit (cross leg) to stand from floor	0.80
3.	Sit to stand from easy-chair	0.60
4.	Sit to stand from sofa	0.80
5.	Stand up from a chair after meal	0.80
Items	**Lying in bed**	**I-CVI**
5.	Getting up from bed	0.90
6.	Turning in bed	0.60
7.	Side lying in bed	0.40

Chart 6. Items generated, domains and percentage level of agreement between experts in terms of item-level content validation index after first round Delphi survey (conclusion)

Comprehensive Knee Osteoarthritis Index (CKOAI): Participation restriction		
Items	**Job performance**	**I-CVI**
1.	Discomfort in sitting position for minimum 2 h continuously	0.80
2.	Rising from high chair (dining/office chair)	0.90
3.	Cross leg sitting on chair	0.70
4.	Standing during working hours	0.80
5.	Walking during working hours	0.80
6.	Cutting paddy/wheat	0.70
7.	Hoeing/digging	0.70
8.	Watering plant/crops	0.90
9.	Milking cows	0.80
10.	Standing in queue during train ticket booking	0.80
Items	**Recreational activities**	**I-CVI**
1.	Not able to sit/stand and gossip for long time	0.60
2.	Gardening	0.80
3.	Sitting in movie theatre difficult	0.70
Items	**Social gatherings**	**I-CVI**
1.	Attending party or get together with friends	0.80
2.	Attending marriage function	0.70
3.	Incomplete kneeling to show courtesy to greet elders	0.70
Items	**Religious activities**	**I-CVI**
1.	Sitting and singing bajana (religious song) in temple/house	0.70
2.	Cross-sitting on floor in temple	0.80
3.	Performing pooja	0.80
4.	Sitting on the heels (praying posture)	0.80
5.	Kneeling down	0.90
6.	Get up from kneel down	0.90
7.	Taking holy water dip in temple premises	0.70
8.	Bowing down by touching head on floor	0.70
9.	Standing in queue in temple	0.60

Comprehensive Knee Osteoarthritis Index (CKOAI): Domain development for functional task		
S. No	**Items**	**I-CVI**
1.	Squatting	0.80
2.	Standing on one foot over firm surface	0.80
3.	Standing on one foot over foam surface	0.70
4.	Standing with narrow base of support	0.60
5.	Turn 90°	0.90
6.	Turn 180°	0.80
7.	Stair climbing (12-step/nine step/four step)	0.90
8.	Gait speed	0.90
9.	Chair sit to stand (Five-repetition chair-stand test)	0.90
10.	Floor sit to stand	0.80

Chart 7. Level of agreement between experts expressed in terms of item-level content validation index for selected domains and items after content validation after second round Delphi survey (to be continued)

Items	Pain	I-CVI
1.	During activity	0.90
2.	Remaining standing for 30 min increases pain	0.90
3.	Interference with usual daily work	1.00
Items	**Stiffness**	**I-CVI**
1.	Knee bending/stiff knee	1.00
2.	Knee straightening	0.90
3.	Stiffness during cold season	0.90
Items	**Knee Alignment and swelling**	**I-CVI**
1.	Knee extension lag	0.90
2.	Knee varus/valgus	0.90
3.	Knee flexion deformity	0.90
4.	Knee swelling after vigorous activities	0.90
Comprehensive Knee Osteoarthritis Index (CKOAI): Activity limitation		
Items	**Stairs**	**I-CVI**
1.	Climbing stairs	1.00
2.	Descending stairs	1.00
Items	**Walking**	**I-CVI**
1.	Walking over uneven surfaces	0.90
2.	Not able to walk fast	1.00
Items	**Toilet use**	**I-CVI**
1.	Squatting	0.90
2.	Getting up from squatting	0.90
3.	Sitting during toilet use	0.90
Items	**Dressing**	**I-CVI**
1.	Wearing lower pant	0.80
2.	Wearing socks/footwear	0.80
3.	Taking off socks/lower pant	0.80
Items	**Household work**	**I-CVI**
1.	Picking up any objects from floor/ground	0.80
2.	Mopping the floor	1.00
3.	Lifting or carrying groceries	0.90
4.	Sweeping with broom	0.80
5.	Washing vessels	0.90
6.	Cooking	0.80
Items	**Transport**	**I-CVI**
1.	Train and bus travel difficult	1.00
2.	Public transport difficult	0.90
3.	Getting in and out of car	1.00
Items	**Sit to stand**	**I-CVI**
1.	Sit to stand from chair	1.00
2.	Sit (cross leg) to stand from floor	1.00
3.	Sit to stand from sofa	1.00
4.	Stand up from a chair after meal	1.00
5.	Getting up from bed	0.80
Comprehensive Knee Osteoarthritis Index (CKOAI): Participation restriction		
Items	**Job performance**	**I-CVI**
1.	Discomfort in sitting position for minimum 2 h continuously	0.80
2.	Rising from high chair (dining/office chair)	0.80
3.	Standing during working hours	1.00
4.	Walking during working hours	1.00
5.	Watering plant/crops	0.80
6.	Milking cows	0.90
7.	Standing in queue during train ticket booking	1.00
Items	**Recreational activities**	**I-CVI**
1.	Gardening	1.00
2.	Attending party or get together with friends	0.90

Chart 7. Level of agreement between experts expressed in terms of item-level content validation index for selected domains and items after content validation after second round Delphi survey (conclusion)

Items	Religious activities	I-CVI
1.	Cross-sitting on floor in temple	1.00
2.	Performing pooja	1.00
3.	Sitting on the heels (praying posture)	1.00
4.	Kneeling down	1.00
5.	Get up from kneel down	1.00
Comprehensive Knee Osteoarthritis Index (CKOAI): Functional task		
S. No	**Items**	**I-CVI**
1.	Squatting	1.00
2.	Standing on one foot over firm surface	1.00
3.	Turn 90°	0.90
4.	Turn 180°	0.90
5.	Stair climbing (12-step/nine step/four step)	1.00
6.	Gait speed	1.00
7.	Chair sit to stand (Five-repetition chair-stand test)	1.00
8.	Floor sit to stand	1.00

Discussion

From the identified 117 item pool under 18 domains, 56 item pools were validated under 14 domains. About 50% of the identified items were excluded. The majority of the excluded items were from the activity limitation domain. The reason might be the difference in the level of agreement among the expert panel of a physiotherapist from various geographical zones of India. 10 expert panel was used in each Delphi survey as it was advised by Lynn that more than 10 was probably unnecessary[25]. The larger sample size would probably lead to issues of data handling and analysis[27]. In the Delphi survey, a panel of identified experts in a particular field is asked to complete a set of questions to identify the panel consensus on specific issue[28]. We have used the Delphi survey to validating the item pool because it has advantages over questionnaires and panel discussions. It is an efficient method over others as the members do not need to interact, which making their response possible even by distance. The consensus developed is without interaction among respondents, and thereby potential bias of one dominant person influencing other's thoughts in delivering their opinion could be eliminated[28]. But the disadvantage of this method were the reminder emails, phone calls and messages on WhatsApp® required to attain the required sample size. Another disadvantage is that the members of the expert panel should be computer or smartphone literate, which made us exclude a handful of potential expert members.

We have set 80% agreement[29] among the members of the expert panel to include in the item pool to be used in scale, CKOI. Green et al.[27] recommended 80% consider that the particular item has attained consensus and also, if 80% of the expert agree with the particular item then it would yield the item content validation index (I-CVI) of 0.80[25]. The findings of the current study provide some preliminary information about the range of items required in a scale representing mobility disability in the community. The identified item pool and domains highlight that the patient has reported problems with relation to their knee OA under various components of the ICF model. The validated item pool has input from both patients with knee OA and physiotherapist experts in treating knee osteoarthritis. The strength of this study lies in the qualitative development of items from IDDI and ELS. The process of using both methods in item pool generation resulted in the overlapping of a few items and the generation of unique items. This would minimize the missed out items. Functional task domain was also added which is unique in this report. This study had a few limitations. The participant recruited for IDDI in this study represented a convenience sample of IKOA that may have led to some degree of selection bias and judging fit of items under the domains were not conducted by Confirmatory factor analysis. Nevertheless, this was the first study to develop and validate the item pool under the ICF framework model. Future studies should consider the use of the statistical method, Confirmatory factor analysis to judge the fit of the item pool under the domains, and random sampling technique in recruiting IKOA. The developed and validated items should be tested for their psychometric and clinimetric properties, for their effective use among IKOA.

Conclusion

The comprehensive impairment, activity limitation and participation restriction item pool for IKOA under the proposed domains have been developed and content validated. These items are recommended for their use in development of new comprehensive knee osteoarthritis index scale (CKOAI).

Acknowledgements

The authors are very grateful to Dr. Vencita Priyanka Aranha, MPT, (Ph.D.), Research Scholar, Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Maharishi Markandeshwar (Deemed-to-be-University), Mullana, India, for providing logistic and technical support in content editing. This study forms a part of Ph.D. theses submitted by the first author, which can be accessed in Shodhganga, a reservoir of Indian Theses (uploaded on September 3rd 2020).

Author contributions

Samuel AJ and Kanimozhi N conceived and designed the study, conducted research, provided research materials, collected and organized data and wrote the first draft of the article. Kanimozhi N provided the logistic support.

Competing interests

No financial, legal or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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