

Study Protocol: Development, Validation and Implementation of Pain Education Module in Patients With Chronic Knee Osteoarthritis: A Mixed Method Study

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How to cite this article: Jui V. Banc, Chhaya V. Verma. Study Protocol: Development, Validation and Implementation of Pain Education Module in Patients With Chronic Knee Osteoarthritis: A Mixed Method Study. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Knee osteoarthritis is the most prevalent musculoskeletal disorder globally, with pain being the most important feature. Pain management is the cornerstone of knee osteoarthritis treatment. This study aims to develop a validated, understandable, and actionable pain education module for patients with Chronic Knee Osteoarthritis in the form of a video in English, Hindi, and Marathi.

Methods: The study will be conducted in three phases. The first phase of the study will include the development of the video in English, Hindi and Marathi. Phase 2 of the study will include validation of the video by experts from different specialties, including physiotherapists, Orthopaedic surgeons, pain interventionists, and people from the general population, using rigorous and robust research methods. The validated English, Hindi and Marathi Pain education videos will then be incorporated into the treatment of patients with chronic knee Osteoarthritis in the third phase of the study. This part of the study will be conducted in the form of a randomized controlled trial, (RCT) in which 120 patients with Chronic Knee OA will be included. With 60 patients in each group, the patients in Group 1 will receive pain education via video and the standard plan of care. Patients in Group 2 will receive only the standard of care. The assessment of patients will be performed by an assessor who will be blinded to the treatment allocation groups before and after treatment. The total treatment duration will be 6 weeks. The additional benefit of using the pain education module will be studied at the end of this study.

Discussion: The pain education module developed, validated, and tested in this study, if found to be effective, can be used for pain education in patients with chronic knee osteoarthritis as a regular treatment protocol. The results of this study may help reduce pain intensity and kinesiophobia and improve function and perception of knee osteoarthritis.

Keywords: *Pain education, chronic knee osteoarthritis, chronic pain, Pain neuroscience education*

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Submission date: August 10, 2025,

Revision date: November 14, 2025

Published date: April 14, 2026

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Introduction

Osteoarthritis (OA) is the most prevalent musculoskeletal disorder globally and the leading cause of chronic pain and disability in adults.^[1,2] It imposes a substantial clinical and economic burden, which continues to rise with aging populations and increasing obesity rates.^[3-5] In India, OA cases rose from 23.46 million in 1990 to 62.35 million in 2019, with a 10% increase in knee OA incidence since 1990.^[6]

Pain is the predominant and disabling symptom of knee OA, affecting function and quality of life.^[7] It typically progresses to wider areas and may involve other lower limb joints.^[8] Consequently, patients often reduce physical activity, influenced by factors such as age, gender, symptom severity, and ethnicity.^[9] Psychosocial factors—including self-efficacy, anxiety, social support, kinesiophobia, helplessness, pain catastrophizing, and depression—also affect pain perception and physical function.^[10-14]

Pain in knee OA is complex and multifactorial, encompassing peripheral, psychological, and neurological mechanisms.^[15,16] It aligns with the biopsychosocial model of the ICF, emphasizing biological, psychological, and social influences on symptoms and suffering. However, both patients and clinicians often attribute knee OA symptoms solely to structural damage, reinforcing the misconception that surgery is the only effective treatment.^[17] Persistent pain after total knee replacement challenges this belief.^[18-20]

Clinical guidelines from ESCEO and OARSI (2019) recommend education, structured exercise, and weight loss as core components of non-surgical management.^[21-23] Patient education—especially pain education—aims to improve knowledge, modify behaviour, and foster positive pain beliefs.^[24,25] A 2022 systematic review demonstrated that education enhances pain, function, and the effectiveness of conservative therapies in knee and hip OA.^[26]

Although existing models like Pain Neuroscience Education, Explain Pain, and Pain-Informed Movement show promise, they are generalized, lack condition-specific and culturally tailored content, and are seldom validated rigorously.^[26-29] Delivery methods are inconsistent, often designed at high

literacy levels and within Western contexts, limiting accessibility for Indian patients.^[30-37]

Current gaps include: (1) Development – absence of an India-specific pain education module for knee OA addressing myths and literacy; (2) Validation – lack of systematic content validation for accuracy and clarity; and (3) Implementation – limited clinician training and feasibility in clinical settings.

To address these, the present study adopts a three-phase approach: (i) development of a multimedia pain education module through expert consensus, (ii) validation for clarity, readability, and cultural appropriateness, and (iii) implementation testing among patients with knee OA. This design aims to deliver an evidence-based, context-specific, and implementable pain education resource for the Indian population.

Material and Methods

The study was conducted in three phases.

Phase 1: To develop a pain education module for patients with chronic knee osteoarthritis (multimedia content) in English, Marathi, and Hindi.

Phase 2: To validate the Pain education module from experts and representatives of general population using the Delphi

Phase 3: To study the effect of using a Pain Education module on pain perception, catastrophization, kinesiophobia, patients' beliefs, and knee function in patients with chronic knee Osteoarthritis: A randomized controlled trial.

Aim:

1. To develop, validate and implement Pain education module for patients with chronic Knee OA
2. To study the effect of pain education module on pain perception, catastrophization, kinesiophobia, and knee function in patients with chronic knee OA.

Objectives for Phase 1:

1. To develop a Pain education module for patients with chronic knee osteoarthritis (multi-media content) in English Marathi and Hindi

Objectives for Phase 2:

1. To validate the Pain education module for chronic knee osteoarthritis from experts & representatives of general population using the Educational Content Validation Instrument in Health (ECVIH)
2. To assess the Pain education module for chronic knee osteoarthritis for understandability and actionability of the multimedia content from experts and representatives of general population using the Patient Education Materials Assessment Tool for Audiovisual materials questionnaire (PEMAT-A/V)

Objectives for Phase 3:

1. To study the effect of Pain education module on patients with chronic knee osteoarthritis plus standard plan of care exercises on pain perception using the Numerical pain rating scale (NPRS) and Pain algometer
2. To study the effect of Pain education module on patients with chronic knee osteoarthritis plus standard plan of care exercises on pain catastrophization using the Pain Catastrophization Scale
3. To study the effect of a pain education module on patients with chronic knee osteoarthritis plus standard plan of care exercises on kinesiophobia using the Tampa Scale of Kinesiophobia.
4. To study the effect of Pain education module on patients with chronic knee osteoarthritis plus standard plan of care exercises on Knee function using the Knee Osteoarthritis Outcome Score (KOOS) and Timed Up and Go test (TUGT)
5. To study the effect of Pain education module on patients with chronic knee osteoarthritis plus standard plan of care exercises on Patient's beliefs using the Knee Osteoarthritis Fears and Beliefs Questionnaire (KOFBeQ)
6. To compare the effect of pain education module plus standard plan of care vs the effect of only standard plan of care exercises on pain perception, catastrophizing, Kinesiophobia, patient's beliefs and knee function in patients with chronic knee osteoarthritis.

Ethical Considerations: The Ethics Committee for Academic Research Projects (ECARP) gave ethical approval for the conduct of the study. Approval no. ECARP/2024/148. The study is also registered in the Clinical Trials Registry CTRI/2025/02/081419.

Study Design

Phase 1: Development of Multimedia Pain Education Module

- a. Study Design: Descriptive
- b. Duration: Approximately 1 year
- c. Sampling Method: Convenient sampling

Research Team:

- 2 experts for script development
- 1 animation artist/video editor/Graphic designer
- 1 language expert (English, Hindi, Marathi)

Procedure:

The development of the multimedia pain education module was guided by conducting a **robust literature review** and expert consensus.

A structured protocol was prepared to ensure transparency and replicability. The protocol for the literature review include:

- **Research Question:** Clearly framed using the PICOT framework to ensure the question is answerable, clinically relevant, and feasible.

P (Population): Adults with chronic knee osteoarthritis

I (Intervention): Pain education interventions (including Explain Pain, Pain Neuroscience Education, Pain-Informed Movement, or other structured educational strategies delivered in any format)

C (Comparison): Usual care, standard education, or no education intervention

O (Outcomes): Improvement in pain knowledge, beliefs, attitudes, pain intensity, function, and self-management behaviours

T (Time): Short-term and long-term follow-up (if reported in included studies)

- **Search Strategy:** Comprehensive search across multiple electronic databases (e.g., PubMed, Scopus, Web of Science, Cochrane Library, CINAHL), using relevant keywords, Boolean operators, and Medical Subject Headings (MeSH).
- **Study Selection Criteria:** Inclusion and exclusion criteria (e.g., study type, population, language, publication timeframe) will be defined to ensure appropriate screening of studies.

The findings from the literature review, along with **expert consensus**, will guide the **script development**. Content will be structured around three key pain education frameworks:

1. Explain Pain
2. Pain Neuroscience Education (PNE)
3. Pain-Informed Movement

The script will also address **common myths and misconceptions about knee osteoarthritis (KOA)**, ensuring that culturally relevant patient beliefs are considered.

The initial draft of the script was developed in **English** for clarity and tested for readability and understandability. The educational module was then be converted into a **multimedia format** (animated/video-based) by a graphic designer and editor. Following this, the content was translated into **Hindi and Marathi**, ensuring semantic accuracy, cultural appropriateness, and linguistic clarity through expert language review.

The **feedback from subject experts and language reviewers** was incorporated to refine the content. And a final version of the module was then incorporated for the next phase, that is the validation of the multimedia content.

Phase 2: Validation of the Module via Delphi Study

- a. Study Design: Delphi Study
- b. Duration: ~6 months – 1 year
- c. Sampling Method: Convenient sampling
- d. Participants:

Expert Panel: Professionals with >10 years clinical experience managing chronic knee OA (orthopaedist, rheumatologist, interventional pain specialist, 2 physiotherapists)

General Population: Two representatives from the general population.

Validation Tools and Processes:

Educational Content Validation Instrument in Health (ECVIH):

Experts and laypersons rated the content. (Table 1)

- o CVI ≥ 0.83 (experts), ≥ 0.78 (general population) = Acceptable.^[38]

Patient Education Materials Assessment Tool for Audiovisual materials PEMAT-A/V: (Table 1) Measures of understandability and actionability. Cut-off score: $\geq 70\%$ ^[39]

Delphi Rounds: Was conducted until threshold scores were met.

Comments and suggestions were used to revise the video modules.

Medical experts with more than 10 years of experience in management of pain in chronic knee osteoarthritis were included in the study. There will be a total of 5 experts: 1 orthopaedic surgeon, 1 rheumatologist, 1 interventional pain medicine expert and 2 physiotherapists trained in pain neurophysiology. Other than the experts' 2 members of the general population were also included in the validation process who were fluent with English, Hindi and Marathi languages.

Data Analysis Plan (Phase 2):

- Content Validity Index (CVI):
 - o I-CVI = (# agreed items) / total reviewers
 - o S-CVI = Average of I-CVI values
- PEMAT-A/V Score Calculation:
 - o (Total agreed / Total possible) $\times 100 = \% \text{ score}$
 - o Cut-off: $\geq 70\%$ for both understandability and actionability

Phase 3: Implementation of Pain education module (RCT)

- a. Study Design: Randomized Controlled Trial
- b. Duration: Approximately 1 year
- c. Participants: Patients with chronic knee osteoarthritis

d. Setting: Musculoskeletal Physiotherapy OPD of The SIA College of Health Sciences, Dombivli

e. Sampling Method: Simple Random sampling

f. Sample Size: 120 (60 per group)

Sample Size Calculation:

- Based on:
 - o $\alpha = 0.05$, Power = 80%
 - o True difference = 0.7 units
 - o SD = 1.27 (Supe et al., 2023)
- Formula from Chow S et al., 2008
- Final size: $\sim 52 + 10\%$ attrition = 60 per group

Randomization:

- Using Excel-generated random number table.
- Participants select a chit with group allocation.

Participants with knee osteoarthritis fitting in the clinical American College of Rheumatology (ACR) criteria^[40] were included in the study. The participant with the age from 50-75 years, with pain lasting for more than 3 months, ^[41]pain on Numerical Pain Rating Scale (NPRS) more than or equal to 4-8 on 10, with grade 1 to 3 radiological severity of Osteoarthritis were included in the study. Participants with recent trauma, fracture or soft tissue injuries, history of knee surgery, known cognitive or neurological deficits were excluded. Those with other known rheumatological, systemic or infectious cause of knee pain were excluded from the study.

A written informed consent was taken from all the participants. They were assigned randomly to one of the 2 groups using a closed seal envelope. Participants of both the groups were assessed by a blinded assessor before the start of the intervention. The assessor was blinded to treatment allocation groups. (Table 2).

Participants in Group 1 received Pain education using the developed pain education module along with the standard plan of physiotherapy management for 6 weeks with 3 sessions/week.

Participants in Group 2 received only the standard plan of Physiotherapy management with 3 sessions/week for 6 weeks.

Both the groups were re-assessed at the end of 6 weeks by the same blinded assessor.

Interventions:

1. Pain Education Module Group:

- Weeks 0-6:
 - o Video 1: *Knee Osteoarthritis*
 - o Video 2: *Pain Education*
 - o Alternated weekly (e.g., Week 0: Video 1, Week 1: Video 2, and so on)
- Session Format:
 - o Videos shown in the OPD
 - o Q&A sessions after each visit
 - o Participants encouraged to reflect and review at home

2. Standard of Care Group:

- Frequency: 3 supervised sessions/week
- Content:
 - o Mobility exercises
 - o Strength training
 - o Balance/proprioceptive exercises
 - o Stretching
- Guidelines Referenced: Clinical guidelines by European Society for Clinical and economic aspects of Osteoporosis, Osteoarthritis and musculoskeletal diseases (ESCEO) and Osteoarthritis Research Society Initiative (OARSI 2019) ^[21-23].
- Pain Algometry: ^[42]
 - o Device perpendicular to medial joint line.
 - o Pressure increased at 2 kp/s.
 - o Average of 3 readings, 20 sec apart.
- Timed-Up-and-Go Test: ^[43]
 - o 3-meter walk from chair to cone and back.
 - o Stopwatch timing.
 - o One practice trial will be given.

Data Analysis Plan (Phase 3):

- Software: SPSS

- Normality Testing: Shapiro-Wilk or Kolmogorov-Smirnov test
- Descriptive Stats: Mean, SD, % frequency
- Between-Group Analysis:
 - o If normal: Independent t-test
 - o If non-normal: Mann-Whitney U test
- Within-Group Comparison:
 - o If normal: Paired t-test (2 points) or Repeated Measures ANOVA (>2 points)
 - o If distribution is not normal: Wilcoxon Signed Rank (2 points) or Friedman test (>2 points)
- Categorical Data: Chi-square test

- Significance Level: $p < 0.05$
- Power: 80%, Alpha: 0.05, Beta: 0.20

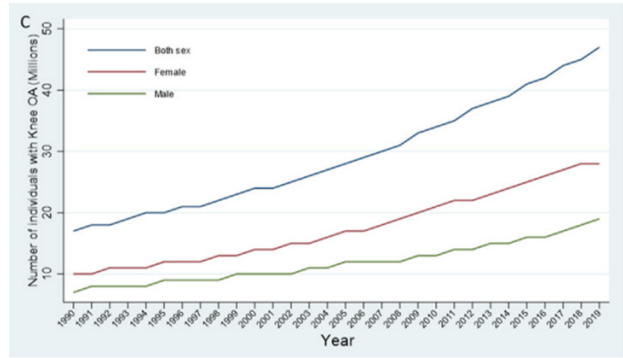


Fig 1: Graph showing trend of rising cases of Knee OA in India from 1990 to 2019

Table 1: Outcome Measures Used in Phase 2:

Sr. No	Outcome Measure	Description	Psychometric Properties	Permission
1	Educational Content Validation Instrument in Health (ECVIH)	Validates content in health education materials	ICC > 0.8	Obtained
2	Patient Education Materials Assessment Tool for Audiovisual materials	Assesses understandability and actionability of AV materials	$\alpha = 0.71$	Public domain

Table 2: Outcome Measures used in Phase 3

Tool	Description	Psychometric Properties	Permission/Source
NPRS	Numeric pain scale (at rest & during activity)	ICC = 0.95, SEM = 0.48, MDC = 1.3	Public domain
Pain Algometry	Measures pressure pain threshold at medial joint line	ICC = 0.909–0.956	Therapist assessed
Pain Catastrophizing Scale	Assesses negative thoughts about pain	$\alpha = 0.87–0.93$	MAPI permission obtained
Tampa Scale of Kinesiophobia	Measures fear of movement	ICC = 0.887, Moderate validity	Author permission obtained
KOOS	Measures knee function (Hindi & Marathi validated)	ICC > 0.75 for all subscales	MAPI permission obtained
Timed-Up-and-Go (TUG)	Assesses function, gait and balance	ICC > 0.94, MDC = 3.4 s	Therapist administered
KOFBeQ	Assesses fears & beliefs in knee OA patients	Cronbach $\alpha = 0.85$, ICC = 0.81	Permission request sent

Results and Discussion

The study hypothesizes that the pain education module would be effective, understandable and actionable. It would help to address the myths and beliefs in the minds of the patients and their caregivers regarding knee osteoarthritis and pain associated with it. The module would be effective in reducing pain intensity, improving pain perception, reducing Kinesio phobia and improving knee function. The existing literature supports the use of pain education strategies in the management of chronic knee osteoarthritis. But the unavailability of a culture specific, understandable and actionable pain education module, prompted us to take up this study. The pain education module thus developed in this study will prove to be of help to address the myths and beliefs in the minds of the patients with chronic knee osteoarthritis.

The pain education module if found to be effective can be used for pain education in patients with chronic knee osteoarthritis as a regular treatment protocol. The Pain education in the form of the video would be easy to administer in the treatment protocol. A similar pain education module can be developed, targeted for other musculoskeletal problems presenting with chronic pain like Low back pain, fibromyalgia, Complex regional Pain syndrome, Rheumatoid arthritis, etc.

We understand that there might be certain limitations to the study.

The pain education module was developed and tested only in 3 languages. So, its applicability may be restricted. India being a diverse nation with a wide range of languages spoken across the country there might be limitations to the use of the pain education multimedia.

Conflict of Interest: There is no conflict of interest.

Source of Funding: None

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