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Protocol for a quasi-experimental study to ascertain the effectiveness of using eKnee School approach to impart self-care education to patients suffering from knee osteoarthritis during COVID-19 pandemic

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Abstract:

BACKGROUND: Knee osteoarthritis (KOA) patients seek improvement in their quality of life by attaining independence in activities of daily living. Literature recommends nonpharmacological intervention as first-line treatment for KOA. The study aims to ascertain the effectiveness of online supervised nonpharmacological intervention sessions of virtual knee school (eKS) training among mild and moderate KOA patients in comparison to routine care during COVID-19 pandemic and assessment of cost-effectiveness of eKS against the routine care for KOA patients during COVID-19 pandemic.

MATERIALS AND METHODS: A quasi-experimental pre-post with control group, enrolling 50 participants each in two groups: usual/routine KOA care or usual care plus KS interventions via virtual mode. Our primary outcome measures are pain, quality of life, and incremental cost-effectiveness ratio. Secondary outcomes include performance-based tests (30-second chair test, timed up and go test, 6-minute walk test) and patient satisfaction. Intervention fidelity will be assessed with a *priori* checklist tailored to eKS assessing adherence, dose, quality, and user engagement in the key components. Quantitative data collection will be conducted at baseline and 6 months. Descriptive data analysis will be carried for quantitative data. For qualitative data, the thematic analysis will be performed; we propose to undertake a deterministic and probabilistic sensitivity analysis to address the issue of uncertainty in the present cost-effectiveness analysis model.

CONCLUSION: The management of KOA through virtual mode emphasizes the concepts of patient-as-person, family-centered, with socially interactive approach. The study will provide information on the effectiveness of nonpharmacological interventions for improving the quality of life of patients suffering from KOA through virtual knee school. Nevertheless, pitfalls in running eKS will be noted, which will help improve all aspects of online medical communications in the future.

Keywords:

Knee osteoarthritis, knee school, nonpharmacological interventions

Introduction

Osteoarthritis (OA) is a leading cause of chronic disability after fourth decade of life.^[1,2] Weight-bearing joints, especially

knee joint, are most affected leading to knee osteoarthritis (KOA). Intractable pain is the most common symptom reported by KOA patients.^[3,4]

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Osteoarthritis Research Society International recommendations and Pan-American league of associations for rheumatology Consensus Recommendations for the Management in Osteoarthritis of Hand, Hip, and Knee recommend self-care, patient education, aerobic or resistive exercises, lifestyle modifications, weight reduction, and various physical therapies as first-line treatment for KOA.^[5,6] These are to be used in conjunction with a pharmacological regimen to decrease pain.^[7] The aim is to promote normal functioning in KOA patients and enhance their quality of life (QoL).

All KOA patients need relief from symptoms. They seek improvement in their QoL by attaining independence in activities of daily living.^[8,9] They desire easy access to low-cost and effective treatment for KOA that includes explanation, counselling, doctor-patient interaction, and guidance for self-care. A randomized controlled trial on nonpharmacological interventions (NPIs) for patients suffering from KOA conducted in a tertiary care institution established that adequate patient-therapist communication for the explanation of the requisite lifestyle modification including the exercises improved the outcome in KOA patients.^[2] Studies have reported that meditation can also help to reduce feelings of pain and alter responses to pain.^[10,11]

Hence, a knee school (KS) for patients suffering from KOA was established as a multidisciplinary endeavor in the outpatient department (OPD) of Post Graduate Institute of Medical Education and Research, an apex medical institute of northern India in November 2019 (CTRI/2020/03/024311).^[12] This involved collective counselling for a group of patients and exercises, after individual data collection and informed consent. Piloting of intervention registered 75 patients for this venture. However, due to COVID-19, the altered scenario of social interactions led to drastic modifications in healthcare delivery modalities, as routine OPDs were suspended. Since continuation with KS sessions was not physically possible during COVID-19, the strategy was changed from 'in-person' KS" to the concept of a virtual Knee School (eKS).^[12] This pilot eKS showed that remote management of KOA using web-based applications was practically feasible.^[12]

Based on the success of the pilot study of eKS, the present study is proposed with an objective to ascertain the effectiveness of online supervised NPI sessions among mild and moderate KOA patients in comparison to routine care; additional objective is assessment of cost-effectiveness of eKS against the routine care for KOA patients.

Materials and Methods

Study design and setting: A quasi-experimental pre-post with control group, enrolling in two groups of participants: Usual/routine KOA care or usual care plus Knee School interventions via eKS (a set of exercises, Dos and Don't, Yoga, meditation, dietary management, and lifestyle modifications).

Time period: The study is ongoing (2021-2023).

Settings: Hospital.

Study participants and sampling.

Sample size estimation

A sample size of 50 patients in each group was calculated at $\alpha = 0.05$, power = 80%, and effect size of 0.57 (based on Jönsson *et al.*^[13] for significant improvement in pain and QoL) between the groups. Thus, 63 subjects (N from Power estimate/1-attrition rate) will be registered in each arm assuming 20% attrition rate.

Participants

Inclusion criteria: The study will include KOA patients who

- Agree to alter their lifestyle and willing to follow-up.
- Are aged 40-65 years of either gender.
- Kellgren/Lawrence [K/L] (grade ≥ 1).^[14]
- Patients having knee pain, the presence of osteophytes in the patellofemoral joint on 30° flexion lateral radiographs.
- IT savvy: patient or caregiver.

Forty years of age as the lower cutoff was selected due to the early prevalence of KOA among Indians.

Exclusion criteria: The study will exclude patients awaiting surgery, those with deformity or intra-articular pathology, and those who have undergone hip or unilateral knee replacement, significant cardiac comorbidity, body mass index >40 , or any comorbidity not allowing proper exercise protocol.

Data collection tool and techniques

Recruitment method and screening procedures

Information for recruitment in the eKS will be circulated through newspapers/social media and e-mail of one of the designated team members of eKS will be provided. Participants will contact one of the designated team members after seeing the ads. E-mail Id will be assessed by the researcher on daily basis. List of participants will be contacted telephonically by researcher and online appointment of the patient with an orthopedic surgeon for consultation will be fixed via virtual mode (or in-person depending on the COVID pandemic situation). Patients

will be asked to share the reports of the investigations with the concerned orthopedic surgeon through WhatsApp during COVID-19 pandemic. Eligibility of the patients for eKS will be assessed in consultation with orthopedic surgeon concerned (after initial work up, investigation, and prescription). Patients who will meet the eligibility criteria will be recruited via the online or in-person mode (depending on the COVID pandemic situation).

During COVID-19, hospital teleconsultation system will also be used for recruiting patients from the OPD of Orthopedics, and Physical Medicine and Rehabilitation (PRM). Contact details of the researcher will be shared with concerned orthopedic and PRM doctors for referral.

After the COVID-19 pandemic is over, a referral system will be established for KOA patients to the eKS room from OPD of Orthopedics and PRM registered in routine OPD. Recruitment of the patients, baseline, and end-line assessment will be done in-person in the eKS room, but sessions will be conducted via virtual mode only. As, the protocol submitted in January 2021, during the COVID-19 pandemic, the authors will keep both the options (online/in-person) for the recruitment of the patients due to uncertainties of the situation. If the restrictions on social distancing will be over, the present study (eKS) being quasi-experimental will not have randomization for the recruitment of the patients.

Intervention

Links of the sessions will be provided to the patients (set of exercises, Dos and Don't, Yoga, meditation, dietary management, and lifestyle modifications) after the recruitment [Table 1, Figure 1]. The set of exercises will include supine hamstring stretch, hamstring isometric, isometric quadriceps, standing quadriceps, short arc lift, isometric quadriceps with medial rotation of the hip, quadriceps isometrics in sitting position, and hip

abduction. All the enrolled patients will be provided with e-link of patient education booklets containing the details of various components, for example, descriptions and pictures of the set of exercises. Customization of the exercises in consultation with orthopedic surgeon, a physiotherapist, and patients/caregivers will be done. Online supervised group sessions will be held by physiotherapists, orthopedists, and other experts for six months [Table 1]. The duration of each session may range from 30 to 45 minutes. The Michie model^[15] may be adopted for designing the lifestyle modifications.

Family members of the patients will also be involved in the online sessions. Patients who report consistent and complete relief will be involved in the online training of new KOA patients. A group comprising of 21 patients each will be accommodated in one online session to ensure attention and assimilation among group members. Overall, three groups comprising of 21 patients each will be formed. The schedule will be kept different for each group, and flexibility will be provided to registered patients to choose any group at their convenience. After every session, feedback will be taken from patients via WhatsApp/telephone and teleconsultation will be fixed with orthopedic surgeon if required. A telephonic helpline may be employed if the need is felt during the study.

Online follow-up of patients will be done as per schedule. During online sessions, the patients will be asked about the degree of relief in their symptoms. Those who report consistent and complete relief in consecutive two online sessions will be removed from the study. The reported relief will be matched with outcome variables.

Participants will be instructed to maintain a logbook to keep a record of the compliance with all the instructions given at KS. Logbooks will be monitored by the researcher on the monthly basis via online mode. Feedback will be taken from these logbooks at end-line.

Figure 1: Schedule of enrolment, interventions, and assessments for eKnee school

| Time point** | Study period | | | | | |
|---|--------------|------------|-----------------------|----------|-------------------|-----------|
| | Enrolment | Allocation | Post-allocation | | | Close-out |
| | | | Jan 2021- Dec 2022 | Jan 2023 | Feb-March 2023 | |
| Enrolment: | | | | | | |
| Eligibility screen | | | | | | |
| Informed consent | | | | | | |
| Interventions: | | | | | | |
| Intervention group (orientation and links to online sessions) | | | | | | |
| Online sessions | | | | | | |
| Control group | | | | | | |
| Assessments: | | | | | | |
| Baseline variables | | | | X | | |
| Demographic profile, Visual analogue scale, WOMAC, QoL | | | | | | |
| Performance based tests | | | | X | | X |

Table 1: List of interventions, sessions, time of outcome measures in eKS

| Sessions/interventions | Time point/ Session | Mode of delivery | Responsibility | No. of sessions |
|--|--|--|---|---|
| Orientation to the patient, Online links to sessions: - Set of exercises, Dos and Don'ts of Meditation, Yoga, Dietary management | Baseline first Session | Online | Principal Investigator and researcher | 1 |
| Demographic profile, VRS*, WOMAC**, QoL | Baseline first Session | Online/telephone | Researcher | |
| Orientation of the video conferencing App | Baseline first Session | Online/telephone | Researcher | |
| Register in Social media/WhatsApp group for coordination | Baseline first Session | Online/telephone | Researcher | |
| Performance-based tests | Baseline first Session | In-person/remotely (depends on COVID-19) | Physiotherapist | |
| Physiotherapy sessions (once fortnightly in 6 months) | Second -12 th | Online | Physiotherapist | 12 |
| Reorientation sessions on meditation, Yoga, dietary management (Once in 2 months) | 13 th -15 th | Online | Yoga and meditation, dietary experts | 3 |
| Query redressal, return demonstration, and experience sharing | 16 th | Online | Orthopedic surgeons, physiotherapists and Experts | Dedicated 10/15 minutes after every session |
| Teleconsultation with Orthopedic Surgeon | On request by the patient 17 th Session | Online | Orthopedic surgeon | - |
| Performance-based tests | End-line 18 th Session | In-person/remotely (depends on COVID-19) | Physiotherapist | 1 session |
| VRS, WOMAC, QoL | End-line 19 th Session | Telephone/online | Researcher | 1 session |
| Feedback | 20 th Session | | Researcher | 1 session |
| Total sessions | 20 sessions | | | |

*Verbal rating scale. ** Western Ontario and McMaster Universities Arthritis Index

Comparator (Usual/routine care)

The KOA patients receiving routine care in the OPD of the study hospital during and after COVID-19 will be considered as comparators. As a routine, KOA patients first report to Orthopedics OPD and after clinical work-up, they are referred for physiotherapy modalities to the PRM department.

As the OPDs are closed during COVID-19 pandemic, the care provided through teleconsultation will be considered as usual care for KOA patients. After easing of the COVID restrictions, the routine care provided to KOA patients via in-person mode in the OPD will be the comparator arm. The patients in the comparator arm will be provided links to resource material after study is over.

Intervention fidelity

It will be assessed with a priori checklist tailored to eKS assessing adherence, dose, quality, and user engagement in the key components.

Primary outcomes

A summary of outcome measures and the time of collection is provided in Table 1 and Figure 1.

Quality of life measures

The EQ-5D-5L^[16] descriptive system covers five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, and each dimension has five levels: no problems, slight problems, moderate problems, severe problems, and extreme problems.

Patient-reported measures

Primary outcomes

Baseline data (VRS, WOMAC) will be recorded by an online link or telephonically by the researcher. Patients will be asked to report "current" pain intensity or pain intensity in the last 24 hours. Depending on the COVID-19 situation, we will use a five-point VRS telephonically, with the words "no pain," "slight pain," "moderate pain," "severe pain," and "unbearable pain."

WOMAC, a self-administered measure consisting of 24 questions to assess the dimensions of pain, stiffness, and function. Patients will be asked to rate the categories as per the scale of difficulty (0 = none, 1 = slight, 2 = moderate, 3 = very, and 4 = extremely). The WOMAC is a valid and reliable outcome measure for KOA in Asian KOA patients.^[2] An anchor question to collect information on the perceived improvement in the pain

will be asked from each KOA patient during end-line assessment to facilitate interpretation of the outcomes.

Secondary outcomes

The performance-based tests will be conducted in-person by the physiotherapists. However, depending on COVID-19 situation, the researcher may devise a way to record these measures by patients at their homes during remote web-based interactions by physiotherapists. Depending on COVID-19 pandemic situation, surrogate variables may be developed to record the same via online mode.

Functional parameters (30-second chair test,^[17] timed up and go test,^[18] 6-minute walk test)^[19,20] to be recorded on the baseline visit of the patient by a physiotherapist. Physical performance tests will be assessed by a physiotherapist other than involved in the supervised sessions.

30-second chair test: This is a proxy measure of leg strength. The participants are required to stand up from a standardized chair as many times as they can over 30 seconds, with a number of repetitions recorded.

Timed up and go test: This is one of the simple and quick tests to assess KOA patients' functional mobility. The intrarater and inter-rater reliability of the timed up and go test measurements shown to be excellent in KOA patients with doubtful to moderate KOA. Patients will be instructed to stand up from the chair, walk 3 meters comfortably, and come and sit back in the chair. The time taken to complete this test will be assessed with a stopwatch timed to the nearest 1/100 seconds.

6-minute walk test: It is valid, reliable, and recommended for those with KOA. It is a standardized walking tolerance test measures maximum walking distance in 6 minutes, with self-initiated rests as desired.

Patient satisfaction

Patient satisfaction with eKS will be measured with a questionnaire on a 6-point Likert scale (1: highly dissatisfied to 6: highly satisfied) for eKS. A semi-structured interview will be conducted telephonically to explore the same.

Patient and public involvement

The proposed study has built on considerable background work undertaken during the pilot study and with input from a broad range of stakeholders, orthopedic surgeons, physiotherapists, and KOA patients.

Data analysis

Quantitative data will be examined on collection to ensure completeness and if required, with prompts

for completion if required. Data will be checked for correctness during data analysis. A descriptive data analysis will be carried out to estimate the measures such as percentage, mean, standard deviation, etc. Also, to test the statistically significant differences in the categorical and continuous data, Chi-square test of independence and paired *t*-test will be used, respectively. Factors will be analyzed using linear regression model to responders to the intervention sessions. Missing values will be imputed using multiple imputation approaches. A complete case and last observation forward analysis will be performed as a sensitivity analysis. Statistical software for social sciences (SPSS) ver 21.0 and Stata ver 17.0 package will be used for analysis. For qualitative data, the thematic analysis will be performed, with two researchers involved in developing a framework within which the data will be interpreted and major themes described.

A cost-effectiveness analysis (CEA) of eKS against the routine care for KOA patients will also be done.

Estimation of costs

A bottom-up micro-costing approach will be adopted to estimate the costs associated with providing NPIs [Table 1] to improve QoL among the mild and moderate KOA patients enrolled in the eKS and routine care.

Perspective

An economic and societal perspective will be considered for costing of eKS intervention and routine care as comparator. The costs incurred by the health system to deliver the intervention activities and the direct and indirect costs incurred by patients of KOA will be captured. The direct costs incurred by KOA patients will be comprised of out-of-pocket expenditures for treatment at the time of healthcare utilization. While the indirect patient costs will primarily cover the loss of productivity in the form of wage losses as a result of KOA treatment and care, a discount rate of 3% will be considered for annualizing the costs of capital nature. More details about both the health system and patient costs are provided below in specific sections.

Health systems costs

The resource consumption under all the activities/ services being delivered as a part of eKS intervention will be considered in the costing. Since the time of diagnosis of the patient and referral to 'eKS' from Orthopedics department till completion of the follow-up visits (N = 20); all the relevant costs associated with eKS modalities will be accounted considering real-world practices.

The costs will be considered under the following heads:

- Human Resource: Scientist, Physiotherapists, Dietitians, Meditation, and Yoga expert.

- Building/Space: The cost of room from where the intervention will be taken.
- Drugs: Data on the prices and number of drugs (Analgesics, Supplements, nutraceuticals, Knee caps) consumed by the KOA patients during the entire study period.
- Consumables: Stationery being used.
- Nonconsumables: Furniture and equipment like computers, printers, e patient information booklets, weighing machine, and stadiometer.
- Overheads: These are costs incurred due to electricity/ water, etc.
- Internet charges, that is, connection and hotspot.

The data on abovementioned cost components will be collected via record review, observation, and interviews. The cost of human resource involved in service delivery will be estimated from the salaries of the scientist/physiotherapists/dietitians, meditation, and yoga experts. The salaries will be apportioned based on time allocated by respective persons in delivering their respective services in the 'eKS.'

Costs pertaining to space will be estimated by measuring the dimensions of space being used for service delivery and the prevailing market rental rates for the study area. The market rental rates will be the best proxy of opportunity cost of space being used. Other costs include those pertaining to consumables, equipment, and overheads like electricity, water, etc., will also be estimated. A record review exercise along with the interviews will be carried out to capture these data.

Out-of-pocket expenditures: KOA patients/caregivers will be interviewed telephonically to collect the information on all direct costs incurred for the treatment of KOA. These costs will primarily include medical expenditures such as drugs and consumables used for treatment and nonmedical expenditures like transportation costs, internet costs, etc.

Indirect costs (Productivity Loss): Indirect costs in the form of wage losses among the KOS patients and their attendants due to the present health condition and its treatment will be considered. Telephonic patient/attendant interviews will be conducted for this part.

Valuation of health outcomes

The health benefits to be considered in terms of reduction in pain and the overall improvement in the QoL in each treatment arm per KOA patient. In terms of model outcomes, the quality-adjusted life years will be computed per KOA patient by EQ-5D-5L and then compared between the two treatment arms.

Cost-effectiveness analysis

We aim to undertake a CEA for eKS intervention comparing against the routine care scenario for KOA patients in India. For the current CEA, a model will be developed considering a lifetime horizon from a societal perspective. A discount rate of 3% will be assumed to adjust the future costs and health benefits to their present worth. The cost and health outcomes data will be integrated in a mathematical model to undertake a CEA. The end point of CEA will be measured in terms of Incremental Cost-Effectiveness ratio using the following formula:

$$ICER = \frac{C^{Intervention} - C^{Control}}{E^{Intervention} - E^{Control}}$$

Here, 'C' and 'E' represents the cost and effectiveness in the two arms of CEA, that is, eKS intervention school and routine care.

Sensitivity analysis

In general, a CEA model is grounded on data from several sources for input parameters and assumptions for modelling. The input data and the assumptions used are potential source of uncertainty in a CEA model and if remain unaddressed, can lead to imprecise estimates. Therefore, we propose to undertake a deterministic and probabilistic sensitivity analysis to address the issue of uncertainty in the present CEA model.

Ethical consideration

Principles of medical ethics, including professional norms for protecting patient privacy and confidentiality as per Medical Council of India and Good Medical Practice Act shall be binding and practiced. The study will be conducted in accordance with the guidelines of the Strengthening the Reporting of Observational Studies in Epidemiology statement and guidance manuscripts generated by International Society For Pharmacoeconomics and Outcomes Research working groups on prospective observational studies. The results will be reported in the best practical way following Consolidated Standards of Reporting Trials guidelines for randomized controlled trials.

The study will not interfere with the pharmacological treatment. Adverse events, if any, resulting from any component of intervention package will be duly recorded. These will also be reported to the institute ethics committee (IEC).

IEC approval has been taken and study has been registered (CTRI/2021/01/030333) with clinical trials registry, India. Participants will be asked to provide voluntary written consent before enrolment.

Opportunities to clarify what participation involves, potential risks, and benefits will be provided by a researcher, and participants are free to withdraw at any time, with no subsequent data collected. Willing potential participants whose computer skills limit participation will be aided to an appropriate level. The present study is exploring a low-risk intervention with supervision as compared with usual care. If potential participants experience acute psychological stress, then referral pathways exist for these people to access urgent specialist mental healthcare at no cost. The results of this study will be disseminated via peer-reviewed journals and local and international conferences.

Data protection, storage and dissemination

All collected data will be deidentified. The data will be stored in a secure, password-protected file on the secure computer network owned by the principal investigator. Data will be aggregated and anonymized during analysis and publication to render individual patient identification impossible. Access to deidentified, individual participant data after the completion of the study will not be considered without consultation with the IEC. E-mail contact with the principal Investigator or the IEC is recommended.

Limitation

A reporting bias specially in the context of compliance of interventions at home will be difficult to rule out. Although, monitoring of the logbooks by the researcher will be helpful in reducing the bias.

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Author contributions

All the authors collectively devised the idea for the study. Prof. M.S.D. is the principal investigator at Post Graduate Institute of Medical Education and Research, Chandigarh, India. All authors participated to the scientific derivation of the protocol and evaluating and submitting the protocol for publication.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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