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Impact of core muscle strengthening on knee pain, patient outcomes, physical function, and cartilage thickness in knee osteoarthritis: Protocol for a randomized controlled trial ☆

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CARE – KOA

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ABSTRACT

Knee Osteoarthritis (KOA) is a degenerative condition that significantly impacts individuals, causing disability. Routine rehabilitation methods primarily involve knee and hip strengthening exercises. While there is limited evidence supporting the potential benefits of core muscle strengthening in KOA rehabilitation, further research is needed to examine the effects of a structured core muscle strengthening protocol on pain, functional abilities, quality of life, and knee cartilage health. This double-blind, randomized controlled trial seeks to investigate the impact of integrating core muscle strengthening into routine rehabilitation. The study will randomly assign 80 participants to either routine rehabilitation or experimental groups, with both groups receiving routine rehabilitation combined with core strengthening exercises in the experimental group over a twelve-week period. The outcomes measured will include pain levels, patient-reported outcomes, physical functional abilities, core muscle and leg muscle strength, and cartilage height of the femur and tibia. Follow-up assessments will occur in the 4th, 8th, and 12th weeks. This novel study aims to provide valuable insights into the role of core strengthening in KOA rehabilitation, potentially influencing rehabilitation approaches and managing disease progression.

- Incorporating core muscle strengthening into routine rehabilitation for KOA could open new possibilities for KOA management.
- This study employs outcome measures recommended by OARSI for a thorough evaluation.
- Additionally, it will investigate the impact on cartilage health, offering fresh insights into disease progression and the effects of exercise

☆ **Related research article:** None.

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Specifications table
This table provides general information on your protocol.

Subject area:	Medicine and Dentistry
More specific subject area:	Rehabilitation and Health Related Research
Name of your protocol:	CARE – KOA
Reagents/tools:	KOOS – Knee Injury and Osteoarthritis Outcome Score LEFS – Lower extremity Functional Scale VAS – Visual Analogue Scale microFET®2 - Digital handheld dynamometer – For muscle strength evaluation Pressure bio feedback unit for core muscle evaluation Diagnostic Ultrasound for femoral and tibial cartilage height
Experimental design:	80 Subjects with Knee OA will be enrolled in the study, after baseline evaluation, they will be randomized into control and intervention group. Outcomes will be assessed at 4, 8 and 12 weeks. Participants will be included in the study after obtaining written informed consent
Trial registration:	The study was then registered with the Clinical Trials Registry India (CTRI/2023/07/054,805).
Ethics:	The independent institutional ethical committee at Kasturba Medical College Mangalore has approved the study and has the ethical number (IECKMCMLR05/2023/206). Participants will be included in the study after obtaining a written informed consent from them
Value of the Protocol:	• The protocol is important to evaluate the effect of a 12 week – structured – core exercise program in addition to routine rehabilitation, in subjects diagnosed with knee osteoarthritis. • This study will highlight the role of core muscle strengthening and its effect on pain, patients reported outcomes, physical function test and cartilage integrity which is essential for disease mitigation. • The study's exploration of the relationship between core and cartilage health may open new avenues for future research, wherein future studies may investigate long-term effects on overall joint health.

Background

Knee osteoarthritis (KOA) is a widely prevalent condition resulting in persistent disability. The combined prevalence of KOA was 16 % for individuals aged 15 and above, escalating to 22.9 % in the demographic aged 40 and beyond worldwide [1]. In India, up to 28.7 % of people who have knee pain and signs of KOA document being unable to perform everyday tasks [2].

Non-invasive management of KOA often aims to reduce the compressive forces on the joint. This goal can be achieved by enhancing lower extremity muscle strength, particularly on the quadriceps muscle. Strengthening the quadriceps muscle impacts the onset and advancement of the disease and holds significance in addressing functional limitations in individuals with KOA [3–6]. The muscles that stabilize the knee joint are known to atrophy and lose strength due to KOA [7]. Core exercise can enhance trunk, pelvic, hip, and knee stability and coordination by stimulating the periarticular muscles of the knee and the lumbopelvic hip complex [8]. Initial implications of the proximal contributions and the kinetic chains have recently been investigated in individuals with KOA, and a link between KOA and poor core has been seen as a plausible avenue attributing to the progression of the disease [9].

Recent research on people with knee OA has addressed kinetic chain and proximal muscle contribution [8]. In almost every gross motor action, core stability plays a significant role [10]. The muscular system is responsible for core stability and also are accountable for preserving the balance needed for the extremities to perform their particular roles, offering the proximal stabilization needed for lower-extremity function and mobility [11].

For the best performance and injury avoidance, core stability is crucial. A weak core may be the cause of an unstable proximal base because all hip muscles originate in the pelvic and lumbar regions. This instability influences higher centers to recruit high-quality muscles and appropriate combinations for both stability and mobility. The ability of the lower extremities to manage and position themselves for functional movements is eventually constrained, which raises the load and risk of injury [9,12,13].

The benefits of adding core muscle exercises to routine rehabilitation In patients with KOA have not been examined extensively in people suffering from KOA-related impairments; hence, exploring this is necessary. Therefore, this study is designed to fill a gap in the current literature management of KOA, by examining the efficacy of integrating core exercises into routine rehabilitation. Specifically, the study will also evaluate the benefits of this intervention on knee pain, patient-reported functional disability, physical function tests, knee strength, and core endurance. Moreover, the study aims to explore the potential relationship between improved core stability and cartilage health, ultimately providing insights into whether this approach can influence disease severity and halt progression.

Description of protocol

Study setting and design

The proposed study is a double-blind patient and outcome assessors-blinded randomized clinical trial that will be conducted in the hospital settings of Kasturba Medical College, Hospitals. The study protocol has been developed with the "Standard Protocol Items: Recommendations for Intervention Trials" (SPIRIT) guidelines and the trial will be reported following the "Consolidated Standards of Reporting Trial" (CONSORT) (Fig. 3).

Sample size

A sample size of 40 participants per group has been determined using a previous study assuming 80 % power, considering 20 % attrition with an alpha error of 0.05.

Z1 − $\alpha/2$ = 1.96 at 95 % CI, Z1 − β = 0.84 at 80 % power, σ = 2.885 (standard deviation), and d = 2 (difference between the mean) were assumed based on a previous study [9].

Randomization

Following the review of eligibility and informed consent, an initial assessment will be completed for all the tests and measures. Subsequently, participants will be randomly allocated to either the intervention or routine rehabilitation group using a computer-generated random number sequence in blocks of six. The final list will be safely stored by an individual, not a part of the study team, and placed into sequentially numbered opaque envelopes.

Subjects

The targeted population comprises individuals who have received a diagnosis of KOA. A total of 80 subjects diagnosed with KOA will be randomly assigned to two groups, the treatment group (n = 40) and the control group (n = 40).

Inclusion criteria

- This study will involve patients referred to the physical therapy department at Kasturba Medical College and Hospitals by orthopedic surgeons for the rehabilitation of impairments related to KOA.
- Orthopedic surgeons will employ standardized criteria for diagnosing KOA, including the patient's medical history and subjective complaints (such as knee pain accompanied by crepitus during active motion, morning stiffness, or bony enlargement), along with an evaluation of age and a physical examination aimed at ruling out other causes of knee pain.
- Additionally, radiographic imaging will be conducted, and the severity of KOA will be determined using the Kellgren and Lawrence (K-L) grade ranging from 1 to 3 [14].

Exclusion criteria

- Patients with end-stage KOA (K-L grade 4) deemed candidates for knee replacement will be excluded.
- Patients with a history of hip OA, joint replacement in lower extremity joints other than the index joint, inflammatory arthritis, spine surgery, lower limb surgery, or corticosteroid injection in the affected knee within the past three months will also be excluded.
- Patients who, on clinical examination, present with a diagnosis of other conditions such as knee sprains or ligamentous injuries will be excluded.

Data collection protocol

The outcomes will be assessed at baseline and again at 4 weeks, 8 weeks, and 12 weeks (Fig. 1, Table 1). To summarize, patients will complete VAS-P, KOOS, and LEFS, and 30STS, FPWT, TUG, and SCT. The primary investigator will conduct the baseline assessments, following which they will be blinded to the follow-up outcome assessments. A radiologist will conduct the imaging test and will be blinded to the participants' group allocation.

Table 1
Time points of data collection.

Outcome measure	Baseline	4 weeks	8 weeks	12 weeks
PRIMARY OUTCOME				
1) VAS	√	√	√	√
2) Patient Reported Outcome	√	√	√	√
SECONDARY OUTCOME				
1) Physical Function	√	√	√	√
a) 30-second sit to stand	√	√	√	√
b) 40 m fast-paced walking test	√	√	√	√
c) Stair Climb Test	√	√	√	√
d) Timed Up and Go Test	√	√	√	√
2) Muscle strength	√		√	√
3) Core endurance	√		√	√
4) USG	√			√

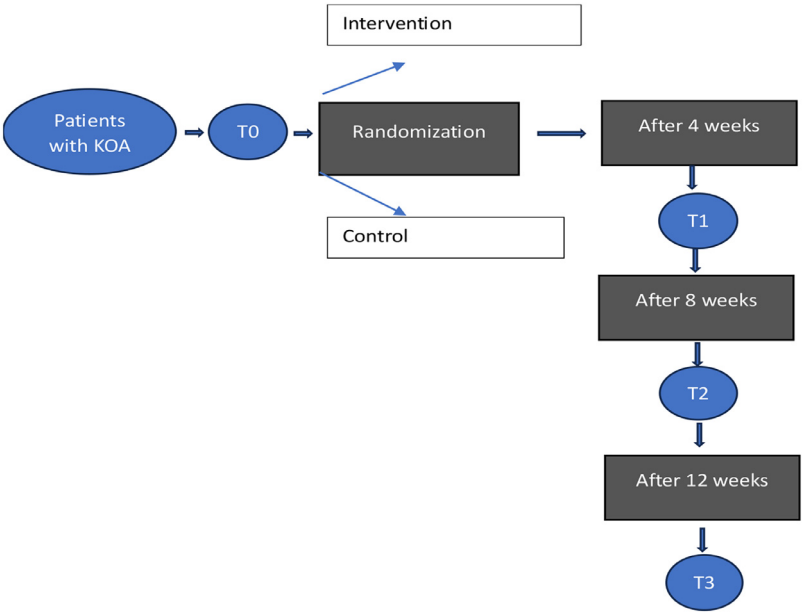

Fig. 1. Layout of the study design.

Procedure

Before enrolling patients in the study, the purpose of the study will be explained to them and written informed consent will be obtained. The procedural flow chart is depicted in Fig. 2. The intervention group will receive the CARE -KOA Program (Table 2) which includes (core+ routine knee rehabilitation exercises) whereas the control group will receive routine rehabilitation exercises to strengthen the hip and knee. (Table 3) over 12 weeks.

Control group intervention

The Control Group will receive a routine strengthening regime for KOA (Table 2), and the exercises will progress in terms of increasing the weights used, alterations in repetitions, and sets for each exercise.

Primary outcome

The patient will be asked to record a point on the VAS, a 10 cm (100 mm) line, reflecting the degree of their discomfort. No pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm), and severe pain (75–100 mm) are the categories used to categorize pain severity [15]. Excellent test-retest reliability has been reported for the VAS scale (ICC = 0.97) and it has defined values for minimal detectable change (MDC = 0.08) [16].

The LEFS has 20 items that inquire about the difficulty in performing LE functions. Each item has response options over a 5-point Likert scale ranging from 0 (great difficulty or inability) to 4 (no problem) to capture impairment in performing that function. The total score for the LEFS is derived by adding the scores for these 20 items. Higher scores signify improved functionality, whereas lower scores suggest greater functional impairments. The measurement properties of the LEFS have been confirmed in multiple conditions affecting LE [16].

KOOS will be used to analyse how osteoarthritis and knee injuries affect people's day-to-day lives. We will use the KOOS, which consists of 42 items spread across five domains, as our major outcome measure. The frequency and intensity of pain, symptoms, difficulties with completing activities of daily living (ADLs), participation in sports and leisure, and the patient's general quality of life are all included in these domains. Participants will mark and score each item on a 5-point Likert scale, where 0 represents no problem and 4 represents the most serious concern. This scoring system allows for a quantitative assessment of the impact of knee injuries and osteoarthritis on various aspects of individuals' lives, providing valuable insights into the effectiveness of the interventions being studied [17,18]. All KOOS subscales have demonstrated acceptable reliability Intraclass Correlation Coefficient (ICC $\geq$ 0.70), except for the Sport and Recreation subscale (ICC =0.65) [19].

Secondary outcome

The secondary outcomes to be assessed will physical function tests including the 30-second sit-to-stand test (30STS), the 40-m fast-paced walking test (FPWT), the stair climb test (SCT) and the timed up-and-go test (TUG). In addition, knee muscle strength,

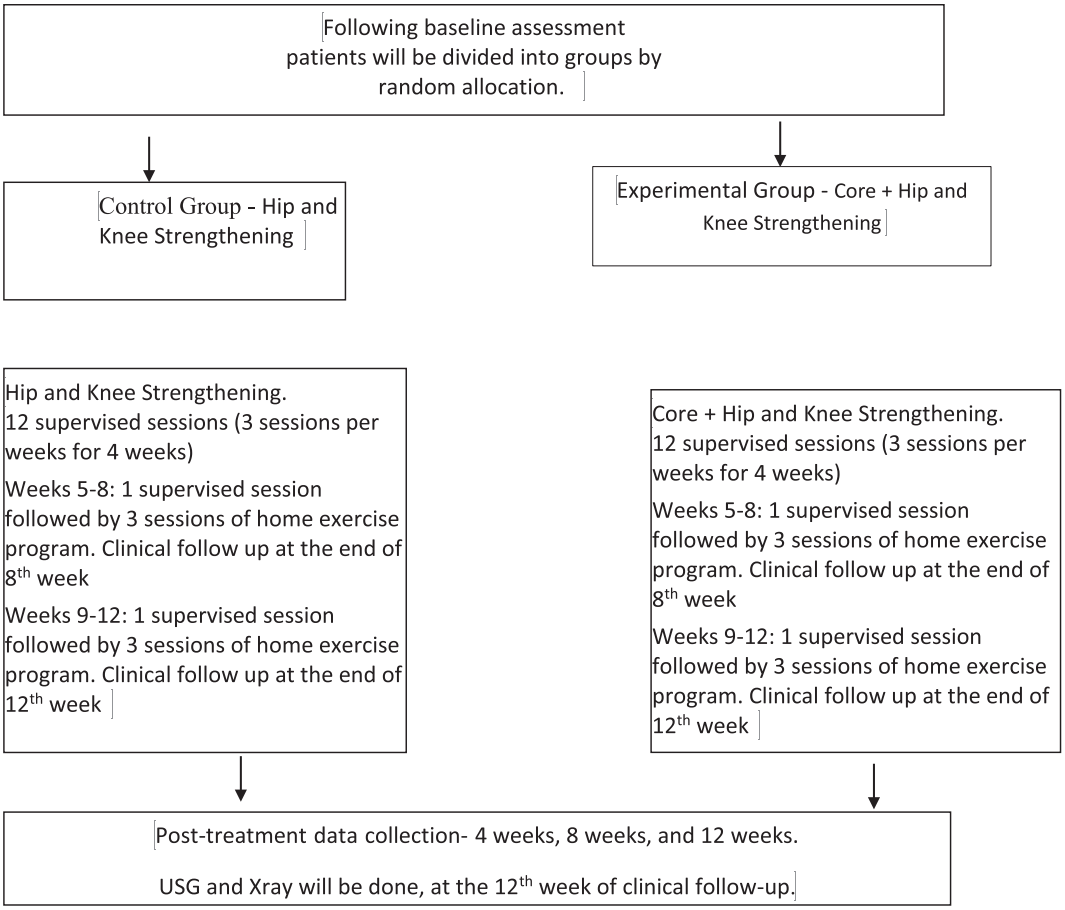

Fig. 2. Research procedural flow chart.

core muscle strength, and endurance will be examined. Patients will also undergo diagnostic imaging exams, including X-ray and ultrasonography (USG), where the latter will measure cartilage thickness.

Physical function tests

30-second Sit-to-Stand Test: The 30STS is an indicator of postural control, lower limb muscle strength, and balance. Participants will sit in a chair without armrests placed against a wall. Participants will keep an erect posture, have their arms crossed against the chest wall, and their feet placed on the floor shoulders width apart. Participants will complete cycles of sit-to-stand motion and the number of completed cycles over 30 s will be considered as the test score. Participants will be given a practice trial, followed by two test trials. The average of these two trials will be recorded as the final score for the CST [20]. The 30STS is known to have excellent interrater reliability in people with KOA [21].

40 m Fast-Paced Walking Test – The FPWT test measures walking speed along a distance of 40 m. Participants will ambulate as fast as possible along a 10-meter path, turn back, and repeat till they have completed 4 cycles (40 m in total). The time taken to ambulate the distance of 40 m will be recorded in meters/second. Participants will complete 1 practice trial and 2 test trials with an average of these two trials considered as the FPWT score. The FPWT is known to have excellent measurement properties in people with KOA [22].

Timed Up and Go: For completing the TUG, participants will sit on a regular-height chair with their back in contact with the backrest. On the command of "Go", participants will get up from a chair, walk to a target located at 3 m (9.8 feet) distance, turn around at the target, walk back to the chair, and sit down. The time (in seconds) taken to complete the task from the command of 'Go' to when they have returned to the chair with buttocks in contact with the chair will be recorded. Participants will get 1 practice trial followed by 2 test trials. The average time for these two trials will be the test result. The TUG has excellent measurement properties in people with KOA [23]

Stair Climbing Test: The SCT assesses the ability of the participant to maintain balance in the affected LE during functional tasks. Participants will step on a 15 cm high step with the contralateral leg and back to the floor. The total number of steps taken in 15 s

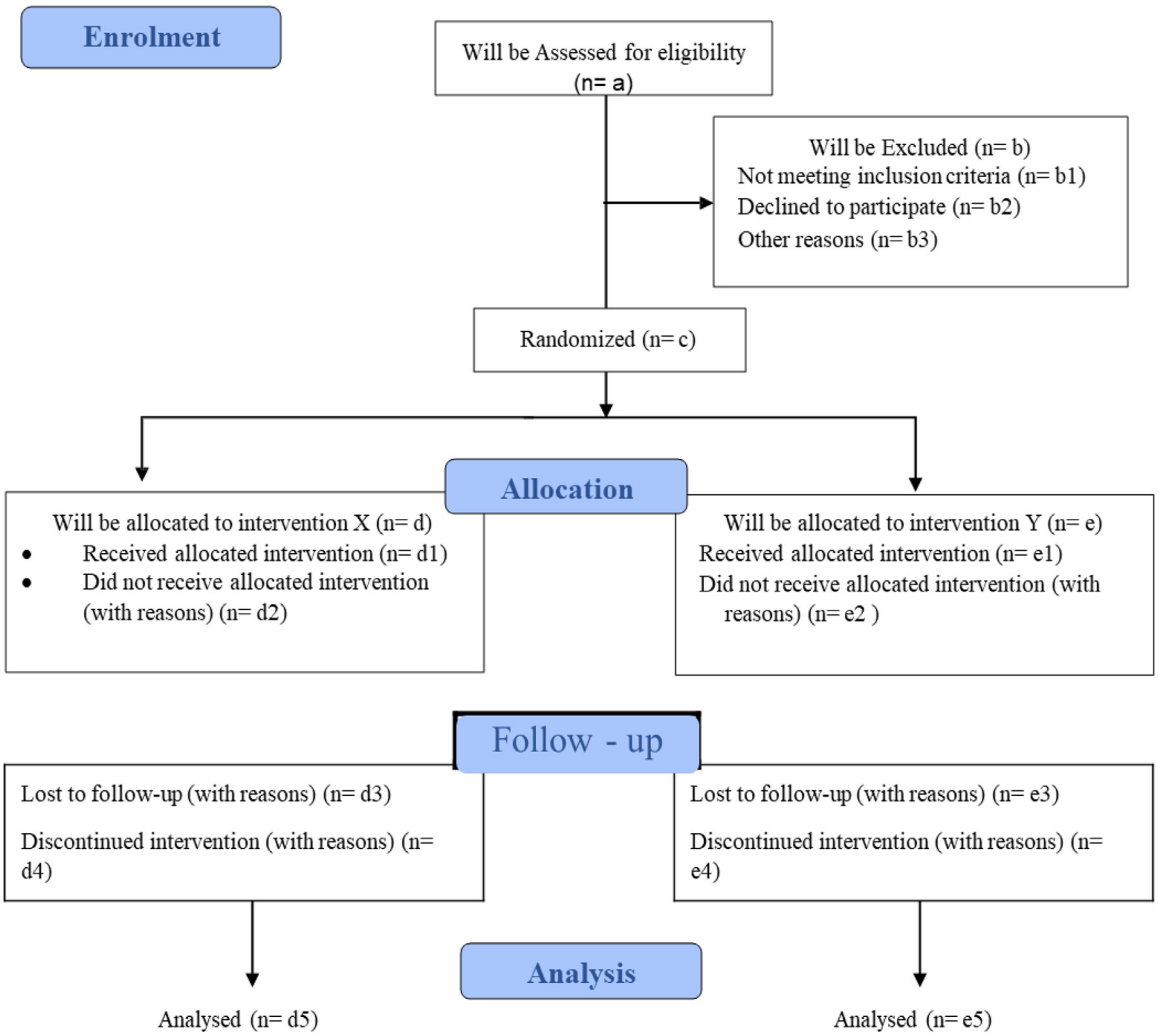

Fig. 3. CONSORT flow chart – explaining the participant allocation.

will be recorded with an average of 2 trials considered the SCT score. The test demonstrates excellent test-retest reliability in people with KOA [24].

Assessment of muscle strength- To assess the strength of knee flexors, the participant will be seated on the edge of the table with knees and hips will be in 90° of flexion. The examiner will instruct the participant to maintain this position for the entirety of the testing. The HHD will be placed on the posterior aspect proximal to the ankle joint. To assess the strength of knee extensors, the participant will be seated in the same position as described above for knee flexion. The HHD will be placed on the anterior aspect proximal to the ankle joint. For assessing the strength of knee flexion, the examiner will ask the participant to bend the knee as hard as possible as the examiner applies counterpressure to prevent any movement. Similarly, the examiner will ask the participant to straighten the knee as hard as possible as the examiner applies counterpressure to prevent any movement while assessing the strength of knee extensors. The HHD has been shown to provide a reliable and valid assessment of LE muscle strength including knee flexors and extensors [25].

Assessment of core muscle strength –Pressure Biofeedback (PBU) is used to evaluate the strength of the core muscles. It provides a numerical assessment of the stability and function of the core muscles. It gauges the pressure exerted on the lumbar spine using an inflatable apparatus. The PBU has shown strong inter-rater reliability in assessing core muscle strength [26].

Assessment of core muscle endurance – The prone bridge test is a tool for assessing core muscle endurance. During the test, the patient assumes a face-down posture, maintaining a straight line from head to heels while sustaining body weight on forearms and toes. Key muscles engaged include the rectus abdominis, transverse abdominis, and multifidus, offering a comprehensive evaluation of core stability. Validated for use in older adults, the test demonstrates strong reliability for assessing core muscle endurance [27].

Assessment of knee cartilage height using USG: Patients will be asked to flex their investigated knee at a 30-degree angle while lying down in the dorsal decubitus position. To evaluate the patellar region, images in the axial plane (transversal) will be taken. The

Table 2
CARE – KOA - progressive core exercises for the intervention group.

Order	Exercises	Reps	Sets	Progression Criteria
1)	CORE ACTIVATION			
a)	Level 1: core activation – Draw in and hold for 10 s	8	2	When the participant can perform the exercise without exertion and keep the pelvis stable during movement, progress to the next level.
b)	Level 2 – Opposite LE on the mat; bent leg falls out	8	2	When the participant can perform the exercise without exertion and keep the pelvis stable during movement, progress to the next level.
c)	Level 3: A, B, or C – Opposite LE is on the table	8	2	When the participant can perform the exercise without exertion and keep the pelvis stable during movement, progress to the next level.
d)	Level 4: A, B, or C – old opposite LE @ 90 of hip flexion with UE	8	2	When the participant can perform the exercise without exertion and keep the pelvis stable during movement, progress to the next level.
e)	Level 5: A, B, or c – Hold opposite LE @ 90 of hip flexion (no UE assistance)	8	2	When the participant can perform the exercise without exertion and keep the pelvis stable during movement, progress to the next level.
f)	Level 6: A, B, or C – Bilateral LE movement	8	2	When the participant can perform the exercise without exertion and keep the pelvis stable during movement, progress to the next level.
2) a)	Bridge – hands at the side	8	2	When the participant can perform the exercise without exertion and keep the pelvis stable during movement, progress to the next level.
c)	Bridge – hands at the side and holds	8 * 10 s hold	2	When the participant can perform the exercise without exertion, keep the pelvis stable and hold 8 repetitions for 10 s to progress to the next level.
d)	Bridge – hands across the chest	8	2	When the participant can perform the exercise without exertion and keep the pelvis stable during movement, progress to the next level.
e)	Bridge – hands across the chest with holds	8 * 10 s hold	2	When the participant can perform the exercise without exertion, keep the pelvis stable and hold 8 repetitions for 10 s to progress to the next level.
f)	Unilateral Bridge	8	2	When the participant can perform the exercise without exertion and keep the pelvis stable during movement, progress to the next level.
g)	Unilateral Bridge – hands across the chest	8	2	When the participant can perform the exercise without exertion and keep the pelvis stable during movement, progress to the next level.
h)	Unilateral Bridge – hands across the chest with holds	8 * 10 s hold	2	When the participant can perform the exercise without exertion, keep the pelvis stable and hold 8 repetitions for 10 s to progress to the next level.
I)	Bridge with both feet on the Swiss ball	8 * 10 s hold	2	When the participant can perform the exercise without exertion, keep the pelvis stable and hold 8 repetitions for 10 s to progress to the next level.
j)	Prone Bridge	2 * 30 s	2	When the participant can perform the exercise without distinct exertion and shows reasonable trunk control, the participant progresses to the next level.
k)	Prone Bridge	2 * 1 min	2	When the participant can perform the exercise without distinct exertion and shows reasonable trunk control, the participant progresses to the next level.
3) a)	Supine – over-head raises with knee bent	8	2	When the participant can perform the exercise without exertion and keep the pelvis stable during movement, progress to the next level.
b)	Supine – holding a stability ball between your hands and knees – same side hand and leg movement	8	2	When the participant can perform the exercise without exertion and keep the pelvis stable during movement, progress to the next level.
c)	Supine Heel tap – Lower one foot at a time and tap the floor with your heel	8	2	When the participant can perform the exercise without exertion and keep the pelvis stable during movement, progress to the next level.
d)	Supine – Straight leg alternating hand and legs	8	2	When the participant can perform the exercise without exertion and keep the pelvis stable during movement, progress to the next level.

Table 3
Routine rehabilitation for the control and intervention group.

Sr. no	Exercise type
1	Static Quadriceps
2	SLR
3	Side-lying Hip abduction
4	Dynamic Quadriceps in sitting
5	Fast knee end-extensions
6	Small Swiss ball between the popliteal fossa and the wall
7	Low step height, light elastic band, straight forward steps
8	Wall squat
9	Forward Lunges

quadriceps tendon enthesis, the patellar tendon (proximal and distal), the medial and lateral collateral ligaments, the topography of the iliotibial tract, and the pes anserine bursae will be examined in the sequence in the longitudinal plane. Patients will then be put in ventral decubitus, where the popliteal fossa will be assessed in the axial and longitudinal planes [28].

To assess the femoral articular cartilage height midpoint measurements will be taken from each of the three locations in the knee, with the knee in flexion to the maximum available flexion range. Measurement points – left medial condyle (LMC), left lateral condyle (LLC), left intercondylar area (LIC), right medial condyle (RMC), right lateral condyle (RLC), and right intercondylar area (RIC) [29].

To assess the tibial cartilage the knee will be flexed to 90° and tibial cartilage height will be taken from each of the three locations – tibial medial condyle, tibial lateral condyle, and the sulcus [30].

Statistical analysis

The collected data will be input into Statistical Package for Social Sciences (SPSS) version 29.0. Initial analysis will involve describing baseline demographics. Demographic and health variables as well as scores for tests and measures will be compared between groups using an independent sample T-test to ensure successful randomization. In addition, independent *t*-tests will also examine differences in all tests and measures within the group between baseline assessment and those conducted at 12 weeks. Differences in KOOS scores across baseline and follow-up assessments will be assessed via repeated measures of Analysis of Variance (ANOVA) to determine the trajectory of improvements. Multivariate regression analysis will examine the benefit of adding core strengthening to the routine rehabilitation of knee functions. The intervention group (treatment versus control) will be the independent variable and the KOOS scores obtained at 12 weeks will be the dependent variable. The model will be adjusted for age, sex, body mass index, presence of low back pain, diagnosis of depression for which participants are actively being treated, and scores for KOOS obtained at baseline. Bonferroni corrections will be considered to minimize the possibility of Type 1 error. An intention-to-treat analysis will also be performed to prevent overestimation of treatment effects and avoid type-I errors. A $p < 0.05$ will be considered statistically significant for all the analyses.

Protocol validation

KOA is a highly prevalent condition that mainly affects the elderly and results in long-term disability. Effective management techniques are vital due to the significant impact they have on everyday activities [31]. This protocol proposes a randomized trial to assess the importance of core muscle strengthening exercises on knee-related functions in patients diagnosed with KOA, and whether these exercises have an effect on pain reduction and improvement in the functional outcome and patient-reported scores.

Research on efficacy of core strengthening exercises in the management of KOA, have been conducted previously, but there were limitations in their findings. The study divided individuals with KOA, into a no-attention control group and a core muscle and routine rehabilitation intervention group [32]. In another study, The effectiveness of routine rehabilitation combined with core muscle strengthening training was compared with traditional rehabilitation alone. Both previous studies lacked an exercise program that specifically targeted the core and activated the TA and multifidus which are paramount for core stability [9]. The effectiveness of routine rehabilitation combined with core muscle strengthening training was compared with traditional rehabilitation alone. Both previous studies lacked an exercise program that specifically targeted the core and activated the TA and multifidus which are paramount for core stability. Moreover, the exercises did not follow a progressive approach that could have optimized the result. The current study aims to design a program targeting these muscles to address the limitations in the exiting research.

Our current approach to KOA management aligns with the Osteoarthritis Research Society International (OARSI) guidelines, which strongly recommend structured land-based exercises [33]. Emphasizing the importance of exercise, alongside recent literature, which supports the influence of core muscles in KOA, our present study focuses on incorporating core exercises into the rehabilitation process. Moreover, our study incorporates outcome measures recommended by the OARSI to ensure a comprehensive evaluation and contextualize our data with research trials worldwide. These measures assess aspects of patients' outcomes, including pain, function, and quality of life [34]. By utilizing these validated outcome measures, our study will provide a comprehensive assessment of the effectiveness of core exercises in the management of KOA.

The key strength of this protocol is its comprehensive nature of intervention. This study combines core-specific exercises with routine rehabilitation to potentially influence the progression of the condition in addition to alleviating symptoms and improving function. The double-blind design reduces observation biases and ensures that any observed results are attributable to the intervention rather than unrelated variables. The longitudinal follow-up at multiple time points along the continuum of care allows for the investigation of both immediate and intermediate effects. This longer follow-up period allows us to provide a broader overview of the intervention's progressive impact. In summary, this study will provide important data for the utility of adding core strengthening to routine rehabilitation in people with KOA. The clinical utility of the results will be significant in the context of a large target population of KOA in India. The study will also trigger similar research studies across different linguistic and cultural contexts in the highly diverse country of India.

Limitations

There are a few limitations to the protocol, specifically that the study results will be limited to one center. This allegedly reduces the generalizability of study results. However, the RCT design, adopting routine rehabilitation protocol that is widely utilized, and use of clinically relevant measures increase the applicability of the findings of this study beyond the context of the study site. Additionally, a potential variable in the study outcomes is the reliance on participants' compliance with a home exercise program, along with adherence to the exercise program.

CRediT author statement

All the authors have contributed equally and have read and approved the manuscript. CE and AS conceptualize the idea, TD writes the protocol, and PPM and SM edit the protocol.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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