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Structured home-based exercise programme and concentric versus eccentric-based stair training programme for pain and function in knee osteoarthritis: a two-phase, double-blinded, randomised controlled trial protocol

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ABSTRACT

Introduction Knee osteoarthritis (OA) is a leading cause of pain and disability worldwide. While exercise is crucial for managing OA, the effectiveness of a well-structured and efficient home-based, self-management exercise programme remains unclear. Therefore, this two-phase randomised controlled trial will evaluate the effectiveness of a structured home-based exercise programme (HEP) and concentric-based stair training programme versus eccentric-based stair training programme (CSTP vs ESTP) to develop an evidence-based approach for knee OA.

Methods and analysis This study will be a participant and assessor-blinded, randomised controlled trial that will enrol 247 knee OA participants. In Phase I, there will be a 1:1 split of participants into: an HEP and a control group P_I for 8 weeks. In Phase II, eligible participants from Phase I will be a 1:1:1 split into: a CSTP, an ESTP and a control group P_{II} for another 8 weeks. The number of exercise programmes will last for 16 weeks, including a 24-week follow-up. The primary outcomes of pain intensity, pressure pain threshold and functional ability will be measured using a numeric pain rating scale, pressure algometer and Western Ontario and McMaster University Osteoarthritis Index (WOMAC). The secondary outcomes of muscle strength, range of motion, aerobic capacity and quality of life will be measured using a modified sphygmomanometer, universal goniometer, 6-minute walk test and 36-item short-form survey. All outcomes will be measured at pretest (T_1), post-test (T_2 and T_3) and follow-up (T_4).

Ethics and dissemination All activities and exercise programmes will follow the Helsinki Declaration of 2020. The findings will be published in peer-reviewed journals and disseminated at international conferences.

Trial registration number CTRI/2025/03/081574.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Knee osteoarthritis (OA) is a major cause of pain and disability, impacting mobility and quality of life. Exercise is a key non-pharmacological treatment, yet the optimal programme structure remains unclear. While a home-based exercise programme (HEP) is cost-effective, a well-structured strengthening exercise integrated into an HEP remains unclear. The role of concentric stair training programme versus eccentric stair training programme (CSTP vs ESTP) in knee OA management is also underexplored.

WHAT THIS STUDY ADDS

⇒ This two-phase RCT evaluates a structured HEP and compares CSTP versus ESTP for knee OA. By assessing pain, pressure pain threshold, function, strength, range of motion and quality of life over 16 weeks (with a 24-week follow-up), it aims to establish a sustainable, evidence-based approach.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Findings could support integrating structured home-based and stair training exercises into OA management, guiding physiotherapists in effective treatment selection. This study may also shape healthcare policies on non-pharmacological OA care and drive future research on personalised exercise strategies.

INTRODUCTION

Knee osteoarthritis (OA) is a typical progressive condition primarily affecting elderly individuals and may cause discomfort and functional limitation.[1] In 2020, a global survey

found 595 million people worldwide suffering from OA. OA most commonly affects the knee, with a worldwide age-standardised frequency of 4307.4 cases per 100 000 people in 2020. Between 1990 and 2020, the rates of years lived with disability by OA site increased by 56.9% for knee OA, which can be increased to 74.9% from 2020 to 2050.[2] Though OA most commonly affects those 65 years older and above, the overall prevalence of knee OA is 22.9% in those over 40 and 16% in those over 15 years of age.[3] Both modifiable and non-modifiable lifestyle characteristics usually influence knee OA. Modifiable characteristics include being overweight and having physical activity, and non-modifiable characteristics include age, gender, genetic background, etc. This condition manifests as pain, stiffness, joint instability, reduced range of motion, muscle weakness, joint cartilage breakdown, joint deformities, poor balance and diminished knee proprioception.[4 5] Lower muscle mass and strength in the knee flexor–extensor muscles contribute to knee OA symptoms and poor health.[6] Concentric leg extensor strength decreased by 11–56% and eccentric strength reduced by 76%, according to isokinetic strength tests in individuals with knee OA.[7] Gradually, patients feel difficulties in regular activities such as walking, squatting, climbing, toileting and household tasks based on disease progress.[8] Knee OA has a substantial disease burden that affects individuals with the illness, their families and society at large.

Treatment options for knee OA include surgical, pharmacological and non-pharmacological methods. Surgical procedures are inherently risky, and long-term medication raises the possibility of side effects. One important non-pharmacological strategy that the Osteoarthritis Research Society International recommends is an exercise programme that is crucial and frequently effective in enhancing the overall functional ability of knee OA individuals, aiming to manage symptoms by improving knee range of motion, muscle strength, functional mobility and balance. As seen during the COVID-19 epidemic, there may be restrictions on clinic-based exercise. However, home-based exercise programmes (HEP) are a more affordable option that also improves accessibility and decreases clinic visits. In previous studies, HEP is designed to include stretching, strengthening, aerobics and various traditional exercises.[9] But postintervention effectiveness of exercise on pain and physical function in patients with knee OA decreases over time. However, incorporating additional exercise programmes after the initial intervention may enhance the long-term effectiveness.[10] The most recent international guidelines recommend muscle-strengthening exercises, which should be included in managing knee OA because of evidence from research demonstrating its long-term efficacy. Numerous studies have shown that strengthening exercise improves psychological health, reduces pain and maintains cartilage integrity. Furthermore, it could enhance the lower limb muscles' ability to absorb shock during walking, enhancing functional performance.[11] Besides, various strengthening exercises, such as isometric, concentric and eccentric, are commonly applied therapeutic interventions for managing people with knee OA. Numerous research studies focus on the effectiveness of concentric and eccentric exercises in increasing muscle strength. However, there is still an ongoing debate on the comparative effectiveness of concentric and eccentric exercise and which kind of exercise is more beneficial for improving functional performance significantly.[12] Although the use of eccentric contractions in muscle-strengthening exercises has gained prominence over the past few years, there is not enough data to prove that this method is better than the others in the research.[13] Considering these limitations, to ensure the long-term effectiveness of knee OA treatments, we developed an efficient and simple-to-implement HEP. We executed a comparative study of two evidence-based strengthening exercise programmes. If successful, the unique concentric and eccentric exercise regimen reported in this research may be easily incorporated into other home-based rehabilitation techniques. No study has examined the effects of concentric and eccentric workouts in this manner for individuals with knee OA. Intending to bridge this gap, this study aims to develop an exercise programme for stair training that combines HEP with both concentric and eccentric aspects. Concentric-based stair training programme (CSTP) and eccentric-based stair training programme (ESTP), particularly through ascending and descending stair training, have shown distinct benefits for muscle function and strength in older people, which may also play a significant role in managing other chronic conditions like knee OA.[14] This finding on stair training methods in older people has motivated our approach to establishing a long-term physical wellness programme for knee OA management that is more accessible, sustainable and efficient.

This study will be conducted in two phases. The primary objective of this study will be to evaluate a sustainable well-structured HEP for knee OA management, comparing the effectiveness of CSTP versus ESTP integrating with an HEP on pain and function. The secondary objectives will be to (1) determine the baseline compatibility in Phase I and Phase II groups; (2) evaluate the sociodemographic characteristics that may contribute to knee OA; (3) find out the effectiveness of structured HEP versus medications with healthy lifestyle education on pain, function, muscle strength, range of motion, aerobic capacity and quality of life in knee OA; (4) find out the effectiveness of CSTP versus ESTP on pain, function, muscle strength, range of motion, aerobic capacity and quality of life in knee OA; (5) investigate the long-term efficacy of two structural exercise programmes in follow-up for knee OA. The study has a two-tailed hypothesis for Phase I and Phase II. In Phase I, an HEP or medications with a healthy lifestyle education may demonstrate superior improvements in outcome measurements in knee OA. In Phase II, a CSTP or ESTP may demonstrate superior improvement in knee OA outcome measurements.

Table 1 SPIRIT table

	Enrolment	Allocation	Post-allocation			
TIME POINT	**$-T_1$**	**T_0**	**T_1**	**T_2**	**T_3**	**T_4**
ENROLMENT						
Eligibility screening	X					
Informed consent		X				
Demographic and clinical assessment			X			
Group allocation		X				
INTERVENTION						
Phase I						
HEP group			X	X		
P_I control group			X	X		
Phase II						
CSTP group				X	X	
ESTP group				X	X	
P_{II} control group				X	X	
ASSESSMENT						
NPRS			X	X	X	X
PPT			X	X	X	X
WOMAC			X	X	X	X
Muscle strength			X	X	X	X
ROM			X	X	X	X
6MWT			X	X	X	X
SF-36			X	X	X	X

CSTP, concentric-based stair training programme; ESTP, eccentric-based stair training programme; HEP, home-based exercise programme; 6MWT, six-minute walk test; NPRS, Numeric Pain Rating Scale; PPT, pressure pain threshold; ROM, range of motion; SF-36, 36-Item Short Form Survey; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials; T_0, group allocation; $-T_1$, prestudy enrolment; T_1, pretest before intervention; T_2, measurement after 8-week; T_3, measurement after next 8-week; T_4, measurement after 24-week; WOMAC, Western Ontario and McMaster University Osteoarthritis Index.

METHODS

Study design

This study will be a two-phase, randomised controlled trial from April 2025 to March 2026 in Jashore, Bangladesh. The participants will be treated in two phases for 16 weeks (three sessions/week), with an additional 24-week follow-up. The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 criteria will be followed to ensure transparency of this study (table 1). The Consolidated Standards of Reporting Trials statement guidelines will confirm that the findings are presented transparently (figure 1).

Study setting

Phase I of this study will be an HEP, and phase II will be conducted at the Dr M R Khan Medical Centre at Jashore University of Science and Technology Jashore, Bangladesh. All 13–16 health awareness programmes and discussion sessions will be held at the Physiotherapy and Rehabilitation Department at Jashore University of Science and Technology, Jashore, Bangladesh.

Sample size

The study participants' number was determined using G*power, V.3.1.9.7 (University of Kiel, Kiel, Germany). In Phase I, according to the calculation, a total of 190 participants is needed for this study (Es=0.41, α=0.05 and power value=0.80).[15] After allowing a 30% dropout, we increased the target sample size to 247 for group allocation. In Phase II, we will recruit all eligible participants from Phase I.

Participants and recruitment

In Phase I, based on eligibility, a total of 247 men and women participants with knee OA will make up the overall sample size and will be assigned to an HEP and P_I control group. After online and offline advertisements, two knee OA health awareness programmes will be organised in the already mentioned settings in Bangladesh. Regional orthopaedic hospitals will also be contacted to acquire target participants. A research assistant will conduct an eligibility evaluation that will be considered an initial basic clinical assessment after participants receive an

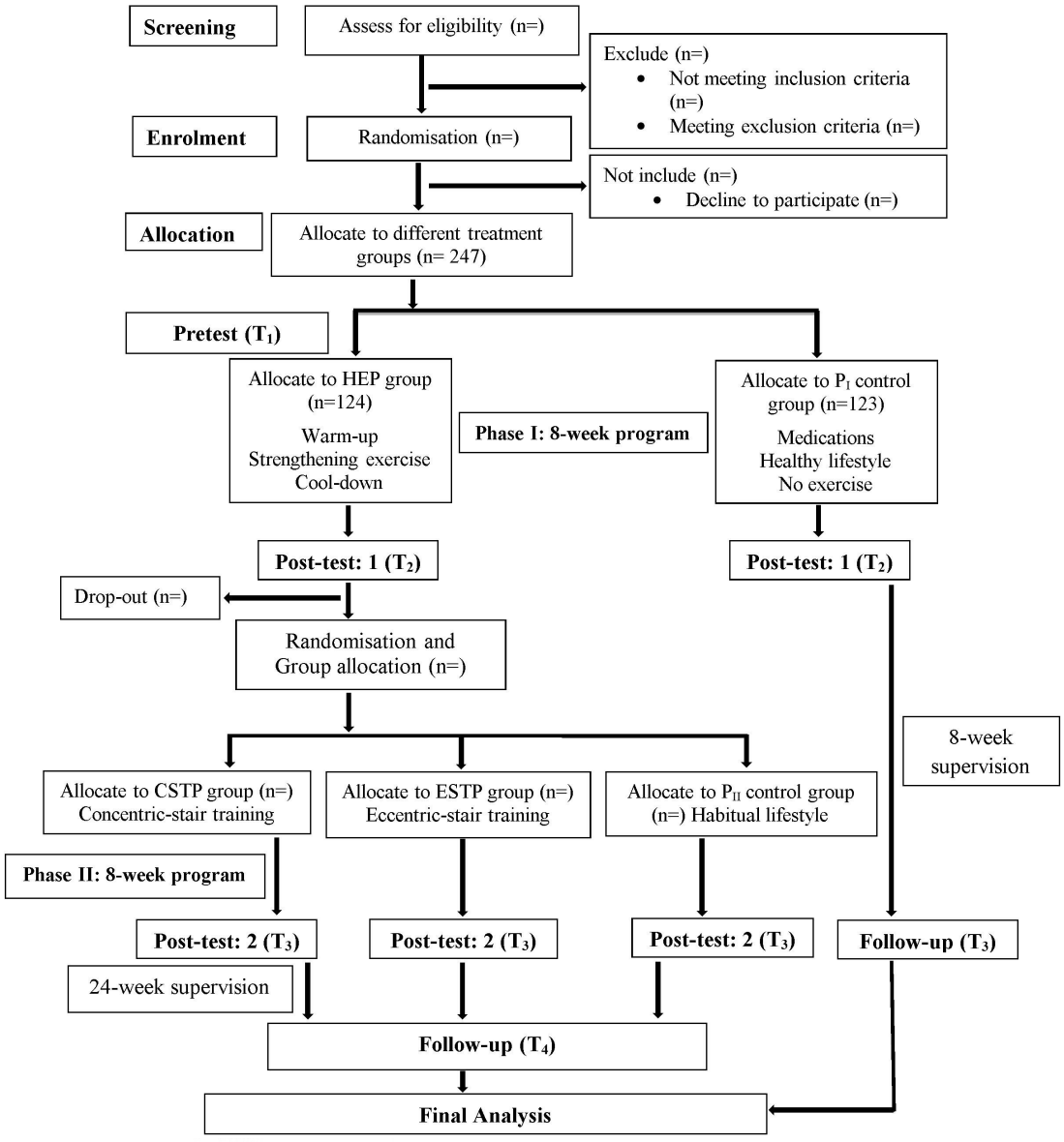

Figure 1 CONSORT flow diagram. CONSORT, Consolidated Standards of Reporting Trials; CSTP, concentric-based stair training programme; ESTP, eccentric-based stair training programme; HEP, home-based exercise programme.

outline of the study's objectives, risks and benefits. Before enrolling, individuals and their legal guardians will sign an informed consent and remain accessible to discontinue participating in the study at any time instead of influencing their intervention course. Then randomisation will be administered using concealed allocation, assigning participants into two groups. Participants will be unaware of the group allocation. A pretest (T_1) will be conducted before the first intervention session. In Phase II, all eligible participants from Phase I will be recruited. All eligible participants' instructions, informed consent, randomisation and group allocation will be held in the same manner as Phase I. This study aims to ensure fair and unbiased recruitment of participants.

Eligibility criteria

An unbiased initial screening procedure will recruit all participants according to the study's eligibility criteria.

Phase I

Inclusion criteria

Individuals will be included in this trial if (1) ages 45–70 for both men and women; (2) the presence of knee OA for at least 6 months following American College of Rheumatology criteria;[16] (3) able to walk without the use of any aids and able to flex the knee beyond 90 degrees;[12] (4) anterior–posterior bilateral standing radiograph presents Kellgren and Lawrence Grade II/III knee OA;[17] (5) having smartphone for watching video tutorial.

Exclusion criteria

Individuals will be excluded if (1) knee surgery has been performed in the previous 12 months;[12] (2) lumbar radiculopathy, vascular claudication, severe anterior-sided knee pain resulting from patella-femoral syndrome or chondromalacia, as well as further neurological, muscular or joint conditions that could impair the function of the lower limbs;[12 17 18] (3) visible malformation of the knee, either varus or valgus;[18] (4) received hyaluronic acid or corticosteroid injections within 3 months of study enrolment;[12] (5) pregnancy;[13] (6) body mass index (BMI) over 30.[19]

Phase II

Inclusion criteria

Individuals will be included if (1) complete the Phase I HEP; (2) pain subsides during walking and ascending/descending stairs.

Exclusion criteria

Individuals will be excluded if they present: (1) present signs of knee OA following American College of Rheumatology criteria;[16] (2) an unusual cardiac response during the 6-minute walk test (6MWT) and ascending/descending stairs.

Randomisation

Participants who meet the eligibility criteria and consent to participate will be randomly allocated to different groups using computer-generated sequencing while maintaining confidentiality. After sample collection, concealed allocation will be performed using the 'rand' function in Microsoft Excel 2010. Except for responsive health professionals, all will remain blinded to group allocation. Randomisation will be performed twice for Phase I and Phase II group allocation.

Blinding

Participants, research assistants, outcome evaluators and data statisticians will all be blinded during the study procedure, but treating healthcare providers cannot be due to the nature of the intervention. Participants will be blinded to group allocation but informed about the proposed interventions throughout the process of informed consent. They will not be informed about the group they have been assigned to. Different assessors will be used for different groups, timelines and phases, and a neutral individual will conduct randomisation. The study will be administered by an independent monitoring staff and a trial manager to ensure coordination and oversight of this study.

Intervention

Phase I

Initially, eligible participants of Phase I will receive two different intervention protocols. Eligible participants of the HEP group will perform an HEP for 8 weeks that will be taught by four qualified physiotherapists with over 7 years of practical experience in musculoskeletal physiotherapy (table 2).[20 21] Each participant will receive three TheraBands (yellow, red and green), a paper version of the material—'Health Knowledge and Home Exercise Guide' and a video of the full exercise regimens in Bengali language. Eligible participants of the P_I control group will take non-steroidal anti-inflammatory drugs regularly for 8 weeks based on their severity and conditions. Participants will also be instructed to maintain a healthy lifestyle. Each participant will receive a paper

Table 2 Exercise protocol

Phase I: home-based exercise programme (HEP)—8-week		
Exercise	**Descriptions**	**Dose**
Warm-up[20 21]	Light walking and marching Joint mobility exercise	5 min
Strengthening exercise[20 21]	Exercise with TheraBand – Knee flexion-extension, terminal knee extension, leg press, calf raise, mini-squat	Stage 1: 3 sets/10 reps (yellow) Stage 2: 3 sets/15 reps (red) Stage 3: 3 sets/20 reps (green)
Cool-down[20 21]	Light stretching - Hip flexor, outer hip, quadriceps, hamstrings	3 reps/15 s hold/5 min
Phase II: concentric and eccentric-based stair training (CSTP and ESTP)—8-week		
Ascending stair training (CSTP)[14 21]	Participants will ascend the stairs from the first to the sixth floor (22 stairs per floor)	Stage 1: 2 reps/110 stairs per rep Stage 2: 4 reps/110 stairs per rep Stage 3: 8 reps/110 stairs per rep Stage 4: 16 reps/110 stairs per rep
Descending stair training (ESTP)[14 21]	Participants will descend the stairs from the sixth to the first floor (22 stairs per floor)	

Phase I: first 8-week; three sessions/week; Stage 1: session 1st–8th; Stage 2: session 9th–16th; Stage 3: session 17th–24th.
Phase II: second 8-week; three sessions/week; Stage 1: session 1st–6th; Stage 2: session 7th–12th; Stage 3: session 13th–18th; Stage 4: session 19th–24th.
Applicable for every exercise: 15 s of rest between each set and 1 min of rest between different modes of exercise.
An elevator will prevent ascending/descending stair training for both groups.

version of the 'Health Knowledge and Advice Guide' material in Bengali. A telephone follow-up session will also include an automated message each week for both groups of participants.

Phase II

After completing phase I, eligible participants will be treated for another 8 weeks of intervention based on the group allocation. Eligible knee OA participants will be randomly allocated to three groups: concentric-based stair training programme (CSTP), eccentric-based stair training programme (ESTP) and P_{II} control group.

For concentric and eccentric-based stair training groups, two to three participants will be grouped and guided by an instructor who will observe participants and advise them to take a short break and drink water when necessary. Participants will also be instructed and encouraged to grasp the stair handrail when necessary. The training session will include general warm-up and cool-down exercises, including light stretching following Phase II. Each session will monitor heart rate and blood pressure before and after stair training. For the P_{II} control group, participants will be instructed to lead a habitual lifestyle without any pain medications.[14 21]

If a satisfactory outcome is not achieved, each participant will be offered further management at the end of this study. Table 2 demonstrates the design of a detailed and precise exercise protocol, including a short description of the interventions and their dosage.

Progression of interventions

The total intervention period for Phases I and II will last 16 weeks, during which participants will receive the designed intervention three times a week. In terms of practice, and based on each participant's circumstances, the frequency and intensity of intervention may differ. To ensure compliance and enhance motivation, each participant will receive a tracker sheet to monitor their HEP. The researcher will also use a checklist to track and assess the number, duration and method of interventions. Participants who cannot complete at least 80% of sessions will be considered dropped out.

Follow-up phase

In Phase I, participants of the P_I control group will undergo an 8-week follow-up period after completing the initial 8-week intervention. In contrast, eligible participants of Phase II will receive their allocated group intervention. In Phase II, all participants will undergo a 24-week follow-up after completing Phase II intervention. All participants will be encouraged to maintain a healthy and regular lifestyle during the follow-up period. Monthly health discussion sessions will be organised to further support long-term engagement and overall well-being, including personalised feedback based on each participant's progress, interactive educational modules on physical activity and disease prevention and peer support discussions to foster motivation and accountability involving participants and their guardians. These sessions will guide general health and lifestyle improvements and address any challenges faced in performing daily activities relevant to knee OA. Finally, after the follow-up period, participants will undergo reassessment to collect follow-up data, ensuring a comprehensive evaluation of the intervention's effectiveness.

Outcome measures

The primary outcomes are pain intensity, pressure pain threshold and functional ability which will be measured using the Numerical Pain Rating Scale (NPRS), pressure algometer and Western Ontario and McMaster University Osteoarthritis Index (WOMAC). The secondary outcomes are muscle strength, range of motion, aerobic capacity and quality of life, which will be measured using a modified sphygmomanometer, universal goniometer, 6MWT and 36-item Short Form Survey (SF-36). Furthermore, sociodemographic factors, including age, gender, BMI, heart rate, blood pressure, presence of various comorbidities (like high blood pressure and diabetes mellitus) that will be measured by the Charlson comorbidity index, regular medications, previous fall episode, physical activity/work status and other relevant factors will be included as generalised determinants and modifiers. The primary and secondary outcomes and the modifiable characteristics will be assessed at the pretest (T_1), post-test (T_2 and T_3) and follow-up (T_4).

Primary outcomes

Pain intensity

The pain intensity will be measured using the NPRS (11-point NPRS), a commonly used tool for measuring pain outcomes (0 means no pain, and 10 means worst possible pain). The NPRS is reliable for assessing pain intensity. Using the NPRS, the assessor will measure the participant's pain intensity during the last 24 hours. The NPRS will also be administered before and after each session; Intraclass correlation coefficient (ICC)=0.95.[22]

Pressure pain threshold

The pressure pain threshold will be measured using a hand-held standard pressure algometer (FPK 20, Wagner Instruments, Greenwich, Connecticut, USA). It is a reliable method for measuring pain sensitivity in knee OA. The tenderest area related to knee OA will be measured three times at intervals of 30 s, and the mathematical average will be observed; ICC=0.91.[23]

Functional ability

The functional ability will be measured using the WOMAC. WOMAC is a valid and trustworthy measure for assessing the functional ability of patients with knee OA. With a total score of 96, this scale comprises three subscales (total of 24 questions); each subscale score ranges from 0 to 4. WOMAC subscales, which measure pain, stiffness and physical function; ICC=0.86 (pain), 0.68 (stiffness), 0.89 (function).[24]

Table 3 Secondary outcomes

Outcome measurements	Measurement tool	Measurement description
Muscle strength	Modified sphygmomanometer	Evaluate knee flexor–extensor and hip flexor–extensor–abductor–adductor muscle strength (0–300 mm Hg). Valid and reliable for clinical assessment. ICC=0.80–0.99.[26 27]
Range of motion (ROM)	Universal goniometer (long-arm)	Measures active and passive knee flexion–extension ROM; ICC=0.990.[28]
Aerobic capacity	Six-minute walk test (6MWT)	Participants will walk as far as possible in 6 min in a 24-m space. Breaks or walking aids are allowed. ICC=0.86–0.96.[29]
Quality of life	36-item short-form survey (SF-36)	Measures health-related quality of life across eight domains (0–100). Higher scores indicate a better quality of life. ICC=0.900.[30]

ICC, Intraclass correlation coefficient .

Secondary outcomes

The secondary outcomes are muscle strength, range of motion, aerobic capacity and quality of life, which will be measured using a modified sphygmomanometer, universal goniometer, 6MWT and SF-36. Details of secondary outcomes are presented in table 3.

Study procedure

In Phase I, after being first screened by data collectors from the health awareness programme and study setting, a brief study explanation and written consent form will be provided to eligible participants. Then, after randomised-based group allocation, participants will be called over the phone into the already mentioned study settings for the pretest (T_1) and intervention guidelines. Then participants will receive an HEP or medications with healthy lifestyle guidelines based on group allocation for 8 weeks. Four responsible personnel will communicate with each participant over the phone weekly with an automated message during the 8 weeks. After 8 weeks, again a post-test (T_2) will be administered for both groups. Then, according to eligibility criteria, the participants will be allocated to three groups based on phase II randomisation. Allocated participants will receive an additional 8-week intervention according to the designed protocol. Ineligible people with knee OA for Phase II will be considered drop-outs from this study and will receive further management of knee OA. Blind assessors will conduct again a post-test (T_3) for Phase II and a follow-up test (T_3) for P_I control group participants. Finally, all participants of Phase II will undergo a 24 week follow-up (T_4) period.

Following the experiment's SPIRIT 2013 criteria, the transparency of this experimental study, study protocol and data collection techniques will be assured (table 1).

Staff training

Online and offline sessions will be employed to conduct the instruction. Training materials, procedural manuals, checklists, the research protocol and the principal investigator for consultation will all be continuously available to all study personnel. The responsibilities of assessors and health professionals will be the programme's main emphasis. Physiotherapists will be trained to lead, communicate in small groups, maintain a welcoming social environment and administer intervention protocols. Assessors will be trained to screen participants, obtain permission, conduct structured interviews and accurately collect data from physical activity tests and questionnaires. Additionally, monitoring staff will oversee physical activity and assist with modification as required.

Data management

Documents will be thoroughly checked for issues and inaccuracies regularly to preserve the authenticity of the data. All data will be verified twice. Following the evaluation, the trial manager, principal investigator and data monitoring staff will have daily access to the final trial data set, which the assessors will validate. When the trial's conclusion is obtained, each author will have comparable access to the private information. The principal investigator will keep all hard and soft copies of the data collected; no access or disclosure of the study participant's identities will be permitted. Only in the rare event that adverse effects are noted throughout the investigation will post-trial intervention be given. There will be two manual data-entering sessions to minimise errors. On encrypted servers, electronic information will be safely preserved. Every participant will be assigned a unique identity number, which will be used to encode every piece of information. In addition to unidentified data, a safe collection of identification numbers will be kept. Unidentified data will be used for statistical analysis to maintain anonymity, and the results will be consolidated.

Monitoring

The monitoring staff will consist of four non-trial personnel who will be monitoring the study. They will oversee the participant's group enrolment, side effects and the intervention regimen. They will also conduct a preliminary analysis and evaluate the data. The principal

investigator will notify the Institutional Review Board if there are any research procedures or intervention modifications.

Statistical analysis

SPSS V.26 for Windows will record and analyse the data. We will evaluate the normal distribution using the bell curve, kurtosis, skewness, Kolmogorov-Smirnov and Shapiro-Wilk test. Descriptive statistics such as mean, SD, frequency and percentage summarise continuous and categorical data. Multivariate analysis of variance and analysis of variance tests will be used to find variations in observational change across groups. Based on data distribution, baseline comparability and between-groups analysis will be assessed using the Mann-Whitney or independent t-test. The within-group analysis will be determined using the paired sample t-tests or the Wilcoxon test. The repeated measures analysis of variance will also be used for data analysis. Intention-to-treat analysis will be used to resolve addresses with missing data. The statistical significance level will be $p<0.05$.

Safety precautions and adverse effects management

Although the intervention is expected not to result in any noticeable side effects, the monitoring staff will keep watching for unexpected occurrences throughout and following the intervention. It will immediately alert the appropriate professionals in that situation. Any unfortunate events that arise will be noted in the SOAP note (Subjective, Objective, Assessment, and Plan) of the professional and communicated to the main researcher. In case of pain, skin irritation or discomfort arising, participants will be educated and instructed to get in touch with their physiotherapist right away. Detailed information about the trial's finalisation will be provided when significant negative effects appear. The principal investigator will report any changes to the strategy or procedure through the monitoring staff to the Institutional Review Board.

Ethical considerations

All actions and interventions will be conducted by the Helsinki Declaration of 2020, any subsequent changes to it, or equivalent ethical principles, in addition to the institutional research committee's ethical guidelines. In addition, this study is already registered as a randomised controlled trial in the Clinical Trials Registry—India (CTRI); registration number: CTRI/2025/03/081574. Participants and their legal guardians will read and sign the informed consent form.

Study status

This study will start to recruit participants in April 2025 and is estimated to be completed within March 2026.

Dissemination

The study outcomes will be presented after the experiment. First, an event will be conducted to explain the findings to researchers, physiotherapists, other medical experts and patients with knee OA. Second, the results will be shared by submitting the research paper to Scopus-indexed high-impact factor journals as an open-access article, ensuring universal access to the study's findings. We will arrange discussion sessions for health professionals to share the findings and impact of the intended protocol. These initiatives are designed to improve the prognosis for people with knee OA.

DISCUSSION

This study will be the first two-phase randomised controlled trial evaluating the effectiveness of a structured HEP and CSTP versus ESTP on pain and function in knee OA. We went through or overviewed many studies where various researchers investigated the effectiveness of HEP and concentric versus eccentric exercise programmes. Still, no study determined the effectiveness of CSTP and ESTP when integrated with a structural HEP for knee OA. That is why this study is going to have a great impact on the management of knee OA.

According to recent studies, the exercise programme is the most effective non-pharmacological treatment option, and it is a safe, low-cost method for treating knee OA that delays disease progression, relieves pain and improves functional ability. Exercise may include aerobic, strengthening, proprioceptive, range of motion and relevant traditional exercise. Exercise can be performed in hospitals or outside hospitals. Recently, one study reported that 44.2% of patients with knee OA decline to participate further in hospital-set exercise programmes.[25] Therefore, researchers investigated the effectiveness of various HEPs for knee OA. The aim of hospital and HEPs is to improve patients with knee OA's overall functional ability. The main differences are that home-based exercise is easier to learn, accessible, time-efficient and cost-effective. Numerous researchers established various efficient HEP. However, the postintervention effectiveness of these exercises on pain and physical function in patients with knee OA decreases over time.[25] So, incorporating additional exercise programmes after the initial intervention may enhance the long-term effectiveness. Besides, effective and efficient strengthening exercises should also integrate with HEPs for long-term effectiveness. Therefore, an evidence-based well-structured simple, cost-effective strengthening exercise integrated HEP is needed for optimal functional outcomes in knee OA.[25] This study will mitigate these limitations by investigating a well-structured cost-effective, sustainable, safe and efficient exercise programme for knee OA. Integrating concentric or eccentric-based strengthening exercises into an HEP may significantly enhance the functional ability of patients with knee OA. This study aims to establish a simple, accessible and effective concentric and eccentric exercise method for knee OA. In previous studies, CSTP and ESTP, particularly through ascending and descending stairs, have shown distinct benefits in older people that may also play a significant role in managing knee OA.[14] Previously, researchers focused on

the supervised concentric and eccentric-based exercise for knee OA. However, their implementation as a self-management strategy remains challenging.[12 13] Besides, no previous study explored this CSTP and ESTP for knee OA. The impact of a systematic stair training programme integrated with an HEP is yet critically unknown for knee OA management. To bridge this gap, this study has been meticulously developed to ensure an adequate sample size that eliminates biases and may determine the substantial effects of a well-structured strengthening exercise integrated HEP. This study investigates the programme's resilience and long-term effectiveness to minimise potential adverse effects and support using evidence-based, cost-effective, strengthening integrated HEPs for knee OA management.

The results of this study will benefit researchers, patients, treatment providers and the physiotherapy profession by enhancing the understanding of knee OA and facilitating the development of effective self-administered intervention alternatives. If successful, the study might enable people with knee OA to take charge of their health by establishing a useful and effective exercise routine at home. This might lessen long-term OA management's financial burden while improving their functional abilities and quality of life.

Being the first two-phase randomised controlled trial to investigate the effectiveness of a structured HEP and CSTP versus ESTP on pain and function in knee OA, this study's strength is that it fills a critical research gap. The participant and assessor-blinded study design improves internal validity by reducing bias and strengthening causal inference. However, the study's focus on a particular Bangladeshi community may restrict its generalisability. Additionally, participant retention problems throughout the 24-week follow-up may impact the final sample size and outcome evaluations.

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Patient consent for publication Consent obtained directly from patient(s).

Ethics approval This study involves human participants and was approved by Institutional Review Board of the Department of Physiotherapy and Rehabilitation, Jashore University of Science and Technology (JUST), Jashore, Bangladesh (ID: PTR-JUST/IRB/2025/02/192404).

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Data availability statement No data are available. The information used in this study was acquired from a third party and is not publicly accessible. Physiotherapy and Rehabilitation graduate programme servers will be password-protected to securely preserve electronic data. A unique identity number will be given to each participant, and all information will be encoded following that number. A distinct, safely kept list that links participant identity numbers with the de-identified data set will be kept apart from it. After data collection, all information will be completely anonymised and made available to authorised persons only.

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