

Efficacy of core stability and supervised hip strengthening on knee osteoarthritis: a Randomized study protocol

Eficácia da estabilização central e fortalecimento supervisionado do quadril na osteoartrite de joelho: um protocolo de ensaio clínico randomizado

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ABSTRACT | INTRODUCTION: Osteoarthritis (OA) is a significant problem associated with pain; it reduces function, and hampered the quality of life. Only a few previous studies have established the comparative effect of core stability and hip strengthening exercise.

OBJECTIVE: To investigate core stability and its relationship with supervised hip strengthening exercise in the management of knee OA. **METHODS:** This is a single centered project, two-group, pre-test, a post-test, randomized clinical trial where Forty-six patients with knee OA will be randomly allocated into two groups, Group A (experimental group 1) and B (experimental group 2) will receive core stability and hip strengthening exercise on three days a week for four weeks respectively across twelve treatment sessions. The primary outcome measure will be Knee Injury and Osteoarthritis Outcome measure (KOOS) in both English and Hindi versions, and secondary outcome measures will be Timed Up and Go test (TUG), Chair stand test to quantify pre and post effect of the intervention.

EXPECTED RESULTS: This study planned to assess the efficacy and importance of core stability and hip strengthening exercise in reducing pain, improving function and quality of life in patients with knee OA. **PROTOCOL/TRIAL REGISTRATION NUMBER:** CTRI/2020/06/025973

KEYWORDS: Exercise. Knee osteoarthritis. Pain. Quality of life.

RESUMO | INTRODUÇÃO: A osteoartrite (OA) é um problema significativo associado à dor, que reduz a funcionalidade e prejudica a qualidade de vida. Apenas alguns estudos prévios estabeleceram o efeito comparativo da estabilização e do exercício de fortalecimento do quadril. **OBJETIVO:** Investigar a estabilização e sua relação com o exercício supervisionado de fortalecimento do quadril no tratamento da OA do joelho. **METODOLOGIA:** Este é um projeto de ensaio clínico centralizado, dois grupos, pré-teste pós-teste, randomizado, onde quarenta e seis pacientes com OA de joelho serão alocados aleatoriamente em dois grupos. Grupo A (grupo experimental 1) e B (grupo experimental 2) receberão exercícios de estabilização e fortalecimento do quadril três dias por semana durante quatro semanas, respectivamente, em doze sessões de tratamento. A medida de desfecho primário será a medida de desfecho de lesão no joelho e osteoartrite (KOOS), ambas as versões em inglês e hindi, e as medidas de desfecho secundário serão o teste Timed Up and Go (TUG), o teste de suporte da cadeira para quantidade pré e pós efeito da intervenção. **RESULTADOS ESPERADOS:** Este estudo planejou avaliar a eficácia e a importância da estabilização e exercícios de fortalecimento do quadril na redução da dor, melhorando a função e a qualidade de vida em pacientes com OA de joelho. **NÚMERO DE REGISTRO DO PROTOCOLO / TESTE:** CTRI/2020/06/025973

PALAVRAS-CHAVE: Exercício. Osteoartrite do joelho. Dor. Qualidade de vida.

Introduction

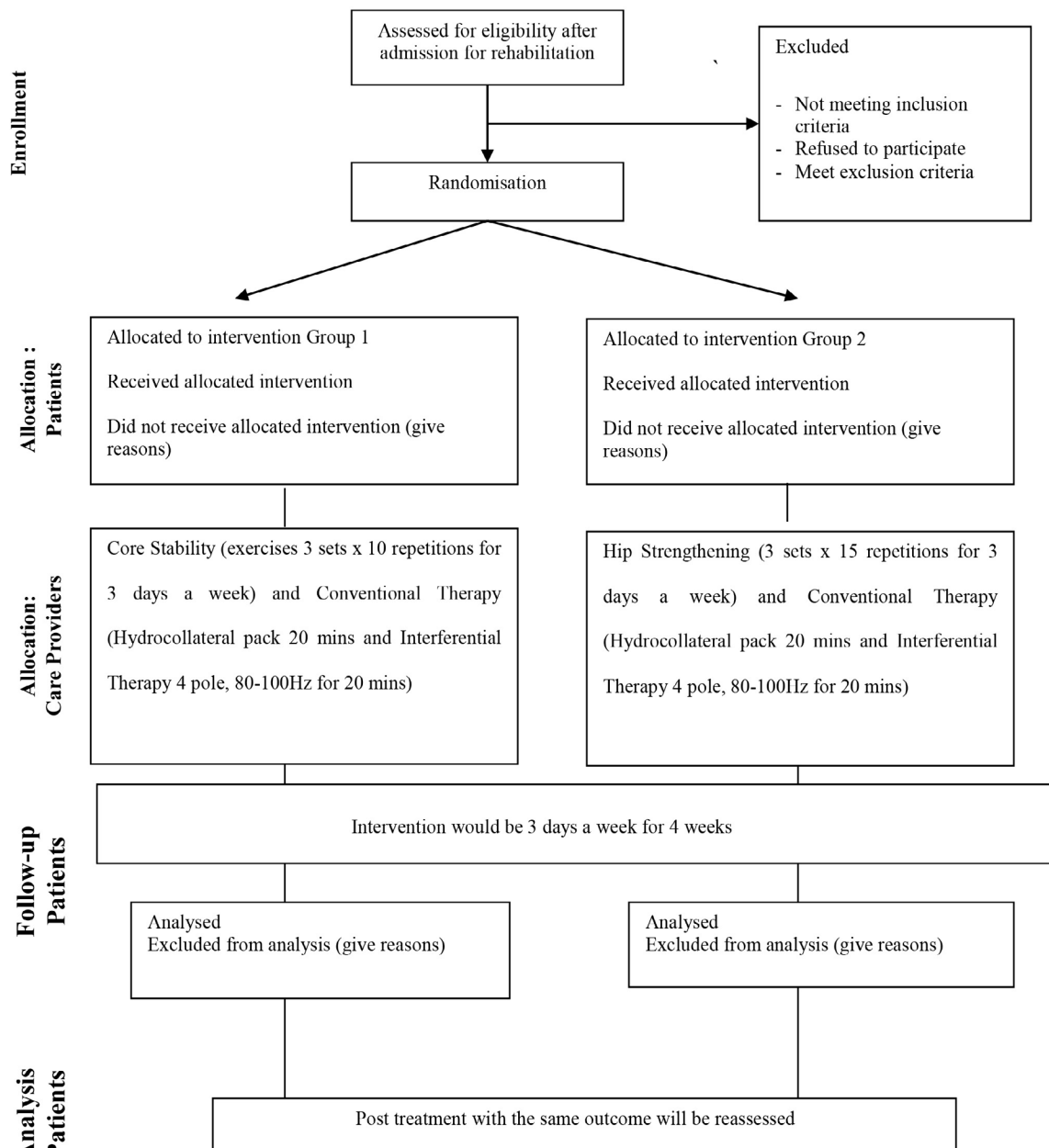
Osteoarthritis (OA) is a chronic degenerative condition that mostly affects individuals in the fourth and fifth decade of life.¹ Globally, 100 million individuals suffer from knee OA and the eighth leading cause of mobility impairment.¹ In India, its prevalence is 22% to 39% and 5.78% in rural areas.^{2,3} Knee OA impairs not only the physical ability but also causes a long-term psychological impact.² Hip abduction weakness results in contralateral pelvic to drop and centre of mass to shift towards the swing extremity. This increases the force on the medial compartment of the stance leg, and the disease starts succeeding. So the lumbopelvic stability is vital to support loads on the knee joint.^{4,5} Core stabilization and muscular synergism of the trunk and hip work is an effective way to improve lower limb strength balance and prevent injury.⁵⁻⁷ Only limited studies are available in context to specific treatment with knee OA population. Hence, more research is required in core stability and hip strengthening exercise along with conventional therapy as a mode of treatment in knee OA.

We hypothesize that no significant difference in pain, function, and overall quality of life in patients with knee OA undergoing core stability and hip strengthening exercise is a null hypothesis. In contrast, the significant difference between them was considered an alternate hypothesis. Therefore, the research question for this randomized clinical trial was: what are the effects of core stability and hip strengthening exercise on pain, function, and overall quality of life in patients with knee OA?

This study aims to determine the effects of core stability and hip strengthening exercise and compare which treatment method is effective in treating patients with knee OA.

Material and methods

Figure 1. Flow chart of study protocol



Trial registration

Ethical clearance was provided by the Institutional research ethical committee of Maharishi Markandeshwar (Deemed to be University), Mullana, Haryana (MMDU/IEC/1730). The study has been registered successfully in the World Health Organization International Clinical Trials Registry, obtained its universal trial number (U1111-1257-2626), and registered in Clinical Trial Registry-INDIA with CTRI number (CTRI/2020/06/025973). The study will be performed in accordance with the Indian Council of Medical Research's National Ethical Guidelines for biomedical and health research involving human participants (2017) and the ethical principles for medical research involving human subjects stated in the Declaration of Helsinki (revised 2013).

Study Design

The study is a single-blinded, single-centered, two-group pretest-posttest randomized clinical trial involving patients with knee OA.

Participant recruitment

Forty-six patients with knee OA will be recruited in the study according to the selection criteria as mentioned in Table 1. The orthopedics and physiotherapy outpatient department will refer patients. Demographic data of the eligible patient, such as the patient's code, gender, age, occupation, and address, will be recorded in a performance that will be pre-designed. A written consent form will be taken for each patient. The assurance that their privacy will be preserved and that their information will be used for research purposes with assured no harm will be given to every patient.

Selection criteria

Table 1. Selection Criteria for participants

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none">Both male and female participants willing to participate.Between the age group 40-60 years.⁷Participants with knee osteoarthritis grade 1, 2, 3, 4 according to Kellgren and Lawrence⁹:<ol style="list-style-type: none">Grade 1- Possible osteophytic lipping, Doubtful joint space narrowing.Grade 2- Definite osteophytes possible joint space narrowing.Grade 3- Multiple osteophytes possible joint space narrowing; Sclerosis.Grade 4- Large osteophytes marked joint space narrowing; Severe sclerosis, including both tibiofemoral and patellofemoral osteoarthritis of the knee.	<ul style="list-style-type: none">Participants having musculoskeletal disorders other than OA knee.Severe knee trauma history within the past six months.Previous intraarticular hyaluronic acid or steroid injection.Meniscal or connective tissue damageSystemic illness, hypo/hypersensitivity disorder, neurological disorders.Un-cooperative individuals will be excluded.¹⁰

Randomization

Criterion based purposive sampling will be used to assign the patients into two groups randomly (experimental group A (core stability) and experimental group B (hip strengthening) with twenty-three patients in each group, via block randomization using the SNOSE method (randomization sequence, the use of sequentially numbered, opaque sealed envelopes). Blocks will have even numbers with a 4 X 12 (48) matrix, suggesting four blocks with 12 rows. Subjects will then be allocated into each block using a random allocation sequence. Block randomization is beneficial because the number of subjects in each group remains similar at all times, increases the comparability

between groups, and there will be no biasing in the randomization of patients; everyone will get an equal chance to select in each group. Patients with knee OA will be assigned to experimental group A (core stability and conventional therapy) and experimental group B (hip strengthening and conventional therapy). Patients will be blinded to the intervention group.

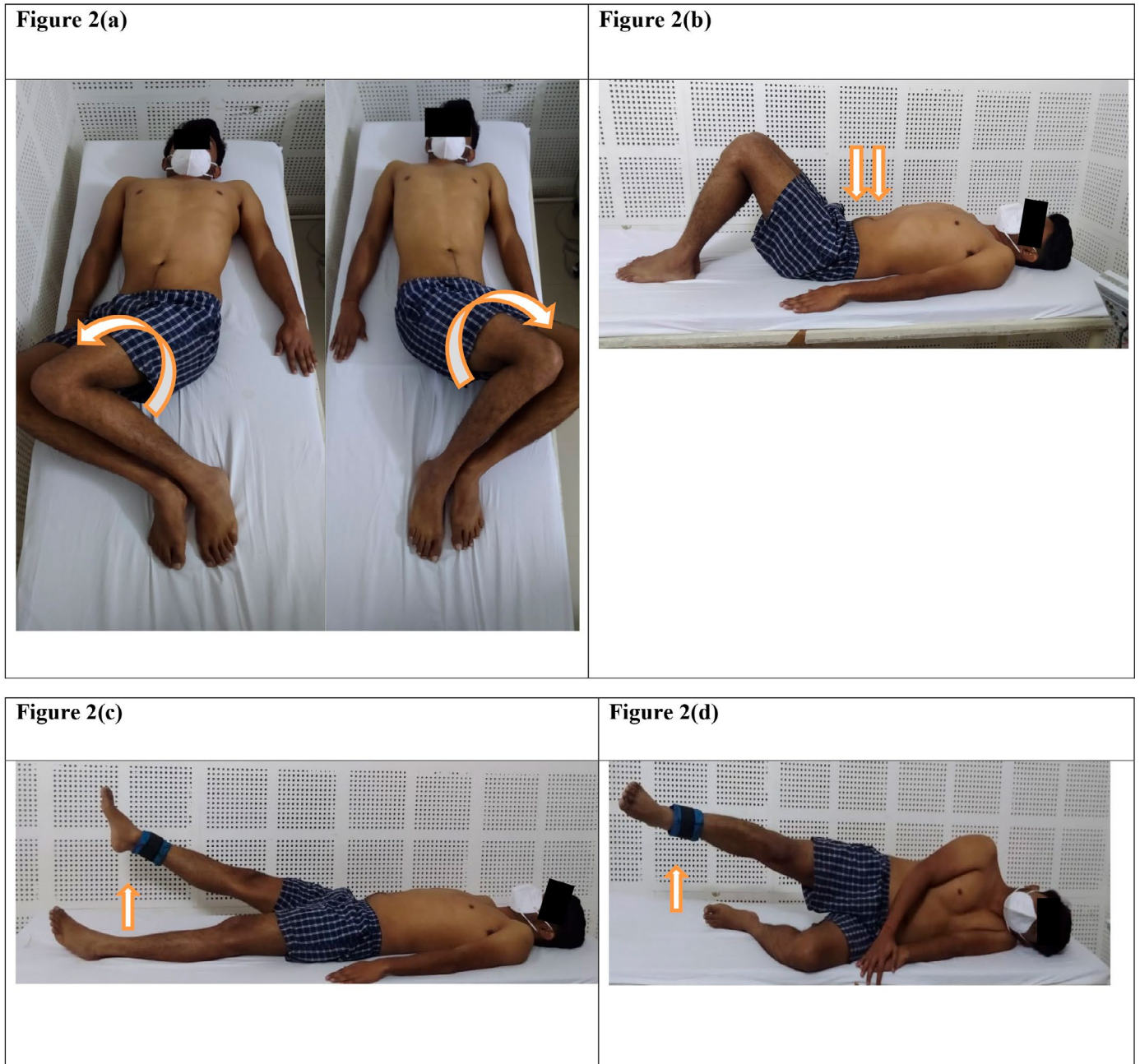
Interventions

After completing all assessments and obtaining baseline measures, the intervention will be conducted. Interventions will be given to both groups, i.e., Experimental Group A (core stability) and Experimental Group B (hip strengthening). Each group will receive twelve sessions of treatment three days a week for four consecutive weeks. Both groups will receive conventional therapy, i.e., hydro collator pack for 20 mins (22.86 x 22.86 cm)^{10,11} and Interferential Therapy (HMS Medical Systems, India) 4 pole with a carrier frequency of 4000Hz and 3900Hz, which generate a beat frequency of 100Hz, sweep frequency was 150Hz applied for 20 mins.¹² Group A will receive a core stability exercise protocol that includes segmental rotations and bent knee hollow hold.⁶ Group B will receive supervised hip strengthening exercise that includes flexion in supine and abduction in a side-lying position with weight cuff on the ankle.⁹ The ankle weight used will be 50% of 10 RM (to check for 10 RM, ask the patient to do a maximum number of repetitions with different weights. For example, if the patient can do it ten times and not perform for the 11th time, 50% of that weight will be used for hip strengthening). The intervention summary is displayed in Table 2.

Table 2. Interventions summary to be specified to the patients

Group 1 exercise protocol						
Core stability exercise programme	Exercise for 4 weeks	Procedure	Patient Position	Frequency	Number of repetitions and sets	Hold time
Exercise 1 [Figure 2(a)]	Segmental Rotation	Keep the abdomen contracted, then slowly rotate both lower limbs to the left, take three deep breaths, and return to the center. Repeat the movement on the right side.	Crook Lying	3 days a week	10 repetitions x 3 sets	3-5 seconds
Exercise 2 [Figure 2(b)]	Bent knee hollow hold	Ask the patient to contract the abdomen by focusing on pulling the umbilicus and rib cage toward the floor while flattening low back against the couch, eliminating the lumbar curve in the spine.	Crook Lying	3 days a week	10 repetitions x 3 sets	12 seconds
Group 2 exercise protocol						
Hip strengthening exercise	Patient Position	Procedure	Frequency	Number of repetitions and sets	Hold time with weight by ankle cuff	
Exercise 1 [Figure 2(c)]	Supine Lying	Ask the patient to raise the leg straight without knee bending	3 days a week	15 repetitions x 3 sets	10 seconds	
Exercise 2 [Figure 2(d)]	Side Lying	The patient will side-lying by keeping the knee flexed towards the chest for steadiness in contact with the couch, then raises the above leg into abduction, placing the hip in mild extension and neutral to avoid rotation.	3 days a week	15 repetitions x 3 sets	10 seconds	

Figure 2. Core stability and supervised hip strengthening exercise protocol



Outcome Measures

The outcome measures will be assessed before the first intervention session and after the execution of the twelfth session.

Primary Outcome Measure

Knee Injury and Osteoarthritis Outcome Measure (KOOS): To evaluate pain and quality of life, KOOS is used in patients with knee OA. KOOS is highly responsive, reliable, and valid to determine alteration for the patient with OA of the knee. It contains five subscales: Quality of life, pain, Activity of daily living, symptoms, and sport/recreation. Every subscale covers several items, scored with a 5-point (4= worst function /extreme pain, 0= full function/ no pain). The mean subscale is divided by 4; the result is multiplied by 100; then, to find out the significant subscale score, this figure is subtracted from 100. The minimum clinically important differences (MCID) for the KOOS in patients with knee OA were reported to be 8–10 points for each subscale. ICC (2,1)=0.85-0.86 (English Version), ICC=0.90-0.97 (Hindi Version).⁷

Secondary Outcome Measures

Timed Up and Go Test (TUG): TUG is used to evaluate function. It assesses the patient's capability to stand from the chair, then walk for three meters, turn, walk back, and sit on the same chair. The TUG is highly responsive and valid to determine alteration in patients with OA of the knee. The minimum clinically important differences (MCID) is reported to be 0.8–1.4s for the TUG in patients with OA of the knee. ICC (2, 1)=0.95-0.98.⁷

Chair Stand Test: The chair stand test is used to evaluate strength. It is similar to a squat test used to measure leg strength, in which the participant stands to erect repeatedly from a chair for 30 seconds. This test is part of the Senior Fitness Test Protocol and is designed to test the functional fitness of senior individuals. ICC (2,1)=0.84-0.92.¹³

Table 3. SPIRIT- (Standard Protocol Items: Recommendation for Interventional Trials)

	Study Period						
	Enrollment	Allocation	Post-allocation (treatment)				Close-out (evaluation)
Time point	0 week	0 week	1st week	2 nd week	3 rd week	4 th week	At the end of 4 th week
Enrollment							
Eligibility screen	X						
Informed consent	X						
Clinical evaluation, inclusion & exclusion criteria	X						
Allocation		X					
Interventions							
Core Stability with conventional Physiotherapy			X	X	X	X	
Hip Strengthening with conventional physiotherapy			X	X	X	X	
Assessments							
Demographic data		X					
KOOS		X					X
TUG		X					X
Chair stand test		X					X

Safety and adverse outcomes

Knee Injury and Osteoarthritis Outcome Measure (KOOS) will be used as a primary outcome measure. Timed Up and Go Test (TUG) and Chair stand test will be used as a secondary outcome measure. All the outcome measures will be used at baseline and after the intervention. A therapist who will provide the intervention will also record any adverse effect and record the grades and severity of the same. Treatment protocol will be set in such a way that it has minimal risk. In any case, if the treatment will cause side effects, then it will be liable to the therapist. According to WHO guidelines for the COVID-19 pandemic, all the safety measures such as wearing gloves and masks will be followed. A separate cabin will be used for the treatment before the temperature monitoring is done. The gathering will be avoided, and sanitization will be done before and after the treatment. Bedsheets will be changed after each session. Patients will be instructed to take care of hand hygiene and use personal protective equipment, such as face masks, etc.

Data monitoring

An independent researcher will perform all the statistical analyses and datasets. A treating physiotherapist will monitor the treatment sessions in each group.

Follow up

The therapist will encourage the patients on the phone to visit for the follow-up on fixed dates.

Sample size estimation

The sample size will be 46 patients with knee OA, which was determined by using statistical G Power 3.1.9.4 software (Heinrich-Heine-Universität Düsseldorf, Germany).⁸ The level of significance at $\alpha = 0.05$ and power of the study was set to 90% ($1 - \beta = 0.9$) with the anticipated effect size of 0.8, a calculation based on the study by Hoglund et al.⁷

After the calculation, the sample size was out to be 46 (including 20% group out) (i.e., 23 participants per group) which will then be randomised into two groups.

Data Analysis

The primary researcher will collect and analyze the data. The data analysis will be done by using Statistical Package for the Social Sciences (SPSS) version 16 (SPSS Inc, Chicago, IL). The level of significance will be set at 0.05. Shapiro-Wilk test will be used to check the normality of collected data as sample size 46. Descriptive statistics will be expressed in mean \pm standard deviation if the data follow a normal distribution. If not, it will be expressed in the median and interquartile range. Depending on the distribution of data, either Paired t-test or Wilcoxon signed-rank test will be used to compare the pre and post-intervention score within the group. In addition, to compare intervention score between the groups, Independent t-test or Mann Whitney U-test will be used for pain, improvement in function and quality of life questionnaire.

Discussion

Knee OA is a chronic degenerative condition that leads to severe disability associated with pain, trouble in activities of daily living, and psychological impression leads to hampered quality of life. In the present study, patients with knee OA will perform core stability exercises and supervised hip strengthening, along with conventional physiotherapy. This study aims to evaluate the effect of core activation exercise and hip strengthening exercises to reduce pain, improve function and accelerate the quality of life in patients with knee OA. To the best of our knowledge, there are only a few studies on core stability and hip strengthening in patients with knee OA, but no comparative study for knee OA to reduce pain, improve function, and quality of life as strengthening exercise is a generally accepted treatment for OA knees. Studies show that core stability improves balance in the lower limb as core stability stands as a popular rehabilitation program and hip strengthening improves flexibility leads to a decrease in pain and improved performance.^{5,6,14} The limitation of this study will be the allocation of participants from the same rehabilitation centre. A limited number of studies comparing the core stability and supervised

hip-strengthening exercises is available; the present study will seek to compare the effects of both exercise protocols among patients with knee OA and the effect on pain, function, and quality of life.

Author contributions

All the authors of the study helped in designing and conducting the research, and all the authors approved the manuscript of the study.

Competing interests

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

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