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Effects of therapist-monitored high and low dose home exercise program in patients with knee osteoarthritis

Submission date
26/09/2025

Recruitment status
No longer recruiting

Registration date
02/02/2026

Overall study status
Completed

Last Edited
02/02/2026

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The current study aimed to compare the effectiveness of therapist-monitored low versus high dose home exercise program (lo-hi dose protocol) in patients with knee osteoarthritis (OA). This is a randomly allocated study that will compare the effectiveness of low-dose and high-dose home exercise programs against a control group receiving usual care, focusing on pain, function, quadriceps muscle strength, and physical performance in patients with knee osteoarthritis.

Who can participate?
Patients aged 50 years and older with knee osteoarthritis.

What does the study involve?
This study will compare [hi vs low vs control home exercise program] to see which is more effective in terms of pain intensity, physical function, physical performance, and sleep quality after 8 weeks of intervention. After baseline assessment, participants will be randomly allocated to three groups: low intensity exercise (Low dose), high intensity exercise (high dose) or usual care (control) groups. In the low-dose and high-dose exercise group, participants will perform an 8-week therapist-monitored individualized home exercise, two sessions per day, 5 days a week. The untreated control group only receive patient education about energy conservation and joint protection techniques.

What are the possible benefits and risks of participating?
Participants will receive a therapist-monitored home exercise program, which will help them manage their pain and improve physical function. There is no known risk because the program will be individualized and monitored by experienced therapists.

Where is the study run from?
Dr. D.Y. Patil Vidyapeeth, Pune, College of Physiotherapy, India.

When is the study starting and how long is it expected to run for?
February 2022 to June 2024

Who is funding the study?
Dr. D.Y. Patil Vidyapeeth, Pune, India.

Who is the main Contact:
Dr Tushar J Palekar, principal.physio@dpu.edu.in

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
DYPCPT/IEC/40/2022

Study information

Scientific Title
Effects of therapist monitored low versus high dose home exercise program in patients with knee osteoarthritis: a randomized controlled trial (Lo-HI dose trial)

Acronym
Lo-Hi dose trial

Study objectives
The goal of this clinical trial is to learn if a high or low dose of home exercise is effective in managing people with knee osteoarthritis.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/04/2022, The Institutional Ethics committee of Dr D Y Patil College of Physiotherapy (Plot no. BGP/190, Near Pavna Industries, Midc Area, Bhosari, Pune, 411026, India; +91 20 6410 8555; rrbhonde@gmail.com), ref: DYPCPT/IEC/40/2022

Study design
Single-blind randomized clinical trial

Primary study design
Interventional

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied

Knee osteoarthritis

Interventions
Researchers will compare [hi vs low vs control home exercise program] to see which is more effective in terms of pain intensity, physical function, physical performance, and sleep quality after 8 weeks of intervention. After baseline assessment, participants were randomly allocated to three groups: low-intensity exercise (low dose), high-intensity exercise (high dose) or usual care (control) groups.

In the low-dose exercise group, participants performed following exercises for two sessions per day or as pain-tolerated: 1) walking for 10 minutes 2) straight leg raising exercise (SLR) for one set of 10 repetitions; 3) single leg standing (SLS) for one set of 10 repetitions; 4) semi squat for one set of 10 repetitions; 5) seated knee extension exercise for one set of 10 repetitions; 6) bilateral hip abduction and adduction exercise, for one set of 10 repetitions; and 7) self-stretching of quadriceps and hamstrings for one set of 10 repetitions.

In the high-dose exercise group, participants performed the same exercise program with an increased number of sets (e.g., 2-3 sets) and repetitions (15-20 repetitions) for a longer duration.

The untreated usual care control group received only patient education regarding energy conservation and joint protection techniques as outlined in the Mayo Clinic Booklet during the trial.

Intervention Type
Behavioural

Primary outcome(s)
1. Pain intensity was measured using a visual analogue scale (VAS) at baseline and week 8
2. Physical function was measured using the Western Ontario and McMaster Universities Arthritis Index (WOMAC) Likert version 3.1 at baseline and week 8

Key secondary outcome(s))
1. Physical Performance was measured using the 30-second chair stand test (30sCST) at baseline and week 8
2. Sleep quality was measured using the Insomnia Severity Index (ISI) at baseline and week 8

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Aged 50 and older
2. Symptomatic knee osteoarthritis diagnosed with grade ≥ 2 OA using the Kellgren-Lawrence severity scale
3. Having knee pain ≥ 2 on a VAS in the past week

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
50 years

Upper age limit
110 years

Sex
All

Total final enrolment
100

Key exclusion criteria
1. Neurological disorders
2. Implanted electrical devices
3. Non-ambulatory status
4. Significant cognitive impairment
5. Systemic inflammatory arthritis (e.g., gout)
6. A history of hip or knee replacement surgery, trauma or surgical arthroscopy of either knee within the last 6 months
7. Prior involvement in a similar study
8. Participation in an exercise program within the last 6 months
9. Intra-articular knee injection within the last 3 months
10. Anticoagulant therapy
11. Recent or imminent surgery (within 3 months), or medical co-morbidities that would preclude participation in exercises

Date of first enrolment
02/05/2022

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
India

Study participating centre
Dr. D. Y. College of Physiotherapy
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Sponsor information

Organisation
Dr. D.Y. Patil Vidyapeeth, Pune

ROR
https://ror.org/00s2qq515

Funder(s)

Funder type
University/education

Funder Name
Dr. D.Y. Patil Vidyapeeth, Pune

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Tushar J Palekar, principal.physio@dpu.edu.in.
Anonymized individual participant data can be accessed.

IPD sharing plan summary
Available on request