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The Effectiveness of Structured Rehabilitation. Program in Early Osteoarthritis Knee:A Randomized Control Study

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Title

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Abstract

Objectives- Osteoarthritis (OA) is a leading cause of pain& disability The randomized controlled trial (RCT) was done to investigate whether a 12-week treatment program of structured rehabilitation program results in greater improvement in pain, function and Quality of life (QOL) compared with usual care in patients with early knee osteoarthritis (KOA).

Design- The patients who were above the age of 40 with a diagnosis of Osteoarthritis of kneewere part of the study. The participants were randomized

in 1:1 ratio into structured rehabilitation program group and usual care group using a computer-based randomization system.
Results- All the 4 sub-scores showed improvement in both groups from baseline at the final follow-up. The change in pain score (11.6), symptom score (11) and QOL score (16.5) was significant in intervention group compared with control group in adjusted DID analysis. Age and gender were the two important factors influencing the reduction in KOOS scores.

Conclusion: Structured exercise regimens should explored as a cost effective modality to ameliorate the symptoms of knee osteoarthritis and improvement in quality of life. Such an exercise programme should include isotonic, isometric and neuromuscular junction exercises. Patient education is also vital.

The randomized controlled trial was registered with the Clinical Trials Registry – India (CTRI) under registration number **CTRI/2023/07/055413** on 20/07/2023.

Keywords- Knee osteoarthritis, Rehabilitation, Exercise therapy, Randomized controlled trial, Quality of life.

Introduction

Osteoarthritis (OA) is a chronic degenerative, non-inflammatory disease mainly affecting weight-bearing joints, most commonly the knee and hip joint[1].It is a leading cause of pain and disability and approximately 528 million people are currently affected globally[1].OA is much more common in women than men and its burden is expected to continue increasing due to the ageing and increasingly obese population[2].

OA of the knee can be classified based on the aetiology into either idiopathic or primary and secondary forms[3]. When there is no known cause, it's referred to as primary OA and occurs mainly due to aging[4]. OA of knee is a huge contributor towards disability among elderly. It has a 47% prevalence among the elderly in India[4].

NSAIDS (topical & oral) and intra-articular injections are the recommended pharmacological modalities of OA knee management[5].Patient education programs, exercises, weight reduction, self-efficacy and self-management programs, use of knee bracesare some of the recommended non-pharmacological therapies[6].

Exercises like the quadriceps strengthening exercises[7], resistance exercises and neuromuscular exercises[8] have a definite role in the management of OA

knee.These should be part of any rehabilitation program aiming to improve the functionality and alleviate pain associated with OA knee. Unfortunately there is a paucity of scientific literature regarding the ideal dosage of exercise to be included in such programmes. Another unexplored modality of exercise incorporation in a sequential stepping up approach.

The purpose of this randomized controlled trial (RCT) was to investigate whether a 12-week treatment program of structured rehabilitation program including ROM exercises, stretching progressive resistance strengthening exercises and neuromuscular exercises results in greater improvement in pain, function and Quality of life (QOL) compared with usual care (only isometric quadriceps strengthening) in patients with early knee osteoarthritis (KOA).

Materials & Methods

The studywas conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines[9]. The completed CONSORT checklist has been provided as a supplementary miscellaneous file.The trial was registered in the clinical trial registry of X (CTRI/2023/07/055413) dated 20th July 2023. The Department of Physical Medicine & Rehabilitation, at a tertiary care centre served as the setting of this study that spammed from July 2023 to December 2023.
The patients who were above the age of 40 with a diagnosis of Osteoarthritis of knee were part of the study. ACR clinical and radiographic criteria (KL grade 1 and 2) was used for identifying study participants. Patients with a knee joint effusion grade of up to 1+ on the stroke test were included.

Patients with history of surgical interventions in the past one year, those with history of lower limb fractures in the last 6 months, and those with history of intra-articular injections in last 3 months were excluded. Patients who complained of pain in knee/hip/back (VAS score > 7) that limited their ability toperform exercises and patients with dementia or any neurological condition that precluded their compliance in the study, werealso excluded.

The sample size needed to detect a 10-point difference between groups in KOOS4 and the individual KOOS subscales(standard deviation of 14, power of 80% and P-value of 0.05 (two-sided)) was 31patients in each arm based on a study done by S.T Skou et.al[10].

The primary outcomes were pain, symptoms, knee-related Quality of Life, Outcome scale (KOOS).The self-administered scale has 42 items and 5 subscales. The subscales were that of pain(9 items), other symptoms (7 items), activities of Daily Living (ADL, 17 items), sports and recreation function (Sport/Rec, 5 items), and knee-related Quality of Life (QoL,4 items). Secondary outcomes were OA pain (measured using Visual analogue scale)and Knee flexors and extensors strength (usingcomputerized muscle testing machine).

All study participants assessed with KOOS questionnaire and VAS Pain scale
Knee Muscle parameters testing with David EVE machine

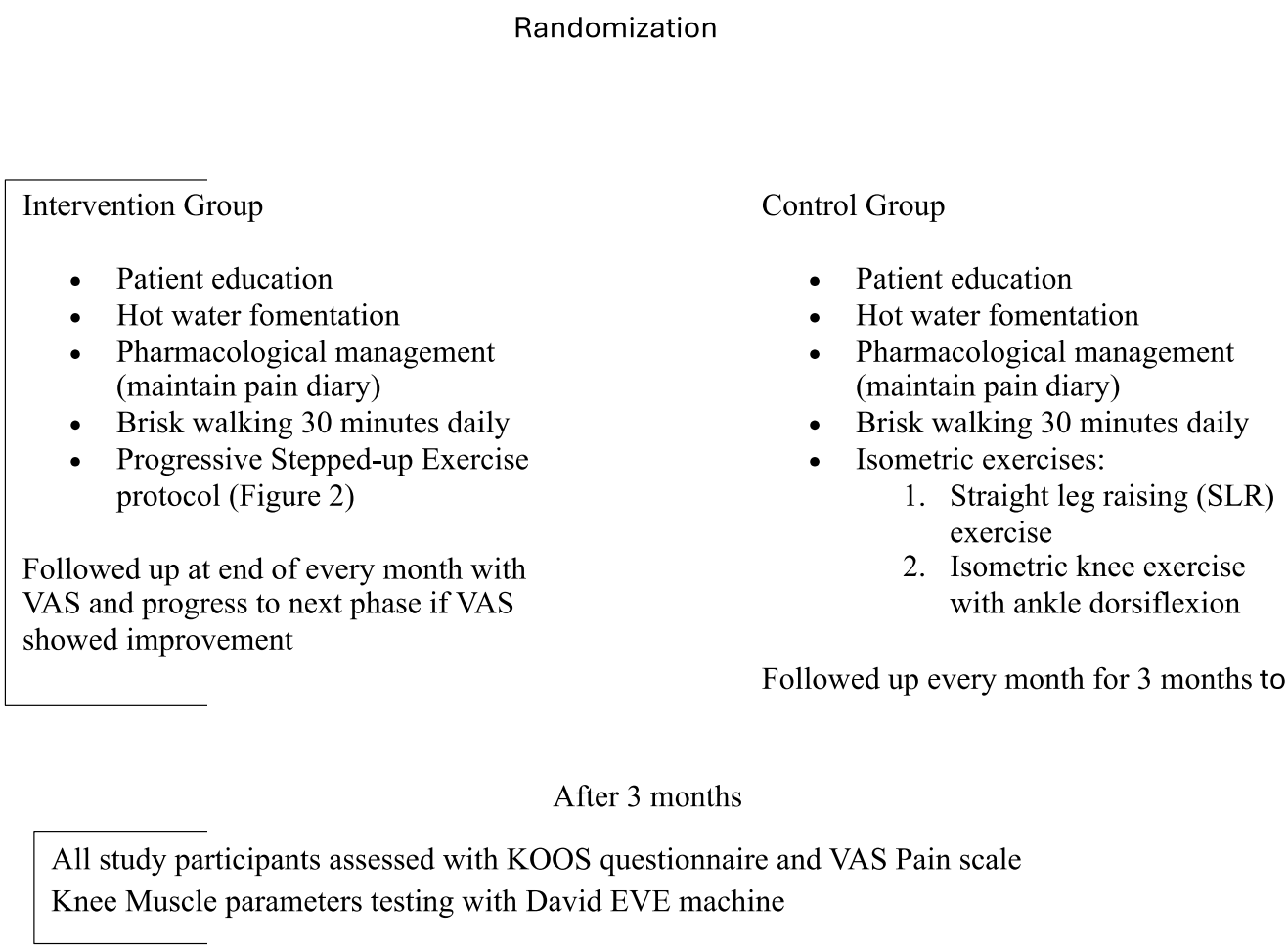


Figure 1. Study Flow diagram.

Figure 1. The study flow diagram.

The figure 1 depicts the recruitment, assessment and intervention details of the study participants. All participants meeting the inclusion criteria were then randomized in 1:1 ratio into structured rehabilitation program group and usual care group using a computer-based randomization system(CONSORT flow diagram supplementary figure 1). The allocation was concealed using sequentially numbered, opaque, sealed containersand masking was done on the investigator and the data analyst.

The details of the intervention and standard care given to the study subjects has been summarised in Figures 1 & 2. The exercise regimen given to the patients has been summarised in supplementary material table S1.

All study subjects received patient education, and advise on hot water fomentation, brisk walking and maintain a pain dairy of taking Tab Paracetamol 650mg as and when required.

In addition to this, thecontrol group was taught isometric quadriceps strengthening exercises at the start of the study and only their VAS score noted at end of every month for 3 months and no other inputs were given.

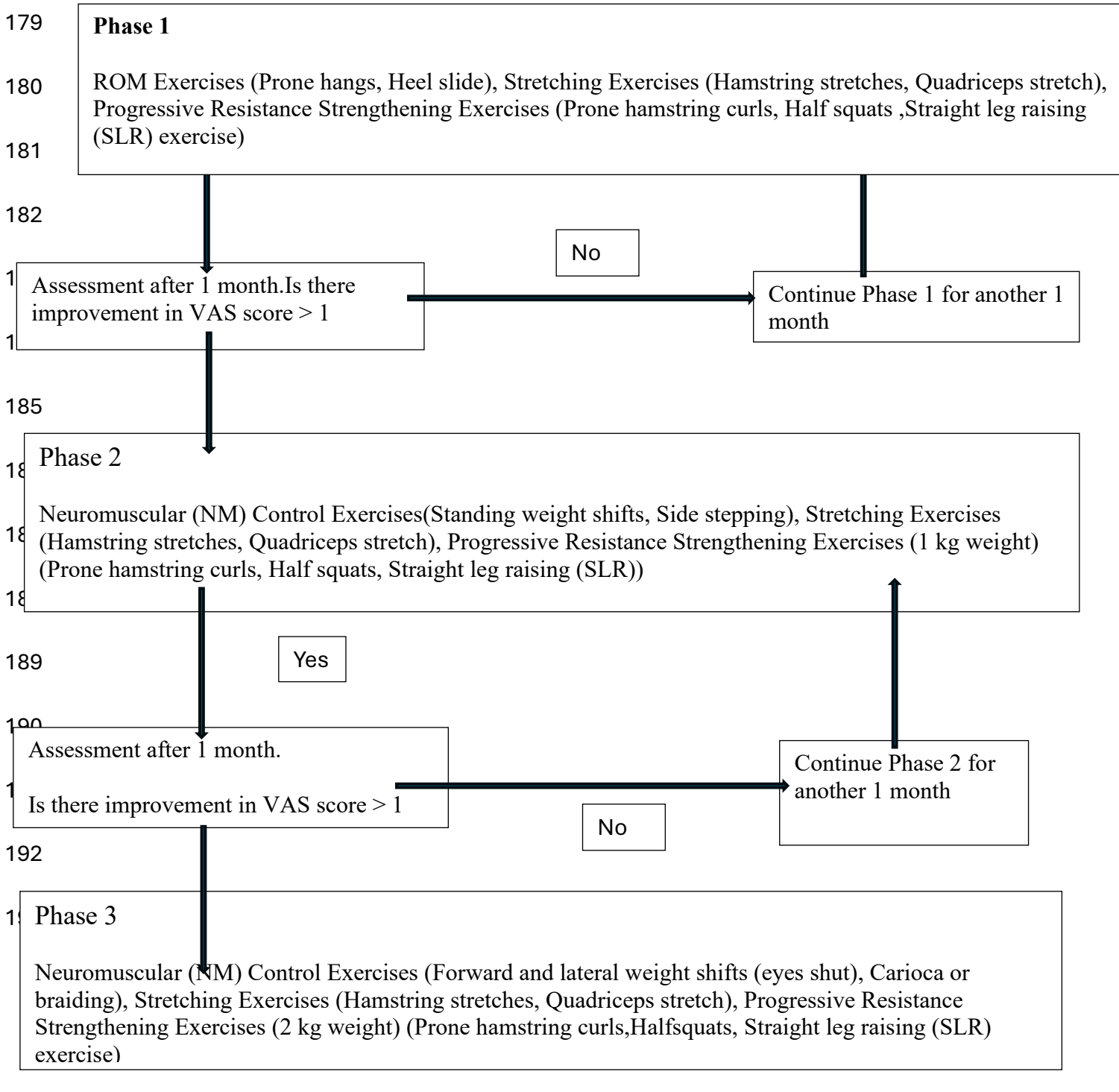


Figure 2. Exercise protocol for the intervention group.

As depicted in Figure 2, the intervention group was then given exercises in a phased manner. Phase 1 included ROM exercises, stretching and strengthening exercises of knee extensors and flexors. At the end of 1 month, their VAS was assessed and those who showed improvement was taken to the next phase, Phase 2. Those who didn't show improvement was advised to continue the phase 1. Phase 2 and 3 included additions of resistance to strengthening exercises along with neuromuscular control exercises and the assessment was same as mentioned above.

In both the groups, to assure the compliance teleconsultation was done every 2 weeks and every month patients were asked to visit the OPD.

At the end of each phase, VAS pain scale of the intervention group was assessed. Control group was followed up every month to ensure the compliance to usual . Then at the end of the intervention, all study participants were evaluated using KOOS scale, VAS scale and David EVE Machine.Exercise protocol for the intervention group is detailed in the Figure 2.

The continuous variables were summarized as median with IQR or mean with standard deviation depending on distribution. Between group comparisons were done using Wilcoxon Rank sum or unpaired t-test.

The difference in change of KOOS sub scores between the groups was calculated using DID model. Both adjusted and unadjusted between group differences were calculated. In the adjusted analysis age, sex and BMI at baseline were also included in the model. The change in mobility parameters were compared between the groups using difference in difference regression analysis. Categorical variables were summarized as frequency and proportions and compared between the groups using chi square test.

Results

The total 62 study participants were randomized with 31 each in the intervention arm and in the usual care (control) arm completing the 3 months follow-up. The treatment was given in phased manner in the intervention group and the patients who responded by improving the VAS were only given the next phase. In the intervention group 24 (77.4%) out of 31 completed all the three phases of the intervention.Demographic and clinical characteristics of both groups at baseline are presented in **table 1.**

Table 1. Sociodemographic Characteristics of the study participants.

		Intervention Arm (n = 31)	Control Arm (n = 31)
Age*(years)*	Mean (SD)	52.2 (7.8)	50.8 (6.7)
BMI *(kg/m^2)*	Mean (SD)	28.0 (3.7)	27.0 (3.2)
Gender	Male	11 (35.5)	12 (38.7)
	Female	20 (64.5)	19 (61.3)
Clinical Symptoms	Swelling	16(51.6%)	19(61.3%)
	Crepitation	31(100%)	23(74.2%)
	Stiffness	23(74.2%)	19(61.3%)

	Difficulty in knee extension	26(83.9%)	28(90.3%)
	Difficulty in knee flexion	23(74.2%)	21(67.7%)
Pain – At start of study Based on the VAS score	Mild	0	2(6.5%)
	Moderate	31(100%)	29(93.5%)

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237 Baseline and final KOOS4 sub-scores (pain, symptoms, ADL, and QOL) of
238 both groups are shown in table 2. All the 4 sub-scores showed improvement in
239 both groups from baseline at the final follow-up with more improvement in the
240 study group.

Table 2. Baseline and End line KOOS of patients

	Intervention Arm (n = 31)		Control Arm (n = 31)	
KOOS sub-scores (Mean with SD)	Baseline	Endline	Baseline	Endline
Pain Score	40.0 (16.6)	69.0 (18.6)	52.3 (13.6)	69.7 (16.2)
Symptom Score	43.4 (13.2)	71.1 (16.0)	47.0 (15.5)	63.6 (14.4)
ADL Score	42.6 (16.5)	67.1 (16.6)	49.4 (13.2)	70.0 (14.2)
Sports/Recreational score	28.4 (21.6)	52.4 (20.5)	23.1 (14.4)	48.4 (20.4)
QOL Score	16.3 (11.1)	57.4 (16.8)	28.6 (14.8)	53.2 (20.5)

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As shown in table 3, The change in pain score (11.6), symptom score (11) and QOL score (16.5) was significant in intervention group compared with control group with p-values 0.04, 0.03 and 0.005 in adjusted DID analysis.

But improvement in ADL was statistically not significant and comparable among both the groups.

Table 3. Difference in Difference model analysis of KOOS

KOOS sub-scores	Between group difference (unadjusted)	p-value*	Between group difference (adjusted)	p-value*
Pain Score	11.6 [0.02, 23.2]	.05	11.6 [0.34, 23.0]	**.04****
Symptom Score	11.0 [0.5, 21.6]	**.04****	11.1 [1.0, 21.1]	**.03****
ADL Score	3.9 [-6.9, 14.7]	.47	3.9 [-6.7, 14.6]	.46
Sports/Recreational score	-1.3 [-15.1, 12.5]	.85	-1.3[14.5,11.9]	.85
QOL Score	16.5 [5.0, 28.0]	**.005**	16.5 [5.0, 28.0]	**.005**

****significant in the regression model, KOOS: Knee Injury and osteoarthritis outcome score; ADL: activities of daily living; QOL: quality of life**

Table 4 shows that age had statistically significant effect on change in pain score, symptom score, ADL score and sports and recreational score. As age increases, chance of improvement in pain, symptoms and ADL decreases.

Gender had statistically significant effect on the change in pain score. Females compared to males showed less improvement in all subscales with pain score showing significant difference (0.01)

Table 4 Adjusted Difference in Difference model analysis of effect of Age, Sex and BMI on KOOS

KOOS Sub-scores	Age	p	Female Sex	p	BMI	p
Pain Score	-0.5[-0.9, -0.1]	**.02***	-8.0[-14.3,1.6]	**.01***	-0.02 [-0.9, 0.8]	.97
Symptom Score	-0.7[-1.1, -0.4]	**<.01***	-1.3[-6.9, 4.3]	.65	0.1[-0.6, 0.9]	.70
ADL Score	-0.4[-0.8, -0.1]	**.03***	-5.4[-11.4, 0.5]	.07	-.04[-0.8, 0.8]	.92
Sports/ Recreational score	-0.9[-1.4, -0.4]	**<.01***	-6.7[-14.1, 0.6]	.07	0.3[-0.7, 1.3]	.52
QOL Score	-0.3[-0.7, 0.1]	.13	-0.2[-6.6, 6.3]	.96	-0.4[-1.3, 0.5]	.38

***significant in the regression model, KOOS: Knee Injury and osteoarthritis outcome score; ADL: activities of daily living; QOL: quality of life**

As shown in supplementarytable 1, both the groups showed improvement in VAS score with intervention group having more improvement. But at all points of observation, the median VAS didn't differ significantly between the groups.

On comparing the improvement in both groups, there was statistically significant increase in strength of extensors in intervention group compared to the controls (supplementary table 2).

Discussion

At the end of the follow up period of three months both the intervention arm and control arm showed an improvement on all domains of knee-related Quality of LifeOutcome scale (KOOS)KOOS.

Statistically significant reduction was observed in the intervention group in the 3 of the 5 subdomains of KOOS- pain score, symptom score and quality of life score. This results underscores the importance of incorporating exercises in the rehabilitation programmes. This idea is backed by similar studies conducted exploring the question.The exercise programme we devised had isotonic, isometric and neuromuscular junction exercises.Isotonic, isometric and isokinetic exercises all had a definite role in improvement in functionality and pain reduction[11]. Isometric exercise can improve hyaluronic acid levels in the joint capsule. Muscle strength recovery and improved proprioception are added advantages[12]. Neuromuscular exercises can enhance balance, muscle activation, functional alignment, and joint stability[13]. Strength training relieves pain, alleviates stiffness, enhances muscle strength, improves physical function, and increases the shock absorption ability of the lower limb muscles[14]. Our study used a phased intervention that incorporated these various forms of exercises. The synergistic effect is reflected in the significant drop in KOOS- pain score, symptom score and improvement in quality of life score.
Irrespective of the grade of the knee osteoarthritis combined balance and strengthening exercise programs can positively impact pain, physical function, and dynamic balance[15]. Combined balance and strength programme can help fall prevention and improve lower limb biomechanics[16].

Isometric exercises and patient education has a definite role in the management of osteoarthritis knee as evidenced by the improvement of KOOS scores in the control group. Combining patient education with exercise regimens seems to improve pain outcomes in Osteoarthritis[17].

Age and gender seems to be two important factors influencing the reduction in KOOS scores. Age is a known risk factor for development of osteoarthritis. Age related alterations in cellular renewaland immune senescence can impact the regeneration of connective tissue, playing a critical role in the onset and progression of OA[18].

Female gender was associated with less reduction pain scores. Poor joint congruence and increased mechanical strain associated with walking can cause cartilage tear contributing towards increased prevalence of osteoarthritis in women [19]. Associated factors like obesity, peculiarities in joint anatomy, and hormonal milieu can account for the increases incidence of osteoarthritis in females[20]. There is significant difference in the pain pathways and pain perception which explains the attenuated improvement in pain scores among the females[20].

Strengths and limitations

The program of structured rehabilitation program is extremely generalizable, simple to learn, and does not require any equipment, which aids learning and program adherence, which are major strengths of our study. Because of the multimodal nature of the treatment program, it is unknown whether all components of our program are required for the effect observed, making it impossible to determine the efficacy of a single treatment modality.
As per our protocol, only those who improved in pain in taken to the next phase as a result all the patients in study were able to complete all the three phases.
We did not include individuals with severe pain (NRS > 7) because we were concerned that exercise would worsen their symptoms. As a result, whether our program can relieve pain and enhance other health outcomes in people suffering from severe pain has not been determined.
The fact that the patients were followed up and closely monitored might have had a Hawthorne effect. The compliance might not be as good as this in real life settings.
Also, our sample size was small compared to other similar studies which might have affected our results. Finally, because our intervention lasted only 12 weeks, we were unable to establish the long-term impact of the exercise intervention on patient compliance or outcomes.

Conclusion
Structured exercise regimens should explored as a cost effective modality to ameliorate the symptoms of knee osteoarthritis and improvement in quality of life. Such an exercise programme should include isotonic, isometric and

neuromuscular junction exercises. Patient education is also vital. The possibility of ensuring compliance to such regimens should also be looked into.

Declarations

This study was conducted and is reported in compliance with the **Consolidated Standards of Reporting Trials (CONSORT) guidelines**.

Ethics approval and consent to participate

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. The approval of the All India institute of medical sciences, New Delhi India institutional ethics committee was obtained (Ref. No.: IECPG-322/27.04.2022, RT-01/30.06.2022). The study was done according to the principles of declaration of Helsinki. Informed consent was obtained from all study participants.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Geethu A. V.: Conceptualization, Methodology, Data curation, Investigation, Writing – original draft.

Gita Handa Thukral: Methodology, Writing – review and editing.

Jose Vincent: Methodology, Writing – review and editing, Manuscript preparation.

Gayathri A. V.: Methodology, Formal analysis, Writing – review and editing.

Sanjay Wadhwa: Supervision, Resources, Writing – review and editing.

All authors read and approved the final manuscript.

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None

Clinical trial number

The randomized controlled trial was registered with the Clinical Trials Registry – India (CTRI) under registration number **CTRI/2023/07/055413** on 20/07/2023.

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Figure 1. Study Flow diagram.

Figure 2. Exercise protocol for the intervention group.

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Table 4 Adjusted Difference in Difference model analysis of effect of Age, Sex and BMI on KOOS

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