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COMPARING THE EFFECT OF TOE-IN GAIT MODIFICATION ALONG WITH CONVENTIONAL PHYSIOTHERAPY IN PEOPLE WITH MEDIAL KNEE OSTEOARTHRITIS

Original Research

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ABSTRACT

Background: Medial knee osteoarthritis (OA) is a progressive joint disorder characterized by pain, stiffness, and reduced mobility, significantly impacting daily activities and quality of life. Conventional physiotherapy remains a primary non-surgical treatment, focusing on pain relief and functional improvement. However, biomechanical interventions, such as gait modification, have shown potential in redistributing joint loads and alleviating symptoms. Toe-in gait modification has been proposed as an adjunct to standard physiotherapy, potentially enhancing clinical outcomes by reducing medial knee loading and knee adduction moment (KAM).

Objective: This study investigates the additional benefits of integrating toe-in gait modification with conventional physiotherapy in individuals with medial knee OA.

Methods: A randomized controlled trial was conducted at Al Madinah Medical Center and Sukoon Rehab Center, enrolling 34 participants diagnosed with medial knee OA. Participants were randomly assigned to two intervention groups: Group A received conventional physiotherapy, while Group B underwent conventional physiotherapy with toe-in gait modification. The intervention was administered three times per week for eight weeks. Outcomes were assessed using the Numeric Pain Rating Scale (NPRS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Data were analyzed using parametric statistical tests.

Results: At baseline, the mean pain score (NPRS) was 7.30 (SD = 0.984) in Group A and 7.86 (SD = 1.219) in Group B. By the eighth week, pain scores decreased to 4.45 (SD = 1.051) and 4.39 (SD = 1.00), respectively (p < 0.01). Functional outcomes also improved, with WOMAC scores declining from 40.53 (SD = 4.888) in Group A and 43.29 (SD = 5.047) in Group B at baseline to 23.06 (SD = 7.301) and 21.35 (SD = 2.029) by week eight (p < 0.01). Group B exhibited slightly superior improvements in both pain and function.

Conclusion: Toe-in gait modification, when combined with conventional physiotherapy, demonstrated significant improvements in pain reduction and functional enhancement in individuals with medial knee OA. While both interventions were effective, the addition of gait modification provided slightly greater benefits, suggesting its potential as a complementary strategy in OA management. Further research is required to explore long-term effects and optimize individualized rehabilitation approaches.

Keywords: Gait modification, Knee osteoarthritis, Numeric Pain Rating Scale, Pain management, Physiotherapy, Rehabilitation, WOMAC.

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INTRODUCTION

Osteoarthritis (OA) is the most prevalent chronic degenerative joint condition, with knee OA being the most common form, particularly in developed countries. It affects nearly 20% of individuals over the age of 45, with a global incidence of approximately 364.6 million cases reported in 2019 (1-4). The primary symptom of knee OA is pain, which is largely attributed to excessive mechanical stress on the knee joint. The medial compartment is predominantly affected, with prevalence rates of 67.8% in Eastern and 85.4% in Western populations (5-7). Since 60-80% of the load during walking is transmitted through the medial knee compartment, this imbalance accelerates OA progression, resulting in pain, joint stiffness, reduced range of motion, muscle weakness, balance impairments, and decreased functional capacity (8). These symptoms contribute to increased healthcare costs and a decline in quality of life, reinforcing the need for effective, non-surgical treatment strategies. Conventional management primarily focuses on pain relief and slowing disease progression through electrotherapy, strengthening exercises (targeting the quadriceps and hip abductors), and manual therapy (6). Among non-surgical interventions, structured land-based exercise programs, particularly walking, play a vital role in disease management. Gait modification has emerged as a promising biomechanical approach aimed at reducing medial knee loading and alleviating pain in individuals with medial knee OA. One of the key biomechanical factors associated with medial joint loading and disease progression is the knee adduction moment (KAM), which reflects the distribution of forces across the knee joint during weight-bearing activities (9-11). Various strategies have been explored to reduce KAM, with modifications in foot progression angle—such as toe-in or toe-out gait adjustments—showing potential efficacy. Studies suggest that adopting a toe-in gait pattern can reduce medial knee contact load by approximately 25.3% within one month (12-14). This is particularly relevant given that conventional treatment options, including the use of assistive devices, achieve only a modest KAM reduction of 10-13% (15-18). While surgical interventions like high tibial osteotomy (HTO) effectively offload the medial knee compartment, they are associated with post-surgical risks and longer recovery periods, making non-invasive approaches more desirable. Gait modification thus presents a viable alternative for mitigating knee joint stress and potentially improving clinical outcomes in knee OA.

Several studies have investigated the impact of gait modification on KAM and knee OA symptoms, demonstrating its potential benefits. Study have reported a 13% reduction in KAM with a 5-degree toe-in gait adjustment in individuals with medial knee OA, suggesting its efficacy as a conservative management approach (19). Another study conducted a literature review and concluded that gait retraining programs effectively minimize KAM, reinforcing their role in knee OA management (20). More recent studies have further substantiated these findings. Wan et al. (2023) examined foot progression angle (FPA) modifications in OA and healthy control participants and found that increasing toe-in FPA significantly reduced KAM across various activities (p<0.001), though the benefits were less pronounced during stair ambulation (21). Additionally, another study analyzed muscle activation patterns and observed that while toe-in gait resulted in the greatest KAM reduction (35%), it also increased flexor activation, highlighting the need for a balanced approach in gait retraining (12). Simic et al. further emphasized the complexity of optimizing FPA adjustments, as different modifications significantly influence medial knee loading (13). Despite these promising findings, Tamura et al. (2024) noted that while gait modification holds significant therapeutic potential, high-quality evidence remains limited, necessitating further research (2). Given the promising evidence supporting gait modification as a non-invasive strategy for reducing medial knee loading, its integration with conventional physiotherapy may enhance clinical outcomes in knee OA management. However, while existing studies suggest a beneficial role of toe-in gait in reducing KAM, a comprehensive assessment of its combined effects with standard physiotherapy interventions remains unexplored. This study aims to evaluate the efficacy of integrating toe-in gait modification with conventional physiotherapy in individuals with medial knee OA, focusing on pain relief, functional improvements, and long-term disease management.

METHODS

This study was a single-blinded randomized controlled trial (RCT) conducted over six months at Al Madinah Medical Center and Sukoon Rehab Center in Lahore. Ethical approval was obtained from the Institutional Review Board (IRB) before study initiation, and all participants provided written informed consent prior to enrollment. A total of 34 participants diagnosed with medial knee osteoarthritis (MKOA) of Grades 1-3, as classified by the Kellgren-Lawrence system, were recruited and randomly assigned to two intervention groups. The sample size was determined using G*Power software to ensure adequate statistical power. Participants were included if they were over 45 years of age, had experienced knee pain for at least one month, and were able to walk independently for a minimum



of 25 minutes. Those with severe MKOA (Grade 4), lateral or patellofemoral osteoarthritis, prior knee or hip surgery, rheumatoid arthritis, or neurological dysfunction were excluded to maintain sample homogeneity (12). Pain intensity and functional limitations were assessed using the Numeric Pain Rating Scale (NPRS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The NPRS, a validated subjective pain assessment tool, required participants to rate their pain on a scale of 0 (no pain) to 10 (worst pain imaginable). The WOMAC index was employed to evaluate pain, stiffness, and physical function, with higher scores indicating greater impairment. Baseline assessments were performed prior to intervention allocation, after which participants were randomly assigned using a sealed-envelope method. The single-blinded study design ensured that participants remained unaware of their assigned intervention group to minimize bias (8).

Group A received conventional physiotherapy, which included a structured regimen of isometric, strengthening, and stretching exercises targeting key muscle groups involved in knee joint stability and function. Electrotherapy modalities such as transcutaneous electrical nerve stimulation (TENS) and a heating pad were also utilized as part of the pain management protocol. The exercise program consisted of quadriceps activation exercises, seated knee extensions, and hamstring and calf stretches, all of which were progressively modified based on individual tolerance and clinical assessment (17). Group B received the same conventional physiotherapy protocol with the addition of gait modification. Participants in this group were instructed to increase the toe-in angle of their affected limb by approximately 5 degrees during ambulation. To ensure adherence and safety, supervised training sessions were initially conducted to familiarize participants with the modified gait pattern. Walking duration started at 10 minutes per day and was gradually increased to 20 minutes after four weeks. Both groups underwent treatment three times per week for eight weeks, with progress monitored through periodic reassessments (9).

Statistical analysis was performed using SPSS software, with appropriate tests applied to compare pre- and post-intervention outcomes between the two groups. Normality of data distribution was assessed, and parametric or non-parametric tests were selected accordingly. Between-group comparisons were conducted to determine the effectiveness of the intervention in reducing knee adduction moment (KAM), alleviating pain, and improving functional performance. The study aimed to explore the role of toe-in gait modification as a non-invasive intervention for optimizing clinical outcomes in individuals with medial knee osteoarthritis (19).

RESULTS

The study included 34 participants diagnosed with medial knee osteoarthritis, with a mean age of 50.94 years (SD = 5.448) in Group A and 51.47 years (SD = 5.614) in Group B. Gender distribution was balanced, with 47.1% males and 52.9% females in both groups. The mean symptomatic side value was 1.59 (SD = 0.507) in Group A and 1.76 (SD = 0.437) in Group B. The normality test confirmed that all Numeric Pain Rating Scale (NPRS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) data followed a normal distribution (p > 0.05), validating the use of parametric statistical tests. Pain intensity, measured using NPRS, demonstrated a significant reduction over time in both groups. At baseline, the mean pain score was 7.30 (SD = 0.984) in Group A and 7.86 (SD = 1.219) in Group B. By the fourth week, pain scores decreased to 6.03 (SD = 0.819) in Group A and 6.20 (SD = 0.839) in Group B. By the eighth week, further reductions were observed, with scores reaching 4.45 (SD = 1.051) in Group A and 4.39 (SD = 1.00) in Group B, indicating a statistically significant effect of time (p < 0.01).

Functional outcomes, assessed through the WOMAC index, also showed notable improvements. The baseline mean WOMAC score was 40.53 (SD = 4.888) in Group A and 43.29 (SD = 5.047) in Group B. By the fourth week, the scores declined to 33.12 (SD = 4.729) in Group A and 35.82 (SD = 6.598) in Group B. At the eighth-week assessment, further reductions were noted, with Group A showing a mean WOMAC score of 23.06 (SD = 7.301) and Group B demonstrating a score of 21.35 (SD = 2.029), signifying a significant functional enhancement over time (p < 0.01). The results indicated that both conventional physiotherapy and toe-in gait training contributed to significant pain reduction and functional improvement. Although both groups exhibited substantial progress, the experimental group, which received toe-in gait training alongside conventional physiotherapy, demonstrated slightly better outcomes in terms of pain reduction and functional enhancement.



Table 1: Descriptive statistics of pain

	Groups	Mean	Std. Deviation	F value	P value
	A	7.30	0.984	97.490	.000
NPRS Baseline	В	7.86	1.219	.951	.000
	A	6.03	0.819	97.490	.000
Pain 4th Week	В	6.20	0.839	.951	.000
	A	4.45	1.051	97.490	.000
Pain 8th Week	В	4.39	1.000	.951	.000

Table 2: Descriptive statistics of WOMAC

	Groups	Mean	Std. Deviation	F value	P value
WOMAC Baseline	A	40.53	4.888	125.448	.000
	В	43.29	5.047	2.083	.000
WOMAC 4th Week	A	33.12	4.729	125.448	.000
	В	35.82	6.598	2.083	.000
WOMAC 8th Week	A	23.06	7.301	125.448	.000
	В	21.35	2.029	2.083	.000

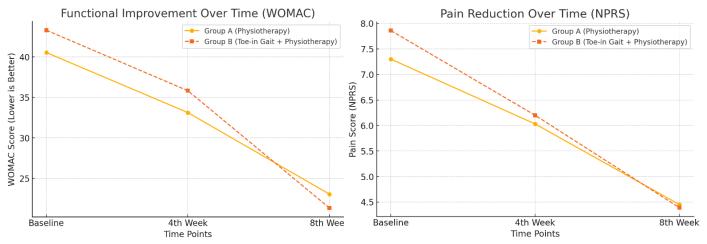


Figure 2 Functional Improvement Over Time (WOMAC)

Figure 1 Pain Reduction Over Time (NPRS)

DISCUSSION

The study evaluated the effectiveness of toe-in gait modification in combination with conventional physiotherapy for managing medial knee osteoarthritis. Findings demonstrated a significant reduction in pain intensity and improvement in physical function over time, with slightly superior outcomes observed in the group that received gait modification alongside physiotherapy. Pain scores, as measured by the Numeric Pain Rating Scale (NPRS), showed a marked decline over the eight-week intervention, with the toe-in gait group exhibiting a slightly greater reduction. Functional improvements were reflected in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores, which also showed a significant decrease in both groups. The normality test confirmed a normal distribution of the data, ensuring the validity of statistical analyses (22). The observed improvements align with previous research supporting the role of gait modification in reducing knee joint stress. Toe-in gait adjustment has been associated with reductions in knee adduction moment



(KAM), a key biomechanical factor contributing to medial knee osteoarthritis progression. Earlier investigations have highlighted that modifying foot progression angle alters load distribution within the knee joint, subsequently reducing pain and enhancing functional mobility. The integration of gait modification with physiotherapy offers a more comprehensive approach to addressing both biomechanical misalignment and muscle imbalances, providing a potential non-invasive alternative to conventional treatment strategies. Previous studies have primarily focused on KAM reduction as an outcome measure, while this study contributes by demonstrating improvements in clinical pain and function scores. These findings suggest that toe-in gait modification, when combined with strengthening and mobility exercises, may enhance overall treatment efficacy (23).

Despite these promising results, several limitations should be considered. The relatively small sample size may limit the generalizability of the findings, necessitating larger-scale studies to confirm the observed effects. The study duration was restricted to eight weeks, and long-term outcomes remain unknown. Medial knee osteoarthritis is a progressive condition, and the sustainability of improvements following gait modification warrants further exploration. The lack of objective biomechanical assessments, such as motion analysis or plantar pressure measurements, restricts the ability to quantify changes in gait parameters accurately. Future studies should incorporate advanced biomechanical assessment tools to validate findings and ensure precision in gait modifications. Furthermore, while toe-in gait adjustment appeared to be beneficial, individual variability in response was not extensively analyzed. Factors such as pre-existing gait patterns, lower limb muscle strength, and patient adherence to gait retraining protocols could influence outcomes and should be considered in future investigations (24). The clinical implications of these findings emphasize the potential of gait modification as a viable adjunct to physiotherapy in medial knee osteoarthritis management. Conventional physiotherapy interventions primarily target muscle strength and joint mobility, while gait modification directly addresses load distribution and biomechanical factors. The combination of these approaches may optimize treatment outcomes by addressing both pain and function more effectively. However, the application of toe-in gait modification should be individualized, considering patient-specific biomechanics to avoid potential secondary effects, such as altered ankle loading (25,26).

Further research is required to establish standardized protocols for gait modification in osteoarthritis rehabilitation. Longitudinal studies assessing the durability of benefits and potential adverse effects are needed. Comparative analyses between different gait retraining approaches, including toe-out adjustments and assistive devices, could provide insights into the most effective strategies for specific patient subgroups. By expanding the evidence base, future studies can refine gait modification protocols and optimize their integration into clinical practice.

CONCLUSION

The findings of this study demonstrate that both conventional physiotherapy and toe-in gait modification effectively contribute to pain reduction and functional improvement in individuals with medial knee osteoarthritis. Significant improvements were observed over time, with the integration of toe-in gait modification showing slightly superior outcomes. These results highlight the potential of combining gait retraining with physiotherapy as a non-invasive approach to optimizing treatment effectiveness. By addressing both biomechanical alignment and muscle function, this combined intervention offers a promising strategy for managing knee osteoarthritis. Future research should focus on long-term effects and individualized application to further refine its clinical utility.



AUTHOR CONTRIBUTIONS

Author	Contribution				
	Substantial Contribution to study design, analysis, acquisition of Data				
	Manuscript Writing				
	Has given Final Approval of the version to be published				
Qurba Kiran	Substantial Contribution to study design, acquisition and interpretation of Data				
	Critical Review and Manuscript Writing				
	Has given Final Approval of the version to be published				
Samra Anwar	Substantial Contribution to acquisition and interpretation of Data				
	Has given Final Approval of the version to be published				
Author	Contribution				
Aisha Siddigua	Contributed to Data Collection and Analysis				
	Has given Final Approval of the version to be published				
Sved Saglaın Babarl	Contributed to Data Collection and Analysis				
	Has given Final Approval of the version to be published				
Sidra Jamal - I	Substantial Contribution to study design and Data Analysis				
	Has given Final Approval of the version to be published				
	Contributed to study concept and Data collection				
	Has given Final Approval of the version to be published				
Muhammad Shazib Butt	Writing - Review & Editing, Assistance with Data Curation				

REFERENCES

- 1. Tamura H, Hirohama K, Hamada K, Imura T, Mitsutake T, Tanaka R. Clinically significant effects of gait modification on knee pain: A systematic review and meta-analysis. Journal of Back and Musculoskeletal Rehabilitation. 2024;37(1):3-12.
- 2. Anwer N, Manzoor N, Kiran Q, Saleem M, Fatima SA, Rehan A. Quadriceps Femoral Angle (Q Angle) Variations in Knee Osteoarthritis Patients. Pakistan Journal of Medical & Health Sciences. 2022;16(09):627-.
- 3. Hutchison L, D'Souza N, Grayson J, Hiller C, Kobayashi S, Simic M. Toe-in and toe-out gait retraining interventions to reduce proxy measures of medial knee joint load in people with medial knee osteoarthritis: Protocol for a randomised placebo-controlled trial. Contemporary Clinical Trials. 2023;134:107355.
- 4. Huang C, Chan PK, Chiu KY, Yan CH, Yeung DSS, Lai CWK, et al. Knee joint loadings are related to tibial torsional alignments in people with radiographic medial knee osteoarthritis. PLoS One. 2021;16(7):e0255008.
- 5. Batool F, Kiran Q, Mubashar H, Gull M, Batool A, Ashraf S. Hamstring Muscle Tightness and Chronic Low Back Pain an Analytical Study on General Population. Pakistan Journal of Medical & Health Sciences. 2022;16(09):637-.
- 6. Pereira DB, de Souza TS, Fuzinato CT, Hagihara RJ, Ribeiro AP. Effect of a programme of muscular endurance, balance and gait exercises with and without the use of flexible and minimalist shoes in older women with medial knee osteoarthritis: study protocol for a randomised controlled trial. BMJ open. 2022;12(9):e061267.
- 7. Booij M, Richards R, Harlaar J, van den Noort J. Effect of walking with a modified gait on activation patterns of the knee spanning muscles in people with medial knee osteoarthritis. The Knee. 2020;27(1):198-206.
- 8. Wan Y, McGuigan P, Bilzon J, Wade L. The effect of foot orientation modifications on knee joint biomechanics during daily activities in people with and without knee osteoarthritis. Clinical biomechanics (Bristol, Avon). 2024;117:106287.



- 9. Tamura H, Hirohama K, Hamada K, Imura T, Mitsutake T, Tanaka R. Clinically significant effects of gait modification on knee pain: A systematic review and meta-analysis. J Back Musculoskelet Rehabil. 2024;37(1):3-12.
- 10. Wan Y, McGuigan P, Bilzon J, Wade L. The effect of foot orientation modifications on knee joint biomechanics during daily activities in people with and without knee osteoarthritis. Clinical Biomechanics. 2024:106287.
- 11. Wan Y, McGuigan P, Bilzon J, Wade L. The effectiveness of a 6-week biofeedback gait retraining programme in people with knee osteoarthritis: protocol for a randomised controlled trial. BMC Musculoskelet Disord. 2023;24(1):984.
- 12. Alonso-Rodríguez AM, Sánchez-Herrero H, Nunes-Hernández S, Criado-Fernández B, González-López S, Solís-Muñoz M. [Efficacy of hydrotherapy versus gym treatment in primary total knee prosthesis due to osteoarthritis: a randomized controlled trial]. An Sist Sanit Navar. 2021;44(2):225-41.
- 13. An J, Son YW, Lee BH. Effect of Combined Kinematic Chain Exercise on Physical Function, Balance Ability, and Gait in Patients with Total Knee Arthroplasty: A Single-Blind Randomized Controlled Trial. Int J Environ Res Public Health. 2023;20(4).
- 14. Boekesteijn RJ, van Gerven J, Geurts ACH, Smulders K. Objective gait assessment in individuals with knee osteoarthritis using inertial sensors: A systematic review and meta-analysis. Gait Posture. 2022;98:109-20.
- 15. Charlton JM, Krowchuk NM, Eng JJ, Li LC, Hunt MA. Remotely delivered, individualized, and self-directed gait modification for knee osteoarthritis: A pilot trial. Clin Biomech (Bristol). 2023;106:105981.
- 16. Dai J, Jin X, Ma JX, Wu YF, Lu B, Bai HH, et al. Spatiotemporal and kinematic gait analysis in patients with knee osteoarthritis and femoral varus deformity. Gait Posture. 2023;105:158-62.
- 17. Donec V, Kubilius R. The effectiveness of Kinesio Taping(®) for mobility and functioning improvement in knee osteoarthritis: a randomized, double-blind, controlled trial. Clin Rehabil. 2020;34(7):877-89.
- 18. Gao B, Li L, Shen P, Zhou Z, Xu P, Sun W, et al. Effects of proprioceptive neuromuscular facilitation stretching in relieving pain and balancing knee loading during stepping over obstacles among older adults with knee osteoarthritis: A randomized controlled trial. PLoS One. 2023;18(2):e0280941.
- 19. Hutchison L, Grayson J, Hiller C, D'Souza N, Kobayashi S, Simic M. Relationship Between Knee Biomechanics and Pain in People With Knee Osteoarthritis: A Systematic Review and Meta-Analysis. Arthritis Care Res (Hoboken). 2023;75(6):1351-61.
- 20. Imboden M, Séguin É, Doumit M. Design and evaluation of an offloading orthosis for medial knee osteoarthritis. Med Eng Phys. 2023;121:104063.
- 21. Li X, Cao Y, Cao Z, Zheng P, Merryweather A, Wang H, et al. Gait Improvement in Patients with Knee Osteoarthritis after Proximal Fibular Osteotomy. Biomed Res Int. 2022;2022:1869922.
- 22. Machado S, Érika S, Brito V, Maciel L, Quintans Júnior LJ, da Silva Junior W, et al. Knee Osteoarthritis: Kinesiophobia and Isometric Strength of Quadriceps in Women. Pain Res Manag. 2022;2022:1466478.
- 23. Ng WH, Jamaludin NI, Sahabuddin FNA, Ab Rahman S, Ahmed Shokri A, Shaharudin S. Comparison of the open kinetic chain and closed kinetic chain strengthening exercises on pain perception and lower limb biomechanics of patients with mild knee osteoarthritis: a randomized controlled trial protocol. Trials. 2022;23(1):315.
- 24. Robert-Lachaine X, Dessery Y, Belzile É L, Corbeil P. Knee braces and foot orthoses multimodal treatment of medial knee osteoarthritis. Gait Posture. 2022;96:251-6.
- 25. Suzuki Y, Ohkoshi Y, Kawakami K, Shimizu K, Chida S, Ukishiro K, et al. Assessing knee joint biomechanics and trunk posture according to medial osteoarthritis severity. Sci Rep. 2023;13(1):19186.
- 26. Vincent KR, Vincent HK. Concentric and Eccentric Resistance Training Comparison on Physical Function and Functional Pain Outcomes in Knee Osteoarthritis: A Randomized Controlled Trial. Am J Phys Med Rehabil. 2020;99(10):932-40.