Scientific summary

What were the main scientific objectives of the grant?

Please note that this trial was conducted as a limited disclosure trial to enhance intervention credibility. Participants were not aware of a placebo gait retraining group allocation and did not receive information regarding the details of any of the other intervention groups. As the trial is in the final stages of completion, meaning participants receiving the intervention and final assessments are being conducted, the lay summary does not provide details of the intervention groups.

The primary aim was to determine the effect of a 6-week gait retraining program (load-reducing toe-in and toe-out intervention) compared to placebo gait retraining intervention on proxy measures of medial knee load (early stance peak KAM, late stance peak KAM, KAM impulse and varus thrust) in people with medial knee OA.

Secondary aims were to determine the effect of the three gait retraining interventions on self-reported pain, and performance- based measures of physical function in people with medial knee OA at 6 weeks. We also aimed to evaluate if the biomechanical and symptomatic effects are maintained at 3 months follow-up.

What did we do to answer this question?

We conducted a three-arm randomized placebo-controlled trial and are in the final recruitment phase at the University of Sydney, Central Sydney (Patyegarang) Precinct, Australia. The study, registered with the Australian New Zealand Clinical Trials Registry (ACTRN 12621000414819) and approved by the Institutional Human Research Ethics Committee, involves participants with medial knee osteoarthritis recruited from the general community.

After online and in-person screening, participants were randomly assigned to one of three gait retraining interventions: toe-out gait, toe-in gait, or placebo gait. Randomization was stratified by the presence or absence of varus thrust, with the first retraining session occurring immediately after the baseline assessment. Over six weeks, participants attended 4-6 clinician-supervised sessions, followed by a post-intervention gait assessment at the primary time-point (one week post-intervention). After the intensive phase, participants were encouraged to continue the gait strategy for three months, with a booster session and a final assessment at 4.5 months.

Gait assessments used a 20-camera motion analysis system (Vicon Vantage 5) and five force plates (Kistler Group) to capture kinematics and ground reaction force (GRF) data. Varus thrust was assessed via 2D video, and randomization was conducted using stratified schedules, with blinding maintained throughout.

Interventions were delivered by an allied health therapist, beginning with knee OA education and baseline foot progression angle (FPA) measurements. The target FPA was set to at least a 10° change from baseline for the index limb, with adjustments made based on comfort. The placebo group focused on upright spinal posture. Biofeedback was provided during sessions, with placebo participants receiving posture-related feedback based on a qualitative checklist.

Biomechanical data are processed using a Vicon CGM 2.4 model, with primary outcomes including knee adduction moments (KAM) and varus thrust. Secondary biomechanical variables are being analysed post-intervention.

Statistical data are being analysed using linear mixed-effects modelling, with significance set at 0.05. Effect sizes will be estimated for changes in KAM outcomes between groups, pain and physical function; and varus thrust status changes analysed using a Chi-squared test.

What did we discover during the grant?

We screened 272 people and successfully recruited and randomized 74 participants for our study on gait retraining for knee osteoarthritis. Of these, 70 have completed the 6-week assessment (current primary outcome attrition rate = 5.4%), and 66 have completed the 3-month follow-up. Due to the randomised-controlled nature of the trial, we must wait for the assessments of the final (4) participants, who are still receiving the intervention, to be collected before conducting the final analysis based on group allocation. However, overall, we have identified the following:

- It was feasible to conduct a gait retraining intervention trial with a placebo component.
- There was good adherence to our gait retraining program, with 89% of participants attending 4-or more of the pre-determined laboratory-based sessions over the initial 6-week period. Participants were also adherent to daily home practise of at least 30 minutes, reporting average daily practise time of 53 minutes (SD=42). There were no differences across groups.
- In conducting preliminary overall assessment of gait retraining as a whole group, we identified that gait retraining for people with knee osteoarthritis improved pain and physical function over the 6 weeks (3-month data yet to be analysed).
- Some participants reduced their knee loading parameters consistently and significantly throughout the gait cycle by between 20-30% (i.e. multiple outcomes demonstrate load reduction across the gait cycle).

What are the next steps for this research?

We have now completed the recruitment and are delivering interventions to the final 4 participants who have entered in the study. All of the final data will be collected by the end of 2025 and we will conduct the final analyses then.

We are now applying for major grant funding (NHMRC) to determine if load-modifying gait retraining can slow the progression of knee OA by including outcomes of joint structure via advanced imaging techniques (magnetic resonance imaging) over the long-term (approximately 12 months). If load-modifying gait retraining can slow disease progression in addition to achieve symptomatic improvements, this will transform the management of knee osteoarthritis which is currently predominantly focused on symptom-modifying rather than disease-modifying.

What is the plan for dissemination of findings?

Thanks to the support of Arthritis Australia in the conduct of this trial, we have published the protocol for the study:

Hutchison, L., D'Souza, N., Grayson, J., Hiller, C., Kobayashi, S., & Simic, M. (2023). 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, 134, 107355. doi:10.1016/j.cct.2023.107355

We have presented about the trial at the following conferences:

2023: Sydney Musculoskeletal Health Annual Scientific Meeting, Sydney

Hutchison, L, D'Souza, N, Hiller, C, Grayson, J, Simic, M 2023, 'The effect of gait retraining

on patient reported outcomes in people with medial knee osteoarthritis: A randomised

placebo-controlled trial'.

2023: Australian Podiatry Association

"Live and Local" Conference – 'Gait retraining for medial knee osteoarthritis', Sydney,

We plan to publish the main outcomes paper and additional secondary outcomes as soon as we finalise the trial, in a peer-reviewed Q1 journal in the rheumatology field.