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Effects of a foot-ankle strengthening programme on clinical aspects and gait biomechanics in people with knee osteoarthritis: protocol for a randomised controlled trial

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ABSTRACT

Introduction Studies have indicated that hip and knee muscle strengthening are effective in reducing pain, improving self-reported function and increasing lower limb strength, without, however, decreasing knee joint overload during gait in patients with knee osteoarthritis (KOA). Recent research has shown that strengthening the foot-ankle muscles improved function in diabetic patients and reduced patellofemoral pain. The aim of this paper is to investigate whether an 8-week therapeutic foot-ankle exercise programme improves pain, functionality, foot strength, foot kinematics and knee joint overload during gait, and decreases medication intake in individuals with KOA.

Methods and analysis This two-arm, prospectively registered, randomised controlled trial with blinded assessors will involve 88 patients with medial tibiofemoral osteoarthritis. Subjects will be randomly allocated to a control group that will receive no specific foot intervention and will follow treatment recommended by the medical team; or an intervention group that will undergo an 8-week physiotherapist-supervised strengthening programme for extrinsic and intrinsic foot muscles, three times a week. The primary outcome will be the pain domain of the Western Ontario McMaster Universities Osteoarthritis Index (WOMAC). The secondary outcomes include WOMAC stiffness and function domains, total WOMAC score, physical function, foot muscle isometric strength, foot kinematics and knee kinetics during gait, and medication intake. Data will be analysed on intention-to-treat principles and a per protocol basis.

Ethics and dissemination Investigators and sponsors will communicate trial results to participants and healthcare professionals through scientific databases and social media. In addition, findings will be reported in peer-review publications, and at national and international conference presentations. Ethics approval: Ethics Committee of the Universidade Federal de São Carlos, São Carlos, SP, Brazil (N° 3.488.466).

Trial registration number NCT04154059.

Strengths and limitations of this study

- To the best of our knowledge, this is the first randomised controlled trial that investigates the effect of strengthening foot muscles on clinical and biomechanics aspects in knee osteoarthritis patients.
- This study exhibits high methodological quality because it is randomised, prospectively registered, with masking of the evaluators, allocation concealment and an intention-to-treat approach.
- We also highlight the external validity of the study. We do not limit participation of patients according to sex, unilateral or bilateral involvement, and use or not of medications.
- The main limitations of the study are the impossibility of masking the therapist or controlling the individuals' expectations about the intervention.

INTRODUCTION

Knee osteoarthritis (KOA), one of the main causes of disability and chronic pain worldwide, is responsible for productivity losses in the workplace and early retirement, thereby increasing public health costs.[1] KOA is clinically characterised by pain, morning stiffness, feeling of joint distortion, oedema and decreased joint cartilage (patellofemoral, medial and lateral tibiofemoral compartments), which may lead to joint deformities and dysfunctions.[2] In the tibiofemoral joint, KOA occurs predominantly in the medial compartment[3] and is usually accompanied by kinetic and kinematic changes in the lower limbs[4] which, added to pain and reduced mobility, are the main causes for the decline in functionality.[5]

A number of kinematic changes during gait were also found in the foot structure of individuals with medial tibiofemoral KOA, such as

the presence of greater subtalar pronation,[6] more everted rearfoot relative to the tibia at initial contact,[7] increased heel supination in relation to the ground[8] and an association between increased pain and knee joint cartilage degradation with the presence of flat feet.[9] In addition, KOA individuals with varus alignment also demonstrated changes in foot kinematics, such as greater rearfoot valgus.[10] All these findings are indicative of decreased foot mobility[7] and can be attributed to a reduction in the compensatory capacity of the foot-ankle joint complex in response to varus alignment.[8 11] Thus, although still inconclusive, there is some evidence on the mechanisms by which kinematic changes in the feet influence pain and knee cartilage degradation.[12]

The medial longitudinal arch is responsible for absorbing impacts and transmitting kinetic energy up the lower limb during gait.[13 14] The intrinsic and extrinsic muscles of the foot act synchronously as dynamic stabilisers to maintain foot posture.[15 16] However, previous studies on KOA reported that weak foot-ankle muscles cause kinetic alterations in the frontal and transverse planes during gait.[17] Moreover, Røsland *et al*[18] observed that foot muscle strength deficits in individuals with KOA were directly related to increased knee pain and stiffness, decreased physical function and more severe KOA. Uritani *et al*[19] also demonstrated that women with KOA have less plantar grip strength, a deficit which may contribute to changes in the kinetic chain of the lower limb during gait.[20]

From a kinetic perspective, the external knee adductor moment (EKAM), a variable related to the internal loads of the joint, mainly in the medial compartment, was found to be directly and positively associated with pain intensity[21] and KOA progression.[22] Previous studies showed increased peak EKAM in several gait phases in KOA patients compared with asymptomatic subjects.[4 23 24]

A decrease in knee joint loads is essential to prevent the aggravation of KOA, because it improves function and slows progression of the disease.[25 26] In order to achieve these therapeutic objectives and based on strong scientific evidence, world organisations are in unanimous agreement that the gold standard of conservative non-pharmacological treatment for KOA is regular exercise.[27 28] However, there is still a need for studies that can determine the most appropriate and effective exercise protocols for KOA treatment.[25]

Research has indicated that 8-week to 12-week physical therapy protocols targeting trunk, hip and knee muscles were effective in reducing pain, improving function and increasing lower limb strength, without, however, decreasing knee joint loads during gait.[29–31] By contrast, the use of minimally flexible shoes reduced knee joint loads during gait[32] and stair descent[33] in women with KOA. In addition, prolonged use of these minimalist shoes (6 hours daily, 5 days a week, for 6 months) not only decreased internal knee loads, but also reduced pain and analgesic intake, and improved self-reported functionality in these women.[34] These results suggest that an increase in the neuromuscular reflexes of foot muscles may minimise impact and knee overload,[32] thereby meeting one of the main therapeutic objectives of KOA rehabilitation.

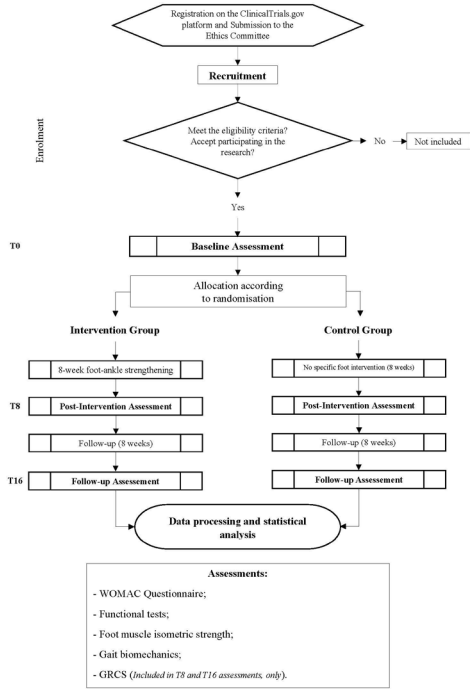

Figure 1 Consolidated Standard of Reporting Trials flow chart illustrating the process of the study. GRCS, Global Rating of Change Score; WOMAC, Western Ontario McMaster Universities Osteoarthritis Index.

However, no studies that evaluated the effect of intrinsic foot muscle strengthening on knee pain and joint loads in individuals with KOA have been found. The potential decline in pain and knee loads could improve function and slow the progression of the disease. As such, the aim of this randomised controlled trial (RCT) is to investigate the effects of an 8-week therapeutic foot-ankle muscle exercise programme on the clinical and biomechanical aspects of patients with KOA. We hypothesise that this strengthening programme will produce clinically and statistically significant improvements in pain, physical function, foot strength and kinematics, knee joint overload and a decline in analgesic intake compared with controls.

METHODS AND ANALYSIS

Study design

This is a two-arm, parallel-group, RCT of interventions designed to evaluate clinical and biomechanical outcomes among patients with KOA. The study protocol is in accordance with the recommendations set forth in Standard Protocol Items: Recommendations for Interventional Trials[35] and Consolidated Standards of Reporting Trials[36] guidelines (figure 1).

Patient and public involvement

Neither patients nor the public are involved in the design, conduct, reporting or dissemination of our research.

Table 1 Study design schedule in accordance with the Standard Protocol Items: Recommendations for Interventional Trials

	Study period			
	Screening	Baseline (T0)	Postintervention (T8)	Follow-up (T16)
Timepoint	Week –1	Week 0	Week 1–8	Week 16
Enrolment				
Eligibility screen	X			
Informed consent	X			
Allocation		X		
Interventions				
Control			—	
Foot-ankle strengthening			—	
Assessments				
WOMAC questionnaire		X	X	X
Physical function		X	X	X
Foot muscle strength		X	X	X
Gait biomechanics		X	X	X
Medication intake		X	X	X
GRCS			X	X

GRCS, Global Rating of Change Score; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

Participants

Eligible participants who provide written consent will be randomised into an intervention or control group: (1) intervention group: individuals with KOA will undergo physiotherapist-supervised strengthening exercises for extrinsic and intrinsic foot-ankle muscles; (2) control group: individuals with KOA will not receive strengthening exercises for foot-ankle muscles. Both groups will continue undergoing the care and treatment recommended by the healthcare team: pharmacological treatment and self-care guidelines.[37]

All individuals will receive a diary to record medications taken for knee pain relief (if necessary), any physical activity performed or any other treatment undergone during the period. The patients of both groups will be evaluated three times in a 4-month period: at baseline (T0), postintervention (T8) and follow-up (T16) (table 1). On completion of study, all individuals will receive the printed exercise protocol and a kit with materials needed to perform the exercises at home.

Sample size

Sample size was calculated to estimate the equality between the foot-ankle muscle therapeutic exercise programme and treatment according to Osteoarthritis Research Society International (OARSI) Clinical Trials Recommendations,[37] based on the average difference (pretreatment and post-treatment) in the WOMAC pain domain immediately after treatment. Previous studies evaluating therapeutic exercises for KOA reported an average post-treatment difference of 2.12 points between the intervention and control groups in the WOMAC pain subscale.[29] Thus, based on an average intergroup difference of 2.12 points and assuming a SD of 3.3 points, we calculated a total of 88 participants (44 per group) necessary to provide 80% power at a 5% significance level and detect this difference, assuming a dropout rate of 15% after randomisation.[38]

Setting and recruitment

Patients will be recruited (study start date: 27 January 2020; end date: recruitment will take place until the groups are filled according to the sample size) by convenience (non-probability) through public announcements and lists of local or regional orthopaedic and rheumatology outpatient clinics, as well as a structured waiting list from the Muscle Plasticity Laboratory of the Physical Therapy Department of the Universidade Federal de São Carlos. Potential patients will be identified by the project manager and the research assistant. A researcher will be trained on how to determine eligibility criteria during initial telephone contact and how and when to contact them for follow-up and data collection.

Eligibility criteria

The trial will be conducted in patients with KOA who fulfil the following eligibility criteria:

Inclusion criteria:

- 40–75 years of age.
- KOA based on clinical and radiological criteria of the American College of Rheumatology.
- KOA (grade II and III—Kellgren and Laurence radiological classification) in the medial compartment of the knee.
- Knee pain between 30 and 80 mm on the visual analogue scale in an attempt to decrease the wide

variability and the possibility of overestimating baseline pain levels.
- Body mass index (BMI) <35 km/m^2.

Exclusion criteria:
- KOA isolated (grade II and III) in the lateral compartment due to biomechanical changes specific to this compartment.
- Physical therapy treatment and/or lower limb strength training (three times per week) in the last 3 months.
- Having worn minimalist shoes for at least 6 hours a day and 5 days a week.
- Having received steroid and hyaluronic acid intra-articular knee injections in the previous 3 and 6 months, respectively.
- History of knee, ankle or hip surgery in the last 2 years.
- Severe knee varus or valgus that requires use of any gait-assistive device.
- Neurological disease.
- Inflammatory arthritis (eg, rheumatoid arthritis).
- Asymptomatic KOA in one or both knees.
- Changing in pharmacological treatment.

Assessment of eligibility criteria, written informed consent, data collection and statistical analyses will be carried out by researchers blinded to group allocation. Participants will receive oral and written instructions about study risks and benefits and provide written informed consent (see online supplemental file 1). The study was approved by the Research Ethics Committee of the Universidade Federal de São Carlos.

Randomisation and allocation

Eligible participants who provide written consent will be randomised into a control group or intervention group. An offsite randomisation schedule will be used to ensure allocation concealment. The schedule will be prepared by an independent researcher (researcher #1) who will have no contact with any of the participants and will not be involved in the recruitment, screening, assessment, enrolment or treatment process. A randomisation list for the study will be created according to a unique computer-generated number sequence. Randomisation will be processed in permuted blocks of two, four and six that will be stored in sequentially numbered sealed opaque envelopes in a location the blind assessors do not have access to in order to guarantee allocation concealment.

Another independent researcher (researcher #2) will allocate patients to the respective groups. KOA patients will be allocated to groups a maximum of 1 week after baseline assessment. Only the physiotherapists (researchers #3) responsible for the locally supervised treatment will know who is receiving the intervention. One physiotherapist (researcher #4), also blind to group allocation, will conduct all clinical, functional and biomechanical assessments. To guarantee the blindness of researcher #4, before each evaluation, patients will be instructed not to reveal which group they belong to.

Moreover, all personal data will be kept confidential before, during and after the study by encoding participants' names.

Masking/blinding

Owing to the nature of the trial it is not possible to blind the patients but they will be instructed not to discuss their experience during the exercise if they incidentally encounter other participants. Furthermore, the study interventions and measurements will occur in separate locations to facilitate assessor blinding.

Intervention

The treatments will be conducted at the Physical Therapy Department of the University. The physiotherapists (researchers #3) in charge of the supervised strengthening programme will be provided with a manual outlining the trial protocol and treatment details and will train for 8 weeks, following all exercise evolution criteria.

Patients allocated to the intervention group will undergo an 8-week physiotherapist-supervised strengthening programme for extrinsic and intrinsic foot-ankle muscles, three times a week. The exercise protocol is simple and easy to perform. The protocol was designed following certain criteria and divided into two phases: 1st–4th week, involving isolated strengthening of extrinsic and intrinsic foot-ankle muscles, and 5th–8th week, consisting of strengthening and functional training of extrinsic and intrinsic foot-ankle muscles (detailed description in online supplemental file 2).

The programme will be conducted according to American College of Sports Medicine recommendations[39]: 3 times a week, with an average duration of at least 60 min; 3 sets of 8–12 repetition maximum (RM), with a mean load of 60%–70% of 1RM; 1-min rest time between sets. Progression criteria will be adopted for each exercise and the discontinuation criteria during any session include cramps, moderate to intense pain, fatigue, dizziness, fear or any other condition that exposes the patient to discomfort.

In each session, patients of the intervention group will be asked to evaluate the subjective perceived exertion of each exercise using a 0 to 10 Likert scale (0=very light or no effort; between 4 and 6=somewhat effort; 10=very hard effort). If the subjective perceived exertion score ranges from 0 to 3 and the physiotherapist considers the patient's performance in each exercise adequate during the supervised session, the exercises will increase in difficulty according to the progression chart in online supplemental file 2. If the exertion score ranges from 4 to 6, the exercise will not increase in difficulty. Thus, patients remain at the same exercise progression while they score between 4 and 6 in each exercise. Finally, if an intervention group patient reports a score between 7 and 10, the exercise will decrease in difficulty until the subject is able to perform it without pain or discomfort.

Each supervised session will be conducted in groups of 10–12 participants. Adherence to the exercise programme

will be calculated as the percentage of the 24 training sessions completed by the intervention group subject between baseline and postintervention assessments. After T8 assessment, the intervention group will be instructed not to perform the exercise protocol in the next 8 weeks (follow-up period). On completion of study (T16), for compliance with ethical requirements, the control group patients will be invited to undergo 8 weeks of treatment, according to the exercise protocol.

Outcome measures

A physiotherapist (researcher #4) blinded to group allocation will perform all assessments. The first will consist of collecting personal details, anthropometric data, and all clinical and biomechanical outcomes. After baseline assessment (T0), all subjects will be scheduled for two further assessments: postintervention (T8) and follow-up (T16).

Primary outcome

Clinical and biomechanical parameters will be evaluated by the investigator at T0, T8 and T16. The primary outcome is the average difference in the WOMAC pain subscale. WOMAC is a self-rated questionnaire that assesses three dimensions (pain, stiffness and disability) using a 24-question, 5-point Likert protocol. The higher the score, the worse the condition.[40]

Secondary outcomes

Self-rated stiffness and function

WOMAC stiffness and disability domains will be used to evaluate the average difference in self-rated stiffness and function. The higher the score, the worse the condition.[40] The total WOMAC score will also be calculated.[40]

Physical function

Physical function will be evaluated applying three tests recommended by OARSI[41]: (1) 30 s chair stand test consisting of rising from a chair as many times as possible, for 30 s. In this test, the more repetitions volunteers perform, the better their condition; (2) nine-step stair climb test, in which the final score is calculated based on the time participants take going up and down nine steps. In this test, the faster volunteers perform, the better their condition; (3) 40 m fast-paced walk test, in which the final score is calculated based on the speed at which participants negotiate four 10-metre circuits (marked by ribbons and bounded by cones), whereby the faster volunteers perform, the better their condition.[41]

Foot muscle isometric strength

Foot muscle isometric strength will be measured according to Mickle *et al*[42] using a pressure platform (emed q-100, Novel, Munich, Germany). KOA patients will stand and push down on the platform twice, as hard as possible, with their hallux and toes, while the examiner instructs them to avoid excessive body sway. The maximum force under the hallux and toes normalised to bodyweight are outcomes of this measurement.

Foot kinematic and kinetics during gait

For kinematic and kinetic gait analysis, patients will be instructed to walk barefoot through a 10 m^2 room at a gait pace between 96 and 120 steps per minute,[43] controlled by a metronome. After familiarisation, five trials will be used for analysis.[44] In both groups, the symptomatic limb with KOA will be evaluated. If the volunteer has bilateral KOA, the most symptomatic limb will be evaluated.

Gait kinematics will be obtained using three-dimensional displacements of passive reflective markers tracked by six infrared cameras at 120 Hz (Vicon Motion Systems, Oxford, UK). The markers will be placed on the pelvis and lower limb and four clusters of four non-collinear markers will be attached around the thigh and shin. Fourteen markers (6 mm in diameter) will be placed on the subject's feet-ankles according to Leardini *et al*[45] and Portinaro *et al*.[46]

Ground reaction forces will be measured by a force plate (AMTI Model OPT 400600HF-2000) embedded in the centre of the walkway, with a sampling frequency of 1080 Hz. The standard inverse dynamics technique will be used to calculate the net internal knee joint moments, considering the inertial properties of segments in Visual 3D software (C-Motion, Rockville, USA). All variables will be calculated using a custom-written Matlab function (MathWorks, Natick, USA).

The following foot kinematics will be analysed: rotation in the three anatomical planes between shin and foot, shin and heel, heel and midfoot, midfoot and metatarsus, heel and metatarsus, and first metatarsus and hallux. Metatarsal bone angles will also be calculated, as follows: sagittal-plane inclination of the first metatarsal bone to the ground; sagittal-plane inclination of the second metatarsal bone to the ground; sagittal-plane inclination of the fifth metatarsal bone to the ground; transverse-plane divergence between first and second metatarsal bones; and transverse-plane divergence between fifth and second metatarsal bones. Medial longitudinal arch deformation will also be analysed.[46]

EKAM will be calculated and normalised by the product of the individual's weight and height. In addition, knee angular impulse (KAI) will be normalised to weight, height and time. The first and second peak of the EKAM and the KAI will be analysed during the gait support phase.[33 34]

Medication intake

At baseline, patients from both groups will receive a diary to record medication intake and these diaries will be collected every 8 weeks. Paracetamol (500 mg) intake every 4 hours will be suggested as support drug to both groups for pain management, according to American College of Rheumatology recommendations for OA treatment.[47] If individuals taking another medication before T0 (non-steroidal anti-inflammatory drugs, for example), they will continue to take it and we will record the amount. Individuals will be excluded whether they

modify the pharmacological treatment during the study period.

Overall status perception

At T8 and T16, patient's overall self-perception will be evaluated by the Global Rating of Change Score,[48] an 11-point scale designed to quantify a patient's improvement or deterioration over time. Higher scores indicate better recovery from KOA.

Data management, monitoring and sharing

All data collected during the trial will be compiled electronically. Data integrity and validity will be verified at the time of data entry (edit checks).

The project manager and research assistant will regularly monitor the study datasets and make recommendations regarding necessary protocol modifications or termination of all or part of the study.

Participant data that underlie the results reported in this paper will be shared after blinding (text, tables, figures, appendices), immediately following publication. In addition, the study protocol and clinical trial report (both with the planned statistical analysis) will be made available by the researchers who proposed the methodology. Requests for data or any form of analysis should be directed to glauko.ft.andre@hotmail.com or tania@ufscar.br. Requesters will be asked to sign a data access agreement.

Any changes made to the protocol will be reported to the research ethics committee via its national website: http://plataformabrasil.saude.gov.br/. Changes will also be included in the clinical trial registry (https://clinicaltrials.gov/).

Statistical analyses

Intention-to-treat statistical analysis will be conducted. Missing data will be treated by imputation methods depending on the type: missing completely at random, missing at random or not at random. Perprotocol analysis will include only patients who attended at least 80% of the sessions and completed the follow-up in the allocated intervention group.

The Shapiro-Wilk and Levene tests will be used to assess data normality and homoscedasticity, respectively. The average difference from baseline to 8 weeks of intervention, and 8 weeks after intervention will be estimated in both groups. Unpaired intergroup comparisons will be analysed using the Student's t-test (or Mann-Whitney U test) and intragroup paired comparisons using the paired t-test (or Wilcoxon signed-rank test). In addition, the fitted analysis of covariance model and post hoc analysis will be used for intergroup comparisons after the intervention, considering relevant covariates such as sex, BMI and initial pain score. The effect size will be calculated using Cohen's d (or Cohen's r). Statistical significance will be assessed at a two-sided p value <0.05. All analyses will be conducted using R V.3.5.3 (The R Foundation for Statistical Computing, Vienna, Austria) in R-Studio V.1.1.463 (RStudio, Boston, USA).

DISCUSSION

We have presented the rationale and design of an RCT on the effects of an 8-week foot-ankle muscle therapeutic exercise programme in KOA patients. The present study exhibits high methodological quality because it is randomised, prospectively registered, with masked assessors, allocation concealment and an intention-to-treat approach. In addition, sample size was calculated to provide adequate statistical power in order to identify possible differences in the study's primary outcome.

We propose a foot-ankle muscle strengthening programme for people with KOA and expect to observe knee pain relief, improved function in activities of daily living, decreased medication intake and lower internal knee loads in patients with KOA. In our strengthening programme, the exercise load will be periodically adjusted to maintain the overload principle of strength training. In addition, progression criteria will be adopted for each exercise, in line with patient limitations.

This clinical trial will provide new data and additional insights into foot training effectiveness, its influence on the clinical and functional aspects of KOA, gait biomechanics and its efficacy in strengthening the muscles of the foot-ankle complex. If our hypothesis is confirmed, foot exercises might be add-on to the structured land-based exercises programmes already recommended by the international guidelines, as conservative treatment option for people with KOA.

Another strength of this trial is its external validity. We decided not to limit the participation of patients according to sex, unilateral or bilateral involvement, and the use or not of medications in order to enable extrapolation of the study findings to a larger portion of the population.

One of the limitations of this study is being unable to mask the therapist or control the individuals' expectations about the effects of extrinsic and intrinsic foot muscle strengthening.

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Contributors GD was involved in drafting this protocol and participated in the conception, study design, assessments, data interpretation, writing and submission of the manuscript. TFS, ICNS and HP-J contributed to the study design, data interpretation and writing the manuscript. AFS, RW, ABM, PRMSS and HP-J took part in management, analysis and data interpretation. All authors read and

approved the final manuscript. GD takes the responsibility for the integrity of the work as a whole.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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