


BMJ Open 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

Daniel Borges Pereira,¹ Tatiane Silva de Souza,¹ Carolina Tayama Fuzinato,¹ Rodrigo Jugue Hagihara,¹ Ana Paula Ribeiro ^{1,2}

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For numbered affiliations see end of article.

Correspondence to

Dr Ana Paula Ribeiro;
anapaulafisioterapia@yahoo.com.br; anapribeiro@prof.unisa.br

ABSTRACT

Introduction Studies have indicated that gait intervention programmes with minimalist shoes are effective for reducing pain, improving functionality and reducing knee joint overload in older women with knee osteoarthritis (OA). Other clinical trials with knee and foot muscle strength training and/or dynamic balance training have also shown clinical and functional effectiveness. Despite promising strategies, there is no evidence of the combination of shoes with gait intervention programmes. Thus, the objective of this randomised clinical trial is to investigate the effects of therapeutic programme of muscular resistance, balance and gait exercises with and without the use of low-cost, flexible shoes on the clinical, functional and biomechanical aspects of older women with medial knee OA.

Methods and analysis This randomised controlled trial with blinded evaluators will involve 36 older women. Twenty-four older women with knee OA (medial compartment) will be randomised to the intervention groups with minimalist shoes (GIC; n=12) or in a barefoot condition (GID; n=12), and 12 older women to the control group (n=12). The intervention protocol will consist of knee-foot muscle resistance and static balance training, reactive and proactive dynamic balance training, and gait training with visual feedback. The intervention will have a duration of two consecutive months, twice a week, totalling 16 sessions. The primary outcomes will be walking pain measured by Visual Analogue Scale and questionnaires: Western Ontario McMaster Universities Osteoarthritis Index and Lequesne Algofunctional. The secondary outcomes will be: 6-min walk test, Falls Risk Awareness Questionnaire, Timed Up and Go Test, and distribution of plantar load during gait and balance by pressure platform. Data will be analysed according to an intention-to-treat approach.

Ethics and dissemination This study involves human participants and was approved by the ethics committee of the Universidade Santo Amaro, School Medicine, São Paulo/SP, Brazil (N°4.091.006). Participants gave informed consent to participate in the study before taking part.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ To the best of our knowledge, this is the first randomised controlled trial to investigate the effects of a therapeutic programme of muscular resistance (knee-foot), balance and gait exercises, with and without the use of low-cost and flexible shoes on the clinical, functional and biomechanical aspects of older women with and without knee osteoarthritis (OA).
- ⇒ This study exhibits high methodological quality because it is a randomised, prospectively registered trial, with blinding 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 unilateral or bilateral involvement of knee OA, and the use or not of medications.
- ⇒ The main limitations of the study are the impossibility of blinding the therapist or controlling the individuals' expectations about the intervention.

Investigators will communicate trial results to participants and healthcare professionals through scientific databases, social media, publications and conferences.

Trial registration number RBR-10j4bw25 in Brazilian Clinical Trial Registry.

INTRODUCTION

Osteoarthritis (OA) affects approximately 250 million people worldwide, and is considered of great impact for public health,^{1 2} especially in older adults, for whom involvement reaches around 80%.^{3–5} Women are the most affected compared with men with a prevalence of 35%–45%.^{6 7} Among the joint segments affected by OA, the knee joint is one of the most affected, characterised as a chronic and degenerative disease associated with pain and gradual loss of

articular cartilage,^{8–10} with a multifactorial origin, directed to biochemical, metabolic and morphological alterations.^{1 3 11} These alterations result in a characteristic clinical framework formed by oedema, crepitus on movement, bone deformities, osteophyte formation, the presence of inflammatory processes,^{3 4} the accumulation of synovial fluid, and weakness of the quadriceps and muscles of the feet, with proprioceptive losses^{11–14} resulting in changes in balance and gait.^{10 15} In addition, knee OA most often presents in the medial compartment of the joint, with a prevalence 5–10 times higher than disease in the lateral compartment.^{4 6 7} The reason for this is that about 60% of load goes through the medial side of the knee during walking.^{6 7}

Excessive (joint overload) and abnormal loads are highly evidenced risk factors for the development and progression of knee OA,^{12 15 16} as they are related to constant mechanical stress on the joint, especially during daily and functional activities, such as walking.^{15–17} During walking, high loads are applied to the knee, usually explained by the knee adduction moment (KAM), the ground reaction force vector that passes medially to the knee during static and dynamic activities.^{12 16 18 19} The increase in KAM tends to force the knee outward, compressing the medial joint compartment.^{16 19} According to the literature, the increase in KAM has been associated with both the severity^{18 20} and progression of the disease,^{12 20–22} resulting in the development and increase in the intensity of knee pain in older women, as well as in worsening of their physical-functional dysfunctions.^{12 19 23}

Another important clinical aspect of knee OA is quadriceps muscle weakness and muscle and proprioceptive deficits in the feet during gait,^{10–12 24} which can alter patients' balance and postural control.¹⁰ Proprioceptive deficits in the feet and changes in balance result from the inflammatory and symptomatic response on the knee joint, which contributes to the reduction in sensory input from the joint^{15 23 25} and the dynamic stability performed by the quadriceps, generating functional instability that limits the ability of older adults to remain in static and dynamic balance,^{25 26} making them more susceptible to falls.²⁷ All these clinical alterations underscore the importance of conservative treatment to minimise disease progression.

Conservative treatment, which is recommended for most patients with knee OA, is aimed at reducing and relieving pain symptoms, reducing knee joint overload, increasing or improving functional activities, preventing or delaying loss of quadriceps muscle strength, and minimising disease progression.²⁸ Among the several evident conservative treatments, specific physiotherapeutic exercises, which include resistance exercises and muscular strength (quadriceps muscle and intrinsic musculature of the feet),^{24 29 30} aerobic exercise, proprioceptive exercises and range of motion exercises,^{31–33} and balance and gait exercises^{34 35} have been indicated for pain reduction, functional improvement, and increased body balance with prevention of falls.³⁶

Intervention protocols with 8–12 weeks of physiotherapy targeting the trunk, hip and knee muscles, as well as muscle resistance and balance training were effective in reducing pain, and improving functionality and loading rates on the knee joint during gait.^{33 34 37} Specifically in gait, an intervention programme on an antigravity treadmill, for 2 weeks (6 days a week, with 30 min sessions), proved to be effective in reducing pain, and increasing knee flexion and extension and muscle strength of the quadriceps during gait.³⁸ With a different rationale, current evidence with gait intervention programmes including flexible, flat shoes, denominated minimalist, has been highlighted in the literature for reducing knee joint loads during gait^{39–41} and activities such as descending stairs,⁴² especially in older women with knee OA. In addition, the use of these shoes for a prolonged period (6 months) not only reduced the internal loads on the knees, but also reduced pain and analgesic intake, improving the self-reported functionality of the older women.⁴³ These results infer that an increase in the reflexes of the foot muscles could minimise the impact and load on the knee of older women with OA, and should be one of the main objectives for a rehabilitation programme.

Despite the promising effects and therapeutic proposal of the gait intervention programme with minimalist shoes to reduce pain symptoms and joint load on the knees of older women with OA, no studies were found that evaluated the effects of the use of minimalist shoes (flexible and without a heel) associated with an intervention protocol with muscular resistance, balance and gait exercises. This association could potentiate the decline in pain, knee and ankle/foot muscle strength, and plantar loads on the knees, as well as improve function and balance, in order to delay the progression of the disease, especially during the SARS-CoV-2 pandemic, which requires social isolation to preserve life, which ends up worsening the progression of OA. Thus, the objective of this randomised clinical trial is to investigate the effects of a therapeutic programme of muscular resistance, balance and gait exercises, with and without the use of low-cost, flexible shoes on the clinical, functional and biomechanical aspects of older women with knee OA. Our hypothesis is that the intervention programme with the use of the flexible, flat shoes, for 2 months (8 weeks with 16 consecutive sessions), will produce clinical improvements in pain, muscle strength and physical function of the knee, as well as improvements in knee pain, balance and patterns of plantar load distribution during gait compared with older women with OA without the use of the footwear, and older controls.

METHODS AND ANALYSIS

Study design

This is a three-arm, parallel-group randomised clinical trial with interventions designed to assess clinical, functional and biomechanical outcomes among older women with and without knee OA. The study protocol is in accordance with the recommendations set out in the Standard

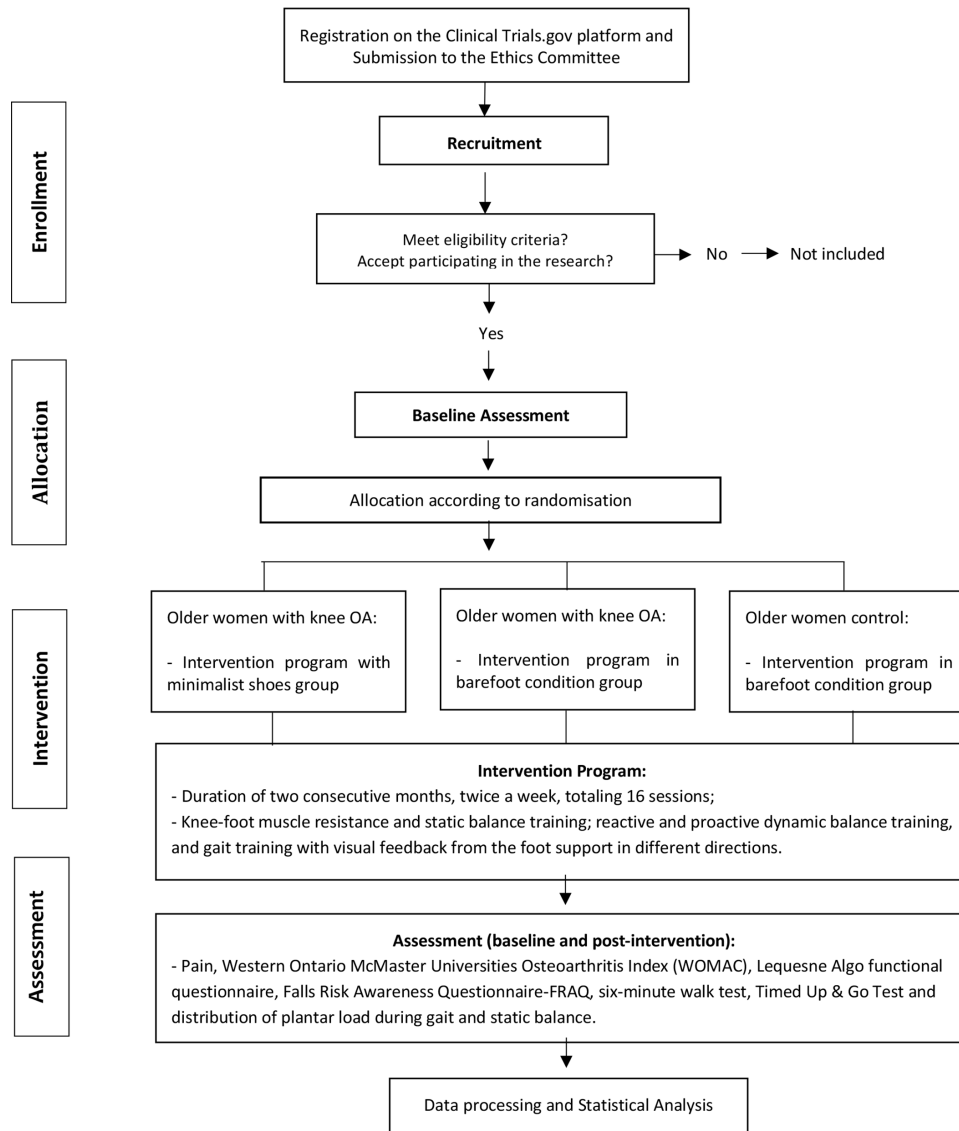


Figure 1 CONSORT: flow diagram of the clinical trials. OA, osteoarthritis.

Protocol Items: Recommendations for Interventional Trials and Consolidated Standards of Reporting Trial Guidelines (figure 1 and table 1) and was registered on the clinical trial platform (RBR-10j4bw25).

Participants

Thirty-six eligible elderly women who provide written consent will be recruited. Twenty-four older women with knee OA (medial compartment) will be randomised to intervention groups with muscular resistance exercise (knee and feet), static and dynamic balance, and walking with minimalist shoes (GIC; n=12) or barefoot (GID; n=12), and 12 older women will comprise the control group (n=12). It is worth mentioning that all intervention protocols will be supervised by a physical therapist providing individual care and taking all safety care recommended during the COVID-19 pandemic, that is, wearing a mask, face shield and gloves, and using alcohol gel, and the patients will be required to wear a mask and use alcohol gel on their hands throughout the blind

randomised controlled clinical trial. The groups will continue to perform the usual care and treatment recommended by the healthcare team during the study: pharmacological treatment and self-care guidelines.

The older women from all groups will be evaluated at two times: at the beginning of the study (T0) and after two consecutive months of the intervention (T8). The sessions will be performed twice a week, totalling 16 treatment sessions of the intervention protocol, with or without the use of minimalist shoes (table 1). During the intervention protocol, all the older women will receive a notepad and guidelines for recording the use of analgesics for the knee, when necessary, for pain management at home. On completion of the study, all subjects will receive an educational kit on the benefits of knee exercise and guidelines for performing daily activities at home.^{24 44}

The older participants of the GIC will wear the footwear throughout the rehabilitation protocol. The shoe is flexible, with a 5 mm non-slip flat rubber sole (minimalist),

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

	Recommendations for interventional trials		
	Study period		
	Screening	Baseline (T0)	Postintervention (T8)
Time point	Week 1	Week 0	Weeks 1–8 (16 sessions)
Enrolment			
Eligibility screening	X		
Informed consent	X		
Allocation		X	
Interventions			
Older women with knee OA			↔
▶ Exercises with use of minimalist footwear;			
▶ Exercises in barefoot condition.			
Older women: Exercises in barefoot condition.			↔
Assessments			
Walking pain (Visual Analogue Scale)		X	X
Western Ontario and McMaster Universities Osteoarthritis Questionnaire (WOMAC)		X	X
Lequesne Algofunctional Questionnaire		X	X
Falls Risk Awareness Questionnaire (FRAQ)		X	X
Timed Up and Go Test (TUG)		X	X
Six-min walk test (T6)		X	X
Gait biomechanics (plantar pressure)		X	X
OA, osteoarthritis .			

and a flat 3 mm ethylene vinyl acetate insole of the slipper type (Calçados Beira Rio SA, Novo Hamburgo, Rio Grande do Sul, Brazil), which provides only foot protection but no correction of medial-lateral control of the hindfoot.^{41–43} During the intervention period, the older women from the GID (without shoes) and control groups will be strictly instructed not to wear slippers or sneakers with characteristics similar to the minimalist footwear (flexible, flat and without heels).

Sample size

The sample size was calculated to estimate the equality between the therapeutic programme of muscular resistance, balance, and gait exercises with and without the use of low-cost flexible shoes and the treatment according to Osteoarthritis Research Society International Clinical Trials recommendations, based on the mean difference (pretreatment and post-treatment) in the WOMAC pain domain immediately after treatment. Previous studies evaluating therapeutic exercises for knee OA reported a post-treatment mean difference of 2.12 points between the intervention and control groups on the WOMAC pain subscale.⁴⁴ Thus, based on an average intergroup difference of 2.12 points and assuming an SD of 3.3 points, we calculated a total of 36 participants (12 per group)

required to provide an 80% power at a significance level of 5% and detect this difference, assuming a 10% dropout rate after randomisation.

Setting and recruitment

Patients will be recruited (study start date: June 2021; end date: September 2022, recruitment will take place until groups are filled according to sample size) for convenience (not probability) through notices and lists from local or regional orthopaedic and rheumatology outpatient clinics in the southern region of São Paulo/SP, in addition to the waiting list for the rheumatology outpatient clinic and the Biomechanics and Musculoskeletal Rehabilitation Laboratory of the Faculty of Medicine of the Universidade Santo Amaro. Potential patients will be identified by the project manager researcher and research assistant. A researcher will be trained on how to determine eligibility criteria during initial telephone contact and how and when to contact participants for treatment, assessment, monitoring and data collection.

Eligibility criteria

The trial will be performed with elderly women with and without knee OA who meet the following eligibility criteria: between 60 years and 80 years of age (due radiographic

Table 2 Intervention protocol with muscular resistance training and static balance: description, execution and parameters of the exercises

Exercises with or without the use of minimalist footwear	Exercise variables	Recommendations
Muscle resistance and static balance training	Protection equipment	Disposable masks, face shield, disposable gloves and alcohol gel
	Support base	Stable and unstable: bipedal, unipodal, semitandem, tandem (figure 1)
	Surface	Stable: mat
	Sensory	Eyes open, eyes closed
	Muscle groups	Knee: quadriceps, hamstrings, tibialis, fibular and triceps surae Foot: flexors, extensors and intrinsic musculature
	Intensity	Defined by difficulty level, fatigue and number of repetitions
	Movement speed	Slow speed (concentric phase 2 s and eccentric phase 4 s)
	Contraction speed	Moderate speed (concentric phase 1 s and eccentric phase 2 s)
Intensity parameters	Frequency	Two sessions/week individually
	Repetitions	Beginner: 10–15 (moderate stamina) Advanced: 8–12 (high stamina)
Progression parameters	Rest interval	2 min every five repetitions
	Progression parameters	No pain or muscle fatigue
	Duration	15 min
	Foot condition	No pain sensation

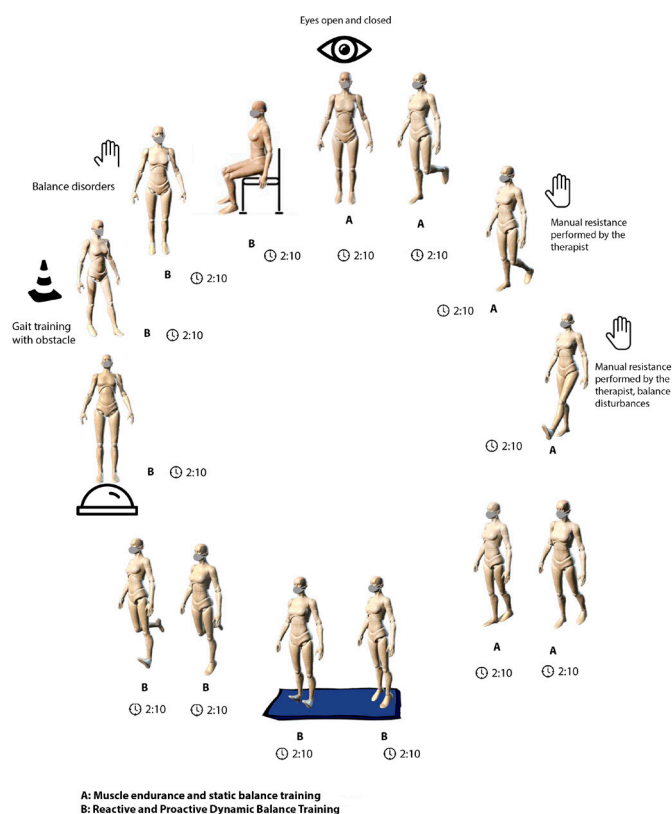


Figure 2 Intervention protocol steps and duration time in older women with and without knee osteoarthritis (OA): (1) muscular resistance and static balance training and (2) Reactive and proactive dynamic balance training (sensory and motor).

OA increased in 43.7% over 80 years); knee OA based on clinical and radiological criteria of the American College of Rheumatology; knee OA (grades II and III—Kellgren and Lawrence radiological classification) in the medial compartment of the knee; knee pain between 30 mm and 80 mm on the Visual Analogue Scale (VAS), in an attempt to decrease wide variability and the possibility of overestimating baseline pain levels; and body mass index (BMI) $<35 \text{ km/m}^2$.⁴²

As exclusion criteria, present isolated knee OA (grade II and III) in the lateral compartment due to specific biomechanical changes in this compartment, asymptomatic knee OA in one or both knees, use of an assistive device or any other daily orthosis for the lower limbs (including insoles), physical therapy, acupuncture, or other physical treatment in the previous 3 months and during the study period, wearing any minimalist footwear for more than 6 hours daily, having received intra-articular steroid and hyaluronic acid injections within the previous 3 months and 6 months, a history of hip, knee, and ankle surgery within the past 2 years, neurological disorders, diabetic neuropathy, and rheumatoid arthritis, as well as severe valgus and varus alignment requiring the use of an assistive device and the inability to walk independently, and changes in pharmacological treatment.⁴⁴

The evaluation of eligibility criteria, written informed consent, data collection and statistical analyses will be performed by researchers blinded to the allocation of patients in the groups. Participants will receive oral and written instructions on the risks and benefits of the study and will provide written informed consent. The study was

Table 3 Intervention protocol with dynamic balance training (sensory and motor), reactive and proactive: description, execution and parameters of the exercises

Exercises	Exercise variables	Recommendations
Dynamic balance training	Protection equipment	Disposable masks, face shield, disposable gloves and alcohol gel
	Support base	Stable and unstable: bipedal, unipedal (figure 2)
	Surface	Stable: mat Unstable: mattress
	Foot position	Shifting weight on toes and heel
	Intensity	Defined by difficulty level, fatigue and number of repetitions
	Frequency	Two sessions/week, individually
Intensity parameters	Repetitions	Beginner: 5 times with 30 s on each side;
		Advanced: 10 times with 30 s on each side.
Progression parameters	Rest interval	2 min every five repetitions
	Progression parameters	Acquire the skill of base support, sensory and motor exercises to evolve to reactive and proactive exercises
Foot position	Duration	10 minutes
	Balance training with sensory exercise	Bipedal
Surface	Support base	Balance disc
		Flat mat made of flexible rubber fabric
Balance training with motor exercise	Walk with obstacles	Normal, tandem, lateral
	Movement speed	Slow, fast
	Sensory	Eyes open, eyes closed
Reactive exercise	Disturbances monitored by the physical therapist	At the level of the shoulder, trunk, hip and ankle joint segments
Proactive exercise	Activities of daily living (ADLs)	Sit and get up from a chair with bipedal support
	Foot condition	Oscillatory support of the plantar base
	Protection equipment	Disposable masks, face shield, disposable gloves

approved by the Research Ethics Committee of Universidade Santo Amaro (under number: 4.091.006).

Randomisation and allocation

Eligible participants who provide written consent will be randomised into the control group or an intervention group. An offsite randomisation schedule will be used to ensure allocation concealment. The schedule will be prepared by an independent researcher (doctor with over 10 years expertise in orthopaedics) 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 (physiotherapist with over 3 years expertise in orthopaedics) will allocate patients to the respective groups. Patients with KOA will be allocated to groups a maximum of 1 week after baseline assessment. Only the physical therapists (researcher 3, with over 10 years expertise in orthopaedics) responsible

for the locally supervised treatment will know who is receiving the intervention. One physical therapist, also blind to group allocation, will conduct all clinical, functional and biomechanical assessments. To guarantee the blindness of the researcher, 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.^{43 44}

Masking/blinding

Due to the nature of this clinical trial in times of the COVID-19 pandemic, it will be possible to blind the patients during the exercise, since the older women will be evaluated and treated individually in a restricted environment (patient and physical therapist) throughout the intervention protocol, respecting all the hygiene protocols, masks, use of alcohol gel, distancing and communication with other participants when leaving the treatment environment.

Intervention

The treatment will be conducted by the department of physiotherapy and rheumatology at the university. The physical therapist (researcher 3, with over 10 years

Table 4 Intervention protocol with gait training with visual feedback: description, execution and parameters of the exercises

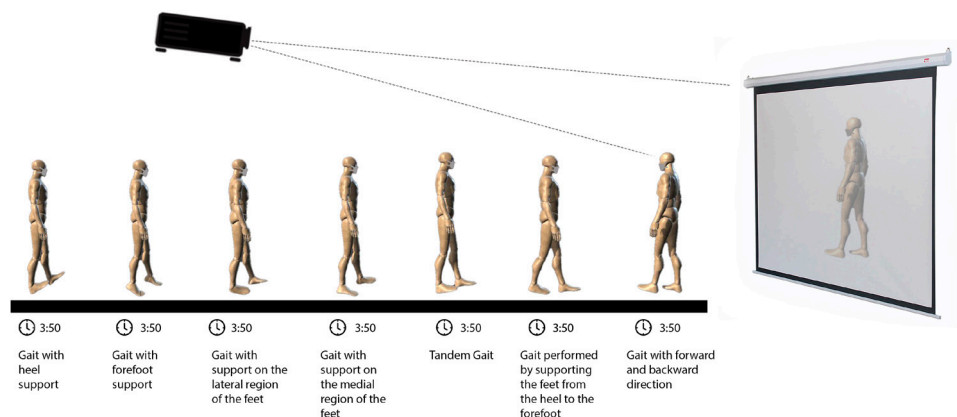
Exercise with or without minimalist shoes	Exercise variables	Recommendations
Gait training with visual feedback	Protection equipment	Disposable masks, face shield, disposable gloves and alcohol gel
	Gait with support and displacement	Heel, forefoot, side edge Medial edge Tandem Displacement from heel to forefoot Forward and backward direction (figure 3)
	Surface	Stable: mat (made of flexible rubber fabric)
	Rolling of the feet in the phases of the gait	Load bearing in the initial phases (heel support), intermediate phase (lateral midfoot support) and propulsion phase (lateromedial forefoot support)
Intensity parameters	Intensity	Walk 112 metres (round trip from exercises)
	Frequency	Two sessions/week individually
	Repetitions	Beginner: 2 times in each gait training
Progression parameters	Progression parameters	Support of the feet in the different phases of gait (initial, intermediate and propulsion contact) with balance disturbance
	Duration	15 min
Gait training with speed	Movement speed	Slow, fast
	Foot condition	Distribution of plantar load on the different regions of the feet

expertise in orthopaedics) will supervise the intervention programme, which will follow all the exercise evolution criteria for two consecutive months, with a frequency of 2 weekly sessions, lasting 45 min each, according to the guidelines of the American College of Rheumatology for the treatment of OA,⁴⁵ with assessments at baseline, after 2 months of the intervention (end of the exercise programme) and after completion of the intervention; the patients will be monitored for two consecutive months.

The intervention protocol (muscular resistance, balance and gait exercises with and without the use of low-cost, flexible shoes) will be divided into three progressive phases, namely: (1) Muscular resistance training (knee-foot) and static balance (table 2, figure 2); (2) Reactive and proactive dynamic balance training (sensory and motor) (table 3, figure 2); and (3) Gait training with visual feedback from the foot support in different directions (table 4, figures 3 and 4). All phases of the intervention

will be carried out with or without the use of flexible, flat shoes (minimalist). The intervention will last for two consecutive months, twice a week, totalling 16 sessions. Patients will be evaluated at the beginning (T0), after two consecutive months of the intervention (T8) and at the end of the intervention.

The shoes that will be used in the intervention are flexible and flat with a thin and flexible rubber sole approximately 5 mm high, slipper type (Calçados Beira Rio SA, Novo Hamburgo, Rio Grande do Sul, Brazil), with an insole of 3 mm ethylene vinyl acetate, double canvas upper (front part of the shoe that covers the dorsum of the foot) and elastic strap, with a mass of between 91 g and 182 g, depending on the size.^{41–43} It is noteworthy that all the exercises proposed in the intervention programme^{33 37 38 46–49} and the use of footwear^{39–43} are based on evidence from the literature in systematic review studies and clinical trials.


Figure 3 Intervention protocol with gait training with feedback visual in older women with and without knee osteoarthritis (OA).

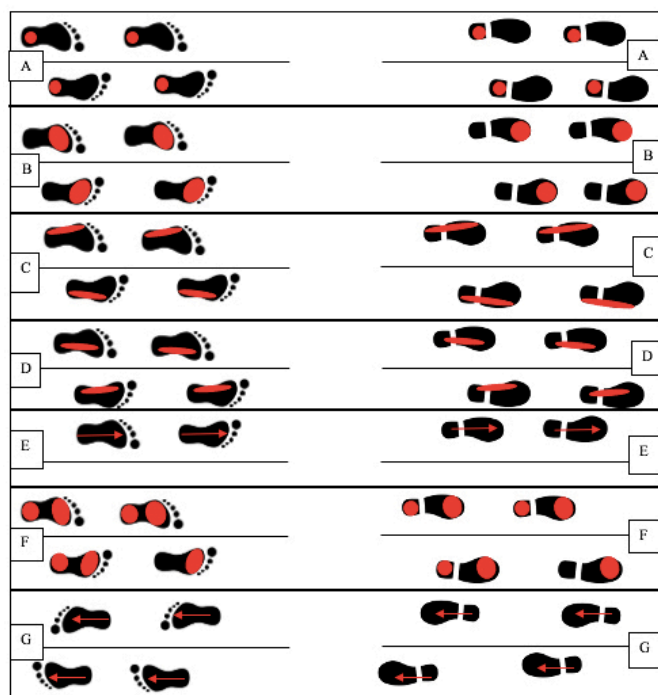


Figure 4 Gait training with foot support strategies: (A) Gait in heel support; (B) Gait in forefoot support; (C) Gait in side edge support; (D) Gait in medial edge support; (E) Gait in tandem; (F) Gait with heel and forefoot support; (G) Gait backwards.

The complete description of the intervention protocol, as well as the performance of the exercises, the progression criteria in each phase, and the volume and duration of the exercises for each intervention phase are presented in tables 2–4. On completion of the study (T8), 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 physical therapist (researcher 4) blinded to group allocation will perform all assessments. The first will consist of collecting personal details, anthropometric data and all clinical, functional, and biomechanical outcomes. After the baseline assessment (T0) all subjects will be scheduled for postintervention assessments (T8).

Primary outcomes

The International Society for Osteoarthritis Research establishes that the WOMAC Questionnaire Pain Score should be chosen as the primary outcome in clinical trials. Another point established by the association is the functionality of these patients, also verified by the rigidity and function of daily living activities in the WOMAC Questionnaire, but also by the Lequesne Algofunctional Questionnaire, both referenced in clinical trial studies and with sensitivity to verify changes and results from intervention programmes.⁴³ Thus, the pain scores from the WOMAC Questionnaire will be used, as well as the

walking pain intensity verified by VAS, and the functionality verified through both questionnaires: WOMAC and Lequesne.

Secondary outcomes

As secondary outcomes, the Falls Risk Awareness Questionnaire (FRAQ)-Brasil, the 6-min walk test, the Timed Up and Go Test (TUG), static balance and plantar load distribution during gait will be applied. Patients' acceptability to the intervention protocol, as well as its suitability and feasibility will be evaluated.

Clinical and functional assessment protocol

This process will be carried out at the beginning (T0) and after 2 months of the intervention (T8) with 16 exercise sessions. The clinical evaluation will consist of a radiological examination to confirm the osteoarthritic involvement, according to the criteria of Kellgren and Lawrence,⁴⁹ followed by the clinical confirmation of the diagnosis of knee osteoarthritis, performed by the follow-up physician. In addition, the quantification of pain will be carried out through application of VAS, ranging between score 0 (represents no pain) and 10 (the worst possible pain) measured on a centimetre scale.⁵⁰

The functional evaluation will consist of the application of the questionnaires: WOMAC (Western Ontario and McMaster Universities Osteoarthritis), the Lequesne Algofunctional Questionnaire, specific for knee OA, to verify the quality of life, and the FRAQ-Brasil Questionnaire. In addition, the 6-min walk test and TUG will be applied. WOMAC assesses three dimensions: pain, joint function and stiffness in patients with knee OA in the 72 hours before the assessment, using 24 questions scored from 0 to 5 points. The highest score represents the worst condition.⁵¹ The Algofunctional Index by Lequesne (1997) is a scale consisting of three sessions: pain or discomfort, maximum distance that the patient can walk, and activities of daily living. Scores range from 0 to 24, with 0 being no involvement and 24 being extremely severe.⁵²

The FRAQ-Brasil Questionnaire will be used to assess the perception of risk of falling in individuals over 65 years of age. This tool was developed at the University of Alberta, Canada, and adapted to the Brazilian culture by Lopes and Trelha in 2013. The questionnaire consists of 25 multiple-choice questions, in which the total score varies from 0 (minimum score) to 32 (maximum score), and the higher the score, the better the awareness of the risks of falling.⁵³

The 6-min walk test will be used to assess the maximum distance (cm) that the patient can walk in 6 min. The test assesses the patient's ability to move during this period. It should be noted that all patients will be instructed to walk as fast and as far as possible during the 6 min period.⁵⁴

TUG will be used to verify physical performance during walking and dynamic balance. The TUG test consists of measuring the time spent in the task of getting up from a chair (from the leaning back position), walking 3 m to a marker on the ground, turning and walking back

along the same route, sitting down again with the back leaning on the back of the chair. To classify the test, time values between 11 s and 20 s are considered normal for frail older adults or disabled patients and values ≥ 20 s are considered impairment in physical performance and balance, with the need for appropriate interventions.⁵⁵

Biomechanical assessment protocol

For the biomechanical assessment of static balance, a pressure platform (Loran, Sensor Medica, Rome, Italy) will be used, with the patient positioned in bipedal support with eyes open and arms alongside the body, while remaining in the quiet static posture for 60 consecutive seconds. The variables evaluated will be: centre of pressure oscillation, anteroposterior oscillation, lateromedial oscillation and velocity.

In the biomechanical evaluation of plantar pressure distribution during gait, the same pressure platform (Loran Sensor Medica, Rome, Italy) will be used, with dimensions: 3240 mm length, 620 mm width, 20 mm height and 29 kg weight. The equipment contains resistive pressure sensors, distributed homogeneously (4 sensors/cm²). The platform will be connected to a desktop notebook to transmit the data collected at a frequency of 100 Hz. The older women will walk at a pre-established cadence. To ensure that they reach this cadence, plantar pressure acquisitions will be monitored using a stopwatch. The older women will be familiarised with the collection environment and the instruments to reduce the retroactive effect, after which they will walk on a flat synthetic rubber track for a distance of 20 m. The steps included in the intermediate 10 m will be timed and validated for the analysis, thus totalling approximately 12 steps, captured in six round trips of the floor with the feet on the platform. The plantar pressure variables measured and analysed will be: (1) Peak pressure per selected area; (2) Maximum force and (3) Contact area (cm²). All plantar pressure variables will be analysed in four plantar areas of the feet. For this, the foot will be divided into four areas: medial and lateral hindfoot (30% of the foot length), midfoot (30% of the foot length), and forefoot and toes (40% of the foot length).⁵⁶

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 data sets 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 anapribeiro@prof.unisa.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://ensaiosclinicos.gov.br>).

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 missing not at random. Per protocol analysis will include only patients who attend at least 80% of the sessions and complete 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 16 weeks of intervention will be estimated in both groups. Unpaired intergroup comparisons will be analysed using the analyses of variance (two-way) or Kruskal-Wallis 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 as a two-sided *p* value < 0.05 . All analyses will be conducted using Statistica software (V.7.0).

Patient and public involvement

The authors state that neither patients nor the public were involved in the intervention protocol of this study, that is, maintaining the blinding for the different intervention groups. However, patients were actively involved in the intervention protocol, as a marker of good research practice because it leads to research that is relevant, better designed, with clearer outcomes, and with a faster uptake of new evidence.

DISCUSSION

We present the design for a randomised clinical trial on the therapeutic effects of a programme of muscular resistance (knee-feet), static and dynamic balance, and gait exercises with and without the use of low-cost, flexible shoes on the clinical, functional and biomechanical aspects of older women with knee OA. The present study has high methodological quality as it is randomised, prospectively registered, with blinded evaluators, allocation confidentiality, and an intention-to-treat approach. In addition, the sample size was calculated to provide adequate statistical power in order to identify possible differences in the primary outcome of the study.

We propose an intervention programme, with and without the use of flexible shoes, without heels, together with a combination of knee and ankle-foot muscular resistance exercises, reactive and proactive balance training, and gait training, in older women with knee OA. We

hope to observe the relief of knee pain, improvement in function in activities of daily living, an increase in body balance, and the reduction in plantar overloads in patients with knee OA. In our programme, progression criteria will be adopted for each exercise according to the patient's limitations.

This clinical trial will provide new data and additional insights into the effectiveness of the association of the combination of knee and ankle-foot muscular resistance exercise with balance and gait training with and without flexible, non-heeled shoes, which are highly recommended by the literature to minimise the moment of force in the medial compartment of the knee in older women with OA,^{39–43} on their clinical, functional and biomechanical aspects. Currently, studies show either the use of exercises for knee OA with a beneficial effect^{45–48 57 58} or the use of footwear with a beneficial effect,^{39–43} however, there is still a gap in the literature on the association of exercise and footwear and its effects in older patients with knee OA. If our hypothesis is confirmed, this intervention programme could be added to the rehabilitation process, in accordance with international guidelines, as an effective conservative treatment option for older women with knee OA.

Another strength of this randomised clinical trial is its external validity. We decided to select patients with unilateral or bilateral involvement of KOA and the use or not of medication, in order to allow the extrapolation of the study findings to a larger portion of the population. One of the limitations of this study is not being able to blind the therapist or control the expectations of individuals about the effects of the intervention protocol.

Author affiliations

¹Post-Graduate in Health Science Department, Biomechanics and Musculoskeletal Rehabilitation Laboratory, Universidade Santo Amaro, São Paulo, Brazil

²Faculty of Medicine, Universidade de São Paulo, São Paulo, Brazil

Twitter Ana Paula Ribeiro @Ana Paula Ribeiro

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s)

Ethics approval The Institutional Review Board (University Santo Amaro, School Medicine, São Paulo/Brazil) ethically approved the study on number: 4.091.006, and we conducted it following the guidelines given in the Declaration of Helsinki (1983). Informed written consent was obtained from all participants prior to the

experiment. Data access and storage comply with National Health and Medical Research Council guidelines. This trial is registered in Brazilian Clinical Trials (number RBR-10j4bw25).

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Data availability statement Data are available upon reasonable request.

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ORCID iD

Ana Paula Ribeiro <http://orcid.org/0000-0002-1061-3789>

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