



## Long-term use of minimal footwear on pain, self-reported function, analgesic intake, and joint loading in elderly women with knee osteoarthritis: A randomized controlled trial☆



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### ABSTRACT

**Background:** Efforts have been made to retard the progressive debilitating pain and joint dysfunction in patients with knee osteoarthritis. We aimed to evaluate the therapeutic effect of a low-cost minimalist footwear on pain, function, clinical and gait-biomechanical aspects of elderly women with knee osteoarthritis.

**Methods:** Throughout a randomized, parallel and controlled clinical trial, fifty-six patients with medial knee osteoarthritis were randomly allocated to an intervention ( $n = 28$ ) or control group ( $n = 28$ ), and assessed at baseline and after three and six months. The intervention involved wearing Moleca<sup>®</sup> footwear for at least 6 h/day, 7 days/week, over 6 months. The pain subscale of the Western Ontario and McMaster Universities Osteoarthritis Index was the primary outcome. The secondary outcomes were the other subscales, Lequesne score, distance walked in 6 min, knee oedema and effusion, knee adduction moment and paracetamol intake. Intention-to-treat analysis was performed using two-way casewise ANOVA ( $< .05$ ) and Cohen's  $d$  coefficient.

**Findings:** Intervention group showed improvement in pain (effect size: 1.41,  $p < .001$ ), function (effect size: 1.22,  $p = .001$ ), stiffness (effect size: 0.76,  $p = .001$ ), Lequesne score (effect size: 1.07,  $p < .001$ ), and reduction by 21.8% in the knee adduction moment impulse ( $p = .017$ ) during gait wearing Moleca<sup>®</sup>. The analgesic intake was lower in the intervention group.

**Interpretation:** The long-term use of Moleca<sup>®</sup> footwear relieves pain, improves self-reported function, reduces the knee loading while wearing Moleca<sup>®</sup>, refrains the increase of analgesic intake in elderly women with knee osteoarthritis and can be considered as a conservative mechanical treatment option. ClinicalTrials.gov (NCT01342458)

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### 1. Introduction

Knee osteoarthritis (OA) can progressively lead to debilitating pain and joint dysfunction (Felson et al., 1987; Peat et al., 2001). Hence, according to the Osteoarthritis Research Society International (OARSI) (Zhang et al., 2010) efforts have been made to improve conservative OA treatments, especially to reduce the pain and improve the self-function function and the ability to perform the activities of daily living.

Conservative biomechanics treatments, such as lateral wedge insoles (Bennell et al., 2011) and canes (Jones et al., 2012) have presented evidences of efficacy in treatment of knee OA (Bennell et al., 2011;

Jones et al., 2012). The use of minimalist (flexible, flat and non-heeled) footwear has been also described as an option to reduce the knee load (Sacco et al., 2012; Shakoov and Block, 2006; Shakoov et al., 2008, 2010, 2013; Trombini-Souza et al., 2011), and suggested as a conservative mechanical treatment for knee OA. The load into this joint is commonly characterized by the external knee adduction moment (KAM) (Miyazaki et al., 2002; Sharma et al., 1998), which is intimately linked with the development and progression of medial knee OA (Sharma et al., 1998). Commonly, two variables are extracted from the KAM waveform: the first peak (the maximum magnitude of the curve), and the impulse (the magnitude and duration during stance phase of the gait) (Robbins and Maly, 2009). These constant and prolonged joint loads can lead to changes in the properties of intra-articular tissues, and consequently, to edema and joint effusion.

Although some studies have reported the effect of a minimalist footwear in reducing knee loading in a short-term (Sacco et al., 2012; Shakoov and Block, 2006; Shakoov et al., 2008, 2010; Trombini-Souza

☆ Minimal footwear as treatment for knee OA.

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et al., 2011) and in six-month period (Shakoor et al., 2013), the long-term effect of this type of footwear on knee pain and self-reported function, which are the main clinical goals when treating patients with OA, has not been tested yet by a randomized controlled trial. If effective, the use of this footwear as mechanical approach can be part of a treatment regime that facilitates the reduction of treatment costs associated with knee OA.

The purpose of this study was to evaluate the therapeutic effect of a low-cost, flexible, non-heeled footwear on pain, self-reported function, clinical (knee oedema and effusion) and gait-biomechanical aspects of elderly women with medial knee OA. We hypothesized that this minimal shoe would: (i) provide pain reduction in the knee, (ii) improve the self-reported function during everyday activities, (iii) reduce analgesic intake, knee oedema and effusion and, (iv) reduce loading (KAM peak and impulse) imposed on the knee during gait.

**2. Methods**

**2.1. Design overview**

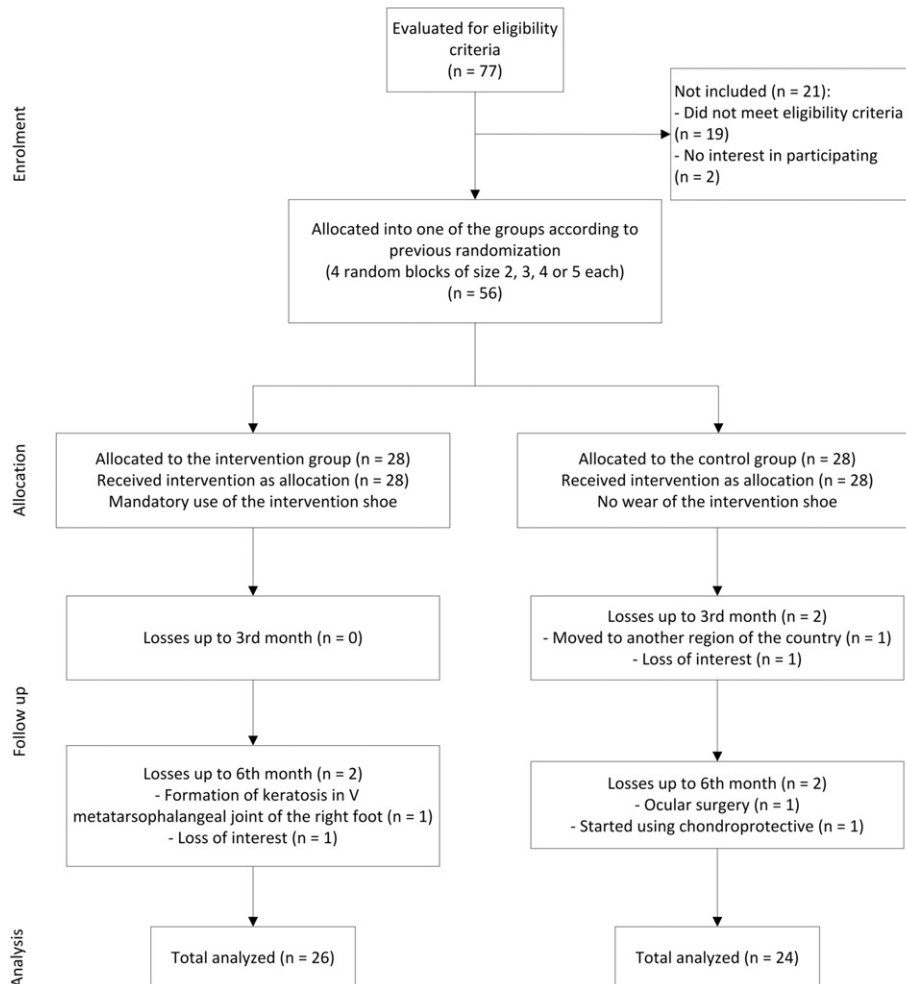
This two-arm, parallel-group randomized controlled trial with blinded assessor was prospectively approved by the Ethics Committee of the School of Medicine of the University of São Paulo. The whole assessment protocol of the present study is described in details in the published paper (Trombini-Souza et al., 2012). Hence, this section will summarize the main methodological aspects (Fig. 1).

**2.2. Patients and setting**

Fifty-six women with medial knee OA were recruited from the primary care center of the University of São Paulo Hospital, and rheumatology ambulatory medical. Participants were recruited between March 2011 and December 2012. The study was conducted in the Physical Therapy Department (in a biomechanics laboratory setting) and in the rheumatology ambulatory medical, both of University of São Paulo Medical School.

The eligibility criteria were:

- women aged 60 to 80 years;
- OA diagnosed according the American College of Rheumatology (Altman et al., 1986) criteria;
- radiographic evidence of medial femorotibial OA classified as Kellgren–Lawrence (Kellgren and Lawrence, 1957) grade 2 or 3;
- knee pain between 3 and 8 on a visual analog scale;
- body mass index <35 kg/m<sup>2</sup> (Shakoor and Block, 2006);
- ability to walk independently without an assistive device for at least 6 hours a day;
- absence of asymptomatic OA of both knees (the patient had to had symptomatic OA in at least one knee)
- absence of diagnosed hip and/or ankle OA, rheumatoid arthritis, or systemic inflammatory arthritis;
- absence of rigid hallux (Rodrigues et al., 2008);
- absence of arthroplasty and/or lower limb orthoses or indication of lower limb arthroplasty throughout the intervention period;



**Fig. 1.** Flow of participants throughout the trial.

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