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# Three-curve rocker-soled shoes and gait adaptations to intermittent claudication pain: A randomised crossover trial

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ABSTRACT

*Background:* Intermittent claudication (IC) is a symptom of peripheral arterial disease where a cramp-like leg pain is exhibited during walking, which affects gait and limits walking distance. Specifically-designed rocker-soled shoes were purported to mechanically unload the calf musculature and increase walking distances until IC pain.

*Research questions:* Do three-curve rocker-soled shoes increase walking distance and what are the biomechanical differences during pain-free walking and IC pain-induced walking, when compared with control shoes?

*Methods:* Following NHS ethical approval, 31 individuals with claudication (age 69 ± 10 years, stature 1.7 ± 0.9 m, mass 83.2 ± 16.2 kg, ankle-brachial pressure index 0.55 ± 0.14) were randomised in this cross-over trial. Gait parameters whilst walking with rocker-soled shoes were compared with control shoes at three intervals of pain-free walking, at onset of IC pain (initial claudication distance) and when IC intensifies and prevents them walking any further (absolute claudication distance). Two-way repeated measures ANOVA were performed on gait variables.

*Results:* When compared with control shoes, rocker-soled shoes reduced ankle power generation (mean 2.1 vs 1.6 W/kg, respectively; $p = 0.006$) and altered sagittal kinematics of the hip, knee and ankle. However, this did not translate to a significant increase in initial (138 m vs 146 m, respectively) or absolute (373 m vs 406 m, respectively) claudication distances. In response to IC pain, similar adaptations in temporal-spatial parameters and the sagittal kinematics were observed between the shoe types.

*Significance:* The three-curved rocker shoes, in their current design, do not augment gait sufficiently to enhance walking distance, when compared with control shoes, and therefore cannot be recommended for the intermittent claudication population.

Clinical Reg No. (ClinicalTrials.gov): NCT02505503.

## 1. Introduction

Intermittent claudication (IC) is the most common symptom of peripheral arterial disease [1]. Atherosclerosis of the lower limb arteries commonly results in ischaemic pain in the calves during physical activity; which is relieved by rest [2–4]. Individuals with IC report a reduced quality of life due to an impairment of physical functions and IC pain which adversely affect gait, limits walking distances and encourages a sedentary lifestyle which has poor cardiovascular and illhealth outcomes [5–12]. Current treatments for IC include surgery and/or conservative interventions such as smoking cessation, drug management and supervised exercise programmes [5,13,14]. However, these treatments can be costly and offer no guarantee of improved walking distance or reduction in the severity of IC pain [15]. Adaptations to footwear could improve walking ability and increase walking distance until the onset of IC pain (initial claudication distance (ICD)) and when the pain intensifies and prevents them walking any further (absolute claudication distance (ACD)) [16]; however the support from

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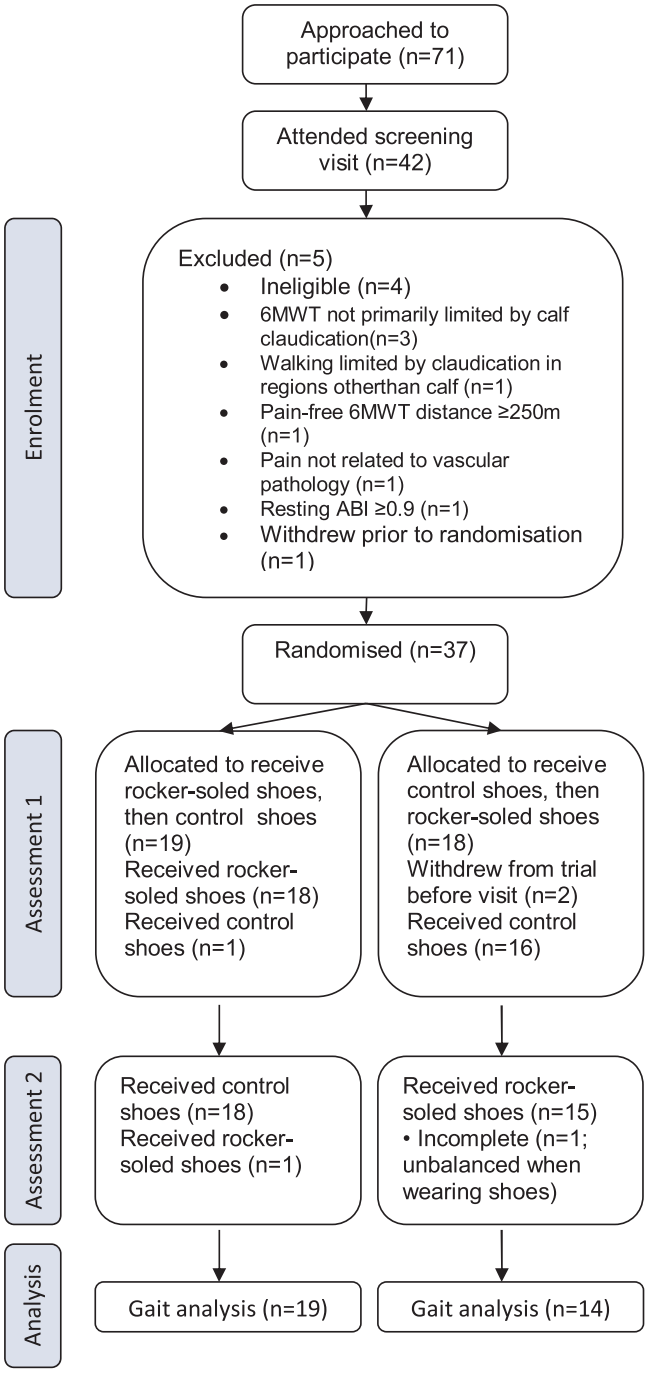


**Fig. 1.** CONSORT flow diagram of the recruitment to the study.

literature is sparse and unclear [13,17–19]. Rocker-soled shoes have been shown to increase the ICD in individuals with IC when compared with standard shoes (+77 m; $p < 0.01$ and +89 m; $p < 0.01$, respectively) [19]. It is hypothesised that a rapid plantarflexion in the early stance phase, which is a gait characteristic of in individuals with IC [20], could hinder the natural rocker of the foot and increase the demand on lower limb musculature. Rocker-soled shoes could facilitate or reinstate the natural rocker of the foot, therefore reducing the demands on lower limb musculature and improving ICD and ACD. A recent pilot study by Hutchins et al. [13] found that a three-curve rocker-soled shoe (Fig. 1) doubled the pain-free walking distance and reduced the intensity of IC pain by 43% when compared with stock therapeutic shoes (n = 8). Hutchins et al. [13] hypothesised that rocker-soled shoes might reduce the metabolic demands and mechanically unload the calf musculature by 25% when compared with un-adapted shoes, thus allowing individuals to increase ICD. This evidence of an unloading effect was from unpublished thesis data [21] and found in healthy participants (n = 12). The applicability of these findings to the IC population is questionable due differences in gait between individuals with IC and age-matched healthy controls, even when walking without IC pain [20,22–24]. In contrast to Richardson [19] and Hutchins et al. [13], our research group has previously reported no difference in ICD during usual pace walking (n = 34) between rocker-soled shoe design and standard shoe (164 ± 132 m vs 160 ± 88 m, respectively) [25]. Direct comparison of the rocker shoe literature in IC is difficult due to subtle differences in shoe design, walking assessments and variation in the description of IC pain given to individuals with IC (e.g. 'bothered by pain' [19] and 'onset of pain' [13,25]). Lastly, the effect of rocker-soled shoes on ACD, which is a key indicator of walking ability, was not considered by Hutchins et al. [13] or by our group, previously [25]. Therefore the aim of this study was to identify the effect of three-curve rocker shoes on walking distance and the biomechanics of walking whilst pain-free, at ICD and ACD.

## 2. Methods

### 2.1. Participants

The study was approved by the NRES Committee for Yorkshire & The Humber - Leeds West (Ref: 15/YH/0107), and prospectively registered (ClinicalTrials.gov: NCT02505503). Participants were recruited from vascular outpatient clinics of a teaching hospital and provided written informed consent to participate. Inclusion criteria were: aged ≥16 years; stable symptoms of IC for ≥3 months; resting ankle-brachial pressure index (ABPI) ≤0.9 and/or imaging evidence of peripheral arterial disease; pain-free walking distance < 250 m on 6-minute walk test with walking limited primarily by calf IC (assessed at screening visit). Those with critical limb ischemia; absolute contra-indications to exercise testing; lower-limb amputation; co-morbidities that limit walking before IC pain (e.g. lower-limb osteoarthritis); ambulation limited by IC in regions other than the calf; major ankle or foot pathology, and; current or previous (within 6 months) use of orthoses, lower-limb braces or customised shoes prescribed by a health professional were excluded from the study. Further information on the recruitment to the study is presented in the CONSORT flow diagram (Fig. 1).

### 2.2. Shoes and randomisation

After participant eligibility was confirmed in the screening visit, shoe size was assessed and both the rocker-soled and control shoes were ordered from an established shoe manufacturer (Chaneco; www.chaneco.co.uk). The rocker-soled shoe was a trainer-type shoe with a black leather upper section, laces, and a specially-designed rocker sole (Patent no.: GB2458741B) (Fig. 2B). The rocker-soled shoes were adapted from the design used in Hutchins et al. [13] but still maintained the same fundamental design of three circular curves. The arcs of these curves were formed from radii centred on the sagittal plane anterior-posterior position of the ankle, hip and knee during a standing position and assuming a vertical line between them all. This design purports to position the ground reaction force lines of action closer to lower limb joint centres, and thus joint moments and powers might be reduced. This would only be true when the lower limb is in vertical position, or at mid-stance. The apex position of the intervention shoe was in line with the anterior-posterior position of the anatomical ankle joint. The control shoe had a through-wedge rocker sole, toe-only curved rocker (Fig. 2A) and an apex positioned proximal to the first metatarsal head. As the control shoe shared characteristics of a typical trainer shoe and was similar in appearance and weight to the rocker-soled shoe, both researchers and participants were blinded.