Effect mechanism of custom-made foot orthoses on foot pronation subjects and chronic low back pain: a randomized controlled trial

Study Design: Double blinded Randomized controlled trial.

Clinical Relevance

Custom-made foot orthoses may contribute to improving chronic low back pain. This question represents an important benefit for patients and for the public health system by reducing expensive treatments, such as surgery or long periods of rehabilitation.

Keywords Low back pain, foot, pronation, posture, custom-made foot orthoses.

NCT number NCT03996980

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Methods

Design

A double-blinded two-arm randomized controlled trial. The participants were randomly allocated to a custom-made foot orthoses intervention group or a placebo orthoses intervention group.

This paper was written according to the CONSORT 2010 Statement guideline for reporting randomized clinical trials (Schulz KF, Altman DG, Moher D, CONSORT Group.

Recruitment

The trial was conducted between January 2019 and September 2019. The participants were between 18 and 65 years old with a diagnosis of nonspecific CLBP and pronated foot (FPI ≥ +6) recruited from the Podiatry Clinic of the University of Seville. Potential participants were initially interviewed briefly to be evaluated in the participation in the study (a qualified podiatrist carried out this initial assessment).The original sample consisted of 105 subjects (54 women and 51 men), 53 corresponding to the experimental group and 52 to the control group. After finishing the follow-up period, there was a loss of 4 subjects (who left the study for unknown reasons or because it was impossible to contact them).

Inclusion Criteria

The inclusion criteria were: Males and females between 18 and 65 years old, presence of CLBP, Foot Posture Index pronated in one or both feet (henceforth, FPI) ≥ +6[16].

Exclusion Criteria

The exclusion criteria were: serious illness, current participation in another research study, pregnancy, previous back or foot surgery, current treatment of foot pathology or back, and leg length discrepancy > 5 mm.

Procedure

We recruited 105 patients of the Podiatry Area of the University of Seville. There was a routine biomechanical lower limb examination to determine the inclusion criteria (Figure 1). A podiatrist assessed the foot posture during the biomechanical assessment based on the six-item foot posture index (FPI≥+6) [16]. The FPI consists of six validated

items measured in a standing relaxed position of the subject; The categories are:

Supinated foot: −1 a -12.

Neutral foot posture: 0 to +5 (neutral).

Pronated foot posture: +6 to +12.

The patients were randomized to either an experimental treatment group or a control group. The main researcher and the participants were blind to which group and kind of treatment was being studied. The random allocation to each group was done by a collaborating researcher who generated the random sequence (blocked randomization based on a random numbers table) and the treatment was administered (experimental/control).

The primary outcome was measured at the moment of inclusion in the study, and after four weeks of use of the orthose treatment. We used the Oswestry Disability Index Questionnaire (ODI) for Lower Back Pain which provides information on disability due to CLBP and its impact on ten daily activities and a 100 mm visual analogue scale (VAS). At the end of the study the control group received the custom-made foot orthoses best suited to them.

Fabrication of foot orthoses

Molds of both feet were obtained for all the participants . The phenolic foam molds were made in a condition of the participant`s feet under weight-bearing. The feet were manipulated before being introduced into the phenolic foam placed in a neutral position. We obtained a positive mold of the feet filling the phenolic foam molds with liquid plaster. The positive mold was used to make the custom orthoses of polypropylene of 3-

mm (heated to 180°C) from the heel to just behind the metatarsal heads, covered with a 2-mm thick polyethylene foam layer of 35-shore in the experimental group. For the control group, placebo treatment, a flat insole was made of polyester resin adjusting it to the size of the foot, but not adapting it, the aim being not to alter the patient's normal function (Figure 1).

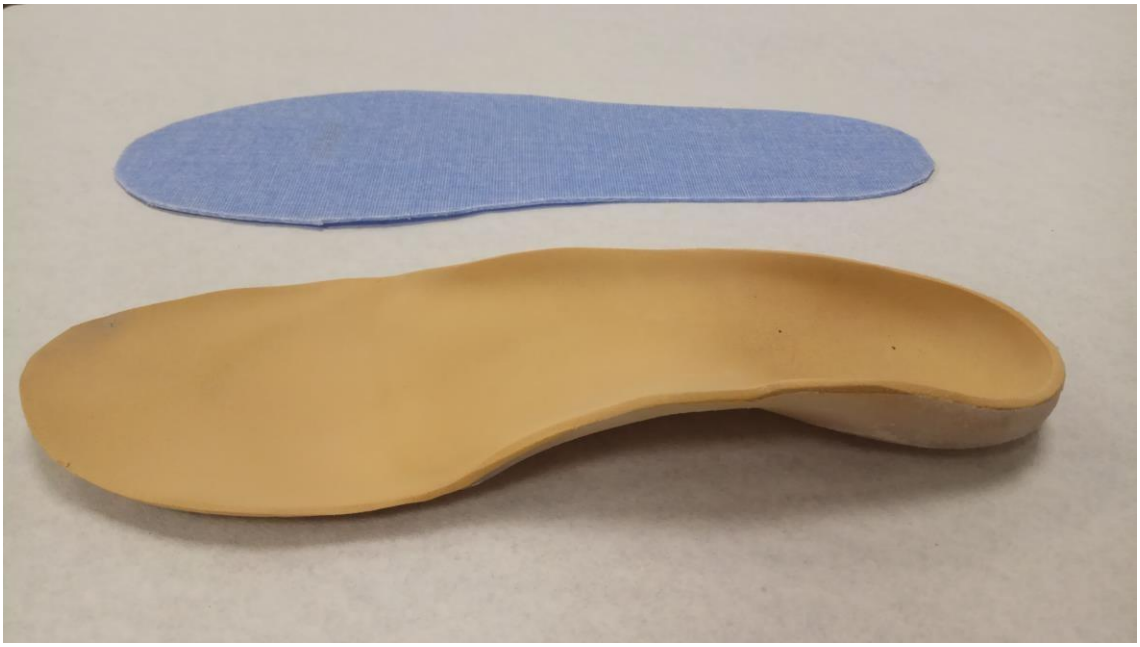


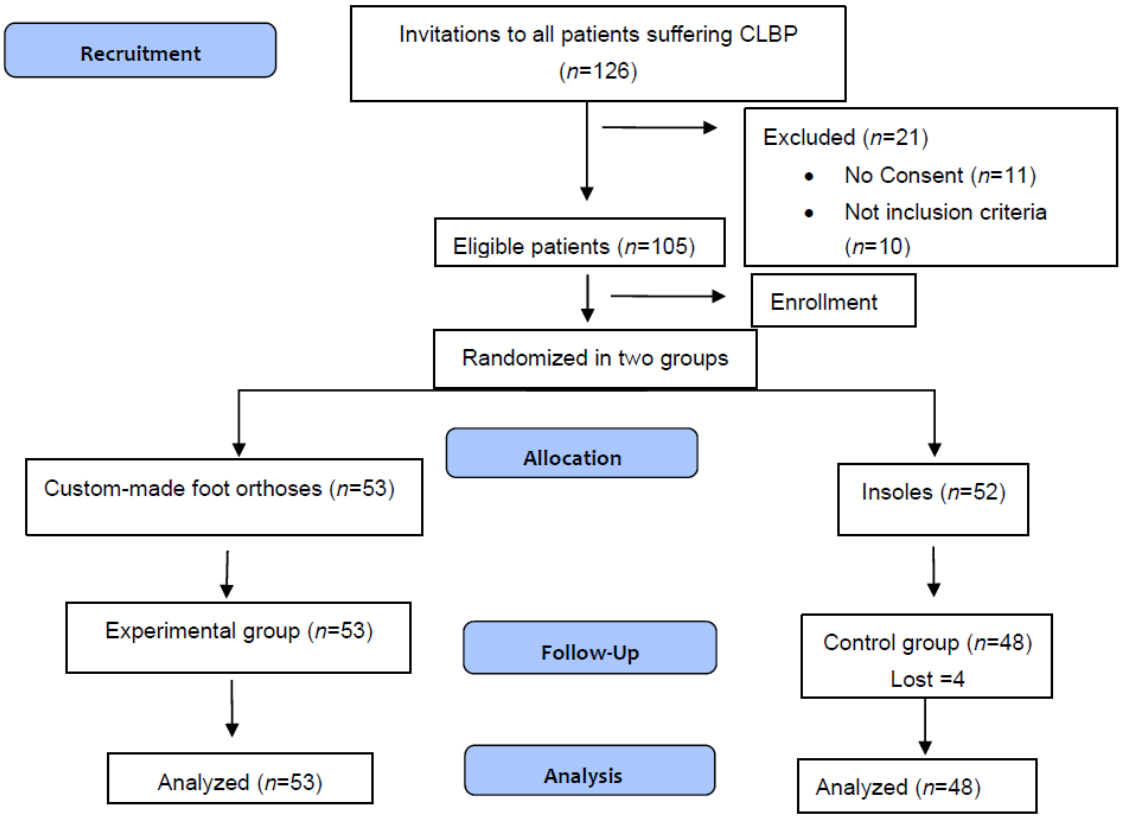
Figure 1. Foot orthoses.

Statistical analysis

The recruitment target was 101 participants (G* Power 3.0.10, Franz Faul, Universität Kiel, Germany). Based on a preliminary study[12] the sampling size necessary was 36 participants in each group. This size was increased to compensate for possible alterations in the statistical significance of the results caused by potential participant dropouts. Therefore, we used a final sample size of a total of 101 participants.

The Student's t test was used for the comparison between means and medians of the groups. Whenever a normally distribution pattern was rejected, the nonparametric Mann–Whitney U test was applied. Secondary outcomes were tested for differences by Pearson's Chi^2 or Student's t-tests.

All analyses were performed using SPSS® version 24.0. A P-value <0.05 was set as statistically significant.



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