Clinical Rehabilitation

# Effectiveness of custom-made functional foot orthoses versus flat cushioning insoles on pain in patients with Systemic Lupus Erythematosus



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## ABSTRACT

**Objective:** To determine the effect of foot orthoses on pain, disability and foot functionality in patients with Systemic Lupus Erythematosus.

**Design**: Randomized clinical trial.

**Setting**: University Podiatric Clinical Area.

**Subjects**: Patients with Systemic Lupus Erythematosus.

**Interventions**: Patients were randomly assigned to either group A, which received custom-made functional foot orthoses, or group B, which received flat cushioning insoles, for 3 months.

**Main measures**: The primary outcome was foot pain, measured by 11-point numeric pain rating scale. Foot functionality and foot-related disability were evaluated using the Foot Function Index, the Manchester Foot Pain and Disability, at the beginning and at days 90.

**Results**: Sixty-six participants (age 47.3±11.9 years) suffering from foot pain, received either the custom-made foot orthoses (N=33) or the flat cushioning insoles (N=33). For the analysis of the data, only participants who had finished the follow up period (90 days) were included. In group A, all variables showed statistically significant differences when comparing the initial and final measurements. Pain showed 6.8±1.6 and 4.2±2.9 in group A, at baseline and at 90 days, respectively Group B showed 6.5±1.5 and 4.7±3.0 at baseline and at 90 days, respectively. None statistically significant difference between groups were found.

**Conclusion**: Both groups showed a reduction in foot pain, disability and activity limitation, although functional foot orthoses group noticed best results diminishing pain. This study suggests that not only controlling the foot function, but providing cushioning to the foot, may have positive effects to manage foot pain in patients with Systemic Lupus Erythematosus.

# EFFECTIVENESS OF CUSTOM-MADE FUNCTIONAL FOOT ORTHOSES VERSUS FLAT CUSHIONING INSOLES ON FOOT PAIN IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: A RANDOMIZED CONTROLLED TRIAL

## INTRODUCTION

Systemic Lupus Erythematosus is a chronic, complex, multi-system autoimmune disease, with a female-to-male ratio of 9:1, that may affect almost any organ and system, including skin, kidney, lung, nervous system, heart or joints.[1] Among them, musculoskeletal involvement is one of the most common and earliest clinical manifestations,[2,3] occurring in up to 90-95% of patients during the course of the disease.[2]

Initially most reports had focused on hand involvement, and feet were paid little attention in both the research and clinical contexts.[3,4] Nowadays, it is known that people with Systemic Lupus Erythematosus experience a wide range of lower limb and foot manifestations,[1,2,5–7] as foot and ankle problems do exist related to the musculoskeletal and vascular systems, the effect of medical treatment of Systemic Lupus Erythematosus on tissue viability, and the reduced resistance to infections.[3] Some studies have described a broad spectrum of musculoskeletal foot involvement in Systemic Lupus Erythematosus, such as arthralgia, deforming arthropathy, lesser toe joint deformities, hallux valgus, hallux limitus/rigidus, or Tailor's bunion.[8,9]. These musculoskeletal alterations could be the origin of foot pain in patients with Systemic Lupus Erythematosus. Some studies have reported that 62% to 80% of patients complained of

foot pain during the course of their disease,[1,8,10,11] all parts of the foot affected being, but overall, ankle, hind foot and metatarsophalangeal joints.

Although the above problems may be associated with mechanical disfunction of the foot, it is not clear whether foot pain in patients with Systemic Lupus Erythematosus is caused by mechanical deficit or by other types of alterations. [1,6,8,10–12] Foot orthoses may provide functional control and/or a cushioning effect, and have been described as an effective therapy to reduce foot pain in some rheumatic diseases.[13–17] When foot pain is caused by biomechanical impairments, functional control is necessary to make foot joints move in a more normal way. However, functional control is not always mandatory to reduce foot pain, especially when the origin of pain is a lack of cushioning. Despite the well-recognized negative impact of Systemic Lupus Erythematosus on foot pain, little attention has been paid to conservative specific interventions, such as foot orthoses, in these patients. Minimal references to this type of treatment have been identified in the literature, both as expert recommendations,[18,19] or as a result of self-reported information by respondents in survey studies.[1,10] But, to the best of our knowledge, no studies exist that address the effectiveness of orthopedic treatment for foot problems in patients with Systemic Lupus Erythematosus. In view of the high frequency of foot pain in these patients, this study aimed to determine the effect of custom-made functional foot orthoses versus flat cushioning insoles on pain in patients with this disease. Secondarily, the effect of this treatment on foot functionality and disability related to foot pain were also evaluated, as it has been previously reported that Systemic Lupus Erythematosus may have a negative impact on these variables.[10,11,20]

## MATERIAL AND METHOD

### Study design and clinical setting

A randomized controlled clinical trial was carried out according to the CONSORT guidelines,[21] and was registered in ClinicalTrials.gov (trial ID: NCT04098055). The study was conducted according to the protocol and good clinical practice principles and Declaration of Helsinki statements. All the participants gave their informed consent to be included, and the study obtained ethical approval from the committee of the Portal de Ética de la Investigación Biomédica de Andalucía (ID: 1494-N-19) and authorized by the Head Office of the Clinical Area of Podiatry of the University of Seville (ID: INV10-19).

For the recruitment of participants, the Spanish Lupus Federation was contacted and informed about the study's aims and characteristics, and informative flyers were elaborated and delivered to the attendees of the national Spanish lupus congress in 2019. Also, the rheumatology unit of the University Hospital "Virgen del Rocio" in Seville was contacted, and some participants were recruited from this institution. Data were gathered in the Clinical Area of Podiatry of the Universities of Seville and Málaga, and private clinics in Córdoba and Jerez de la Frontera. The study's start and end dates were November 2019 and February 2022, respectively (the reason for such a long period was the unexpected impact of the COVID-19 pandemic and related confinements). The University of Seville was responsible for the integrity and conduct of the study. This study was non-funded except for the cost of orthoses materials provided by the University of Seville. This institution had no influence on the results.

## Inclusion criteria and random allocation

The eligible participants were between 18 and 67 years old (the working age in Spain), had a diagnosis of Systemic Lupus Erythematosus confirmed by a consultant rheumatologist, fulfilled the American College of Rheumatology criteria,[22] and presented foot involvement with a self-reported pain (either unilateral or bilateral) with a minimum threshold score of ≥3 for at least 3 months at inclusion, measured using the 11-point Numeric Pain Rating Scale. Participants were excluded if they had been using any foot orthotic treatment for 30 days prior to the study, presented ulcers or wounds in their feet, had cutaneous lupus without systemic involvement, had other systemic diseases such as diabetes mellitus, neurological problems, or cognitive deterioration, previous osteoarticular foot surgery, needed walking assistance, or refused to use appropriate and healthy footwear for orthosis.

The participants were randomly assigned to one of the two study groups (group A or group B). The participants in group A were given the custom-made functional foot orthoses, while those in group B received flat cushioning insoles. Randomization was conducted by using the Microsoft Excel macro AleatorMetod.xls, publicly available at www4.ujaen.es/~mramos/EPIP/AleatorMetod.xls. The simple randomization process was carried out according to the order of appointment, so that the first patient treated was number 1. The participants themselves chose the day and time of the appointment with the research team within an established time without knowing the order number that they would have or the corresponding random assignment.

## Interventions

Clinical and demographic data were collected including age, sex, weight, height, and years since diagnosis of Systemic Lupus Erythematosus. After a biomechanical

examination, the Foot Posture Index was recorded and phenolic foam casts of the patient's feet under weight-bearing conditions were obtained. With the participant standing on a podoscope, the foot was manipulated before being introduced into the phenolic foam to place the subtalar joint in the most neutral position possible, always maintaining the forefoot plantar plane parallel to the floor. In the case of Foot Posture Index values between +6 and +12, the examiner held the distal third of the participant's leg and exerted external rotational force to the leg until the mirror of the podoscope showed an incipient loss of the first ray footprint; that is, until the first metatarsal began to lose contact. At that moment, the examiner stopped applying external rotational force to the leg. This maneuver was repeated several times by the examiner, as the external rotation applied to the leg in contact with the glass was the same as that applied when introducing the foot into the phenolic foam. The same procedure with internal rotation of the leg was carried out for Foot Posture Index values between −12 and −1. For feet with Foot Posture Index values between 0 and +5, the examiner applied resistance against pronation or supination to maintain the foot in its physiological relaxed position.

Custom-made functional foot orthoses consisted of a polypropylene layer of 3 mm from heel to just proximal to the metatarsal heads, and an upper sheet of 5 mm, 30 Shore A polyethylene foam. These orthoses were obtained from the casts of the participants' feet and had the objective of providing functional control of the foot as well as cushioning. Flat cushioning insoles consisted of a flat insole made of the same material as the upper layer of those used in group A, with the only aim of providing cushioning but not functional control. Participants in both groups were told that the foot orthoses assigned had to be used seven days a week for a minimum of eight hours per day during the follow-up period (three months), wearing healthy shoes (that is, no more than a 3 cm

drop, wide and spacious with removable, laced or Velcro insole, good posterior buttress, medial-lateral stability, and flexibility in the metatarsophalangeal dorsiflexion area).

All the participants were blinded, since they did not know what types of foot orthoses they were given in the study (functional or cushioning). The only information that they were given was that the research would evaluate the effectiveness of two types of foot orthoses to treat pain in patients with Systemic Lupus Erythematosus.

The clinical variables were measured in person at the beginning (baseline) and at the end of the follow-up period (3 months). Once a month the participants were called by phone to ensure that they were using the foot orthoses correctly and to collect pain-related information (11-point Numeric Pain Rating Scale and pain days). The researchers who performed the measurements and collected data at the baseline and after 3 months, and by phone calls once a month, were not the same as those who conducted the randomization, adapted the foot orthoses, and gave them to the participants. Thus, they were also blinded.

**Data collected**

The primary endpoint was foot pain, measured by the 11-point Numeric Pain Rating Scale and Foot Function Index (foot pain domain). Pain days were also recorded as the number of days on which the patient felt foot pain in the previous week by assigning a whole number between 0 and 7.

Other outcomes were foot functionality and disability related to foot pain. Foot functionality was measured using the Foot Function Index. This is a questionnaire with 23 items divided into three domains: foot pain, disability and functional limitation. The values range from 0 and 100, with higher values corresponding to greater pain,

disability, and limitation. Disability related to foot pain was measured using the Manchester Foot Pain and Disability Index. This is based on 19 statements, two of which are related to the difficulty in performing work or leisure activities and are excluded from the questionnaire if the respondent is of a retirement age. The remaining items constitute three constructs (sub-scales): functional limitation, pain intensity, and concern with personal appearance. The values of this index range from 0 to 38, with higher values corresponding to greater disability.

**Sample size calculation**

The minimum sample size was calculated using the 11-point Numeric Pain Rating Scale variable as a reference, with the following formula to compare mean values between populations:

$$\mathrm{n} = \frac{2s^2(z_{\alpha/2} + z_{\beta})}{d^2}$$

where $s$ is the standard deviation based on previous studies on foot characteristics in rheumatoid diseases,[23] $\alpha$ is the type I error, $\beta$ is the type II error, and $d$ is the minimum difference to be detected with 11-point Numeric Pain Rating Scale.

$$n = \frac{2s^2(z_{\frac{\alpha}{2}} + z_{\beta})^2}{d^2} = \frac{2 \cdot 1{,}9^2 \cdot (1{,}96 + 0{,}84)^2}{2^2} = 14{,}15 \cong 15$$

Thus, at least 15 people were needed in each group to compare the mean values. In this study, 66 patients were initially recruited, in consideration of possible losses.

**Data analysis**

The analysis of the data was carried out using the statistical software IBM SPSS Statistics 25 (IBM, Armonk, NY, USA). The descriptive data provided the mean values

and the standard deviations or the absolute frequencies and percentages depending on whether the variables were scalar or categorical.

Shapiro–Wilk tests were conducted for the inferential analysis to determine the most appropriate test to use. When data showed a normal distribution by groups, a t-test was carried out for independent samples, and the Mann–Whitney U test was used for the between-group comparison when there was no normal distribution. The paired Student's T test or Wilcoxon signed rank test were used for within-group analysis when there were normal and no normal distributions, respectively. Friedman´s two-way analysis of variance by ranks for comparisons of the 11-point Numeric Pain Rating Scale and pain days monthly through the follow-up period were used when there were normal and no normal distributions, respectively. To ensure that losses did not affect the results, the analysis was carried out including only those participants who completed the 3-month follow-up. The a priori confidence level was 95%.

## RESULTS

Ninety-nine people with Systemic Lupus Erythematosus were eligible for potential selection. Sixty-six participants (age 47.3±11.9 years, Body Mass Index 27.9±6.2, years since diagnosis 15.8±10.2) were finally included in the study, 33 in group A and 33 in group B. Sixteen participants were eventually lost in group A with 17 remaining, and 10 people were lost in group B with 23 remaining. Therefore, the final sample consisted of 40 female participants. A flow diagram with the reasons for exclusion and withdrawal is shown in Figure 1. Descriptive data are shown in Table 1. No significant differences were observed between the two study groups in terms of descriptive variables, pain or function at the baseline. Due to the large percentage of losses, the same initial comparison was made including in the analysis only those participants who completed

the follow-up (N = 17 in group A and N = 23 in group B). Both groups remained homogeneous as no significant differences were observed (P > 0.05 in all the variables).

Table 2 shows data after a 3-month follow-up. Both groups showed a reduction in foot pain after the follow-up. However, there were no significant differences in foot pain, foot disability or foot function between groups.

Both types of orthoses produced changes in several of the evaluated variables after 3 months within groups (Table 3, supplementary material). Regarding the monthly assessment of foot pain, faster improvement was achieved in group B with an 11-point Numeric Pain Rating Scale, and in group A with "days with pain" (Table 4, supplementary material).

## DISCUSSION

The main aim of this work was to investigate whether two different types of foot orthoses could reduce foot pain in people with Systemic Lupus Erythematosus. Although group A showed a greater reduction of pain after the follow-up, the difference between groups was not significant. To the best of our knowledge, this is the first study assessing the effectiveness of foot orthoses in foot pain of patients with Systemic Lupus Erythematosus.

Systemic Lupus Erythematosus Management is complex and the main recommendations are focused on ensuring long-term survival, preventing organ damage, controlling disease activity and minimizing comorbidities.[24,25] Although medication is the first-line treatment, several non-pharmacologic remedies have been studied in patients with Systemic Lupus Erythematosus.[26–29] However, few references have been found in the literature regarding the use of foot orthoses for these patients.

Beilstein and Hawkins[18] simply recommended them during the active disease process to help correct calcaneal eversion and forefoot deformities secondary to soft-tissue laxity and muscle imbalance. Otter et al.[10] reported that only 22% of the respondents of their study had been prescribed insoles. Cherry et al.[1] found that the most frequent intervention for foot problems was the provision of foot orthoses. However, this was only reported by 27% of the participants, who evidenced a clear request for further assistance.

Several authors have described functional alterations of the foot and ankle in Systemic Lupus Erythematosus which can be related to foot pain. Morales-Lozano et al.[8] found significantly more limited tibiotalar mobility, pathological Jack's test, abnormal Foot Posture Index (both pronated and supinated) and abnormal footprint in Systemic Lupus Erythematosus feet than control feet, and more limited ankle mobility and higher values of Foot Posture Index (more pronated feet) in painful lupus feet in comparison with painless lupus feet. Stewart et al.[11] reported that, compared to controls, patients with Systemic Lupus Erythematosus had less muscle force for movements of the ankle joint, a significantly higher Foot Posture Index (indicative of a more pronated feet), and changes in some gait parameters. These abnormal biomechanical variations may favor functional disability and activity limitations,[11,12] which could be the reason why foot orthoses with functional control contribute to reducing foot pain levels in these patients, as shown in this study.

On the other hand, beneficial effects in reducing pain can also be achieved only with cushioning effects, without functional control, because foot pain may be associated with problems other than biomechanical alterations.[2,5,30] Reilly et al.[5] did not observe significant correlations between radiological and clinical features in a group of patients in which 80% had peripheral arthritis and 66.7% had at least one radiographic

abnormality in their feet. Iagnocco et al.[6] observed no significant differences in the ultrasound inflammatory scores of metatarsophalangeal joints in lupus feet among participants with and without the presence of clinical joint involvement. This dissociation between clinical and ultrasound imaging findings suggests a condition of subclinical synovitis that may be the origin of pain with no relation to biomechanical abnormality. Neurological deficits, also a common feature in Systemic Lupus Erythematosus,[31] could be correlated with other aspects of foot pain.[32] Foot pain potentially caused by these and other abnormalities may improve without a functional control but with a cushioning effect. Beneficial effects with cushioning insoles have been observed in several studies on Rheumatoid Arthritis feet.[15,16,33] This may be because functional alterations are not the main cause of pain in patients with Systemic Lupus Erythematosus.

Foot pain was chosen as the main outcome measure in this study because it is a prevalent complaint reported by patients with Systemic Lupus Erythematosus.[7,10,11] A significant change of the 11-point Numeric Pain Rating Scale for foot pain scores was seen over the three months in within groups and could be considered an important difference for patients.[34] However, no significant differences were observed between groups, which means that both types of foot orthoses equally reduced foot pain after three months.

This study has several potential limitations. The most important is the small numbers of participants who completed the follow-up. The study started on November 2019, and since the declaration of the worldwide pandemic of COVID-19 on March 11th, 2020, some participants drastically diminished their activity (and therefore the use of orthoses) because of the need for confinement, loss of work, or attempts to minimize the potential for transmission of the virus through non-essential face-to-face activities. No participant

exclusions were observed due to problems with foot orthoses, but there were many losses because they recognized that were not using them as indicated by the research team. The small numbers in this study does reduce the external validity of the findings and therefore limit any definitive conclusions. However, a minimum sample size needed to get 80% power was respected. Further studies with larger numbers of participants are needed to substantiate any trends shown here. Secondly, other pathologies related to Systemic Lupus Erythematosus that can influence foot pain, such as vascular and neurological problems[18], may have affected the outcomes.

The British Society for Rheumatology guideline for the management of Systemic Lupus Erythematosus in adults,[35] highlights the importance of professional footcare in patients with this disease. No previous research has been done on the role of foot orthoses, although the need for professional footcare has been also recognized by patients with Systemic Lupus Erythematosus.[4] This study suggests that not only controlling the foot function, but also providing cushioning to the foot, may have positive effects on foot pain reduction. This work could be an initial step to consider foot orthoses as a feasible and safe therapeutic alternative to bear in mind to provide these patients with an environment of less foot pain without the need for modifying the habitual oral medical treatment.

**Clinical Messages**.

Patients with Systemic Lupus Erythematosus suffer from foot pain.

Foot orthoses help reduce foot pain and disability in patients with Systemic Lupus Erythematosus. Custom-made foot orthoses should provide the foot with functional control and cushioning .

**Author contributions.** ICPT contributed to the data acquisition, data analysis and interpretation, and drafting of the paper. MRB contributed to the study conception and design, data acquisition, data analysis and interpretation, and drafting and revision of the paper. GDM contributed to the data acquisition, data analysis and interpretation, and drafting of the paper. MCVB contributed to the data acquisition, data analysis and interpretation, and drafting of the paper. JMCL contributed to the data acquisition and drafting of the paper. JRO contributed to the data acquisition and drafting of the paper. PVMM contributed to the study conception and design, study supervision, data acquisition, data analysis and interpretation, and drafting and critical revision of the paper. The authors have provided final approval of the version to be submitted and any revised version.

**Competing interests.** The Authors declare that there is no conflict of interest.

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Table 1. Descriptive data and comparison between groups at baseline. FPI: Foot Posture Index; FFI: Foot Function Index; MFPDI: Manchester Foot Pain and Disability Index.

| | Foot Functional Orthoses N = 33 (50%) | | | | Cushioning Insoles N = 33 (50%) | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Median | IQR | Mean | SD | Median | IQR | p |
| Age | 46.8 | 10.9 | 46 | 39-53 | 47.8 | 12.9 | 47 | 40.0-55.5 | 0.743[1] |
| BMI | 28.0 | 5.6 | 26.2 | 24.2-31.5 | 27.8 | 6.8 | 25.4 | 22.8-33.4 | 0.526[2] |
| LES Evolution | 15.7 | 10.0 | 12 | 8-23 | 15.9 | 10.6 | 15 | 6-23 | 0.929[1] |
| Right Foot FPI | 3.7 | 3.6 | 4 | 1.5-6.5 | 3.9 | 3.2 | 4 | 2.0-5.5 | 0.771[2] |
| Left Foot FPI | 3.5 | 3.4 | 3 | 1.0-6.5 | 4.4 | 3.1 | 4 | 2.5-6.5 | 0.152[2] |
| 11-NPRS | 6.7 | 2.0 | 7 | 5-8 | 6.6 | 1.9 | 7 | 5-8 | 0.900[1] |
| Days with Pain | 5.3 | 2.2 | 7 | 3-7 | 5.2 | 2.2 | 6 | 3.5-7.0 | 0.728[2] |
| FFI-Pain | 61.3 | 20.0 | 62.9 | 47.6-78.6 | 68.5 | 17.6 | 71.4 | 57.1-82.9 | 0.125[1] |
| FFI-Disability | 47.8 | 23.9 | 46.7 | 37.7-66.7 | 53.5 | 28.7 | 56.7 | 28.3-83.3 | 0.270[2] |
| FFI-Activity Limitation | 13.6 | 16.5 | 10 | 0-23 | 20.5 | 21.3 | 14 | 2-34 | 0.172[2] |
| Total FFI | 45.5 | 19.8 | 42.4 | 30.5-60.2 | 50.6 | 19.5 | 51.9 | 33.6-68.3 | 0.289[1] |
| MFPDI-Functional limitation | 10.2 | 5.4 | 11 | 7-14 | 12.3 | 5.1 | 13 | 7.5-17.0 | 0.114[1] |
| MFPDI – Personal appearance | 0.7 | 1.3 | 0 | 0-1 | 1.1 | 1.3 | 1 | 0-2 | 0.104[2] |
| Manchester-Pain | 6.2 | 2.3 | 6 | 4-8 | 6.8 | 2.2 | 7 | 5.5-8.0 | 0.183[2] |
| MFPDI - Work/Leissure | 2.0 | 1.6 | 2 | 0-4 | 2.1 | 1.6 | 2 | 0-4 | 0.791[2] |
| Total MFPDI | 18.9 | 8.2 | 19 | 13.5-23.0 | 22.2 | 8.6 | 23 | 15-29 | 0.116[1] |

[1]Paired Student's T Test

[2]Wilcoxon signed rank test

Table 2. Comparison of foot pain, disability and function between groups after 3-moths follow-up. FFI: Foot Function Index; MFPDI: Manchester Foot Pain and Disability Index.

| | Foot Functional Orthoses N=17 (42.5%) | | | | Cushioning Insoles N=23 (57.5%) | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **Mean** | **SE** | **Median** | **IQR** | **Mean** | **SE** | **Median** | **IQr** | **p** |
| 11-NPRS | 4.2 | 2.9 | 5 | 2-7 | 4.7 | 3.0 | 5 | 2-7 | 0.664[1] |
| Days with Pain | 3.0 | 2.6 | 3 | 0.5-5.5 | 3.6 | 2.9 | 3 | 1-7 | 0.607[2] |
| FFI-Pain | 40.2 | 29.5 | 33.3 | 15.6-67.2 | 43.9 | 29.6 | 47.8 | 14.4-73.3 | 0.766[2] |
| FFI-Disability | 33.3 | 29.1 | 34.4 | 5.0-58.9 | 37.1 | 27.9 | 41.1 | 7.8-65.6 | 0.871[2] |
| FFI-Activity Limitation | 5.3 | 6.2 | 4 | 0-12 | 8.5 | 11.7 | 0 | 0-18 | 0.787[2] |
| Total FFI | 30.1 | 22.8 | 27 | 12.4-50.0 | 33.3 | 23.2 | 38.7 | 8.7-53.9 | 0.745[2] |
| MFPDI- Functional limitation | 7.4 | 4.6 | 7 | 3.5-11.0 | 9.9 | 5.5 | 12 | 4-14 | 0.127[1] |
| MFPDI - Personal appearance | 0.4 | 0.8 | 0 | 0-0.5 | 1.0 | 1.5 | 0 | 0-2 | 0.290[2] |
| MFPDI -Pain | 5.1 | 2.5 | 5 | 4-7 | 6.5 | 5.1 | 6 | 4-8 | 0.607[2] |
| MFPDI - Work/Leissure | 1.7 | 1.3 | 2 | 0-3 | 2.9 | 6.6 | 1 | 0-3 | 0.957[2] |
| Total MFPDI | 14.5 | 7.4 | 15 | 9.5-20.5 | 18.8 | 10.0 | 18 | 10-27 | 0.142[1] |

[1]Paired Student's T Test

[2]Wilcoxon signed rank test

Table 3. Within groups differences after 3-month follow-up. FFI: Foot Function Index; MFPDI: Manchester Foot Pain and Disability Index

| | **Foot Functional Orthoses** | | | **Cushioning Insoles** | | |
|---|---|---|---|---|---|---|
| | Baseline (n=17) Mean (±SD)[Median] | 3 months (n=17) Mean (±SD)[Median] | p | Baseline (n=23) Mean (±SD)[Median] | 3 months (n=23) Mean (±SD)[Median] | p |
| 11-NPRS | 6.8 (±1.6) [7] | 4.2 (±2.9) [5] | 0.002[1] | 6.5 (±1.5) [7] | 4.7 (±3.0) [5] | 0.0005[1] |
| Days with Pain | 5.1 (±2.2) [7] | 3.0 (±2.6) [3] | 0.011[2] | 5.5 (±2.3) [7] | 3.6 (±2.9) [3] | 0.006[2] |
| FFI-Pain | 61.4 (±18.2) [61.4] | 40.2 (±29.5) [33.3] | 0.005[1] | 69.5 (±17.9) [70.0] | 43.9 (±29.6) [47.8] | <0.001[2] |
| FFI-Disability | 49.0 (±22.9) [44.4] | 33.3 (±29.1) [34.4] | 0.032[2] | 50.9 (±28.2) [51.1] | 37.1 (±27.9) [41.1] | 0.007[2] |
| FFI-Activity Limitation | 11.8 (±15.8) [6] | 5.3 (±6.2) [4] | 0.079[2] | 19.2 (±20.1) [10] | 8.5 (±11.7) [0] | 0.002[2] |
| Total FFI | 47.3 (±20.6) [43.9] | 30.1 (±22.8) [27] | 0.010[1] | 49.5 (±18.4) [44.8] | 33.3 (±23.2) [38.7] | <0.001[2] |
| MFPDI-Functional limitation | 8.7 (±4.9) [8] | 7.4 (±4.6) [7] | 0.189[1] | 11.6 (±5.4) [13] | 9.9 (±5.5) [12] | 0.013[1] |
| MFPDI- Personal appearance | 0.4 (±0.7) [0] | 0.4 (±0.8) [0] | 0.317[2] | 1.2 (±1.4) [1] | 1.0 (±1.5) [0] | 0.490[2] |
| MFPDI-Pain | 6.3 (±2.1) [6] | 5.1 (±2.5) [5] | 0.114[1] | 7.2 (±2.0) [8] | 6.5 (±5.1) [6] | 0.012[2] |
| MFPDI-Work/Leissure | 1.9 (±1.7) [2] | 1.7 (±1.3) [2] | 0.521[2] | 1.8 (±1.7) [2] | 2.9 (±6.6) [1] | 0.761[2] |
| Total MFPDI | 17.3 (±7.4) [31.8] | 14.5 (±7.4) [15] | 0.091[1] | 21.8 (±9.0) [23] | 18.8 (±10.0) [18] | 0.010[1] |

[1]Paired Student's T Test

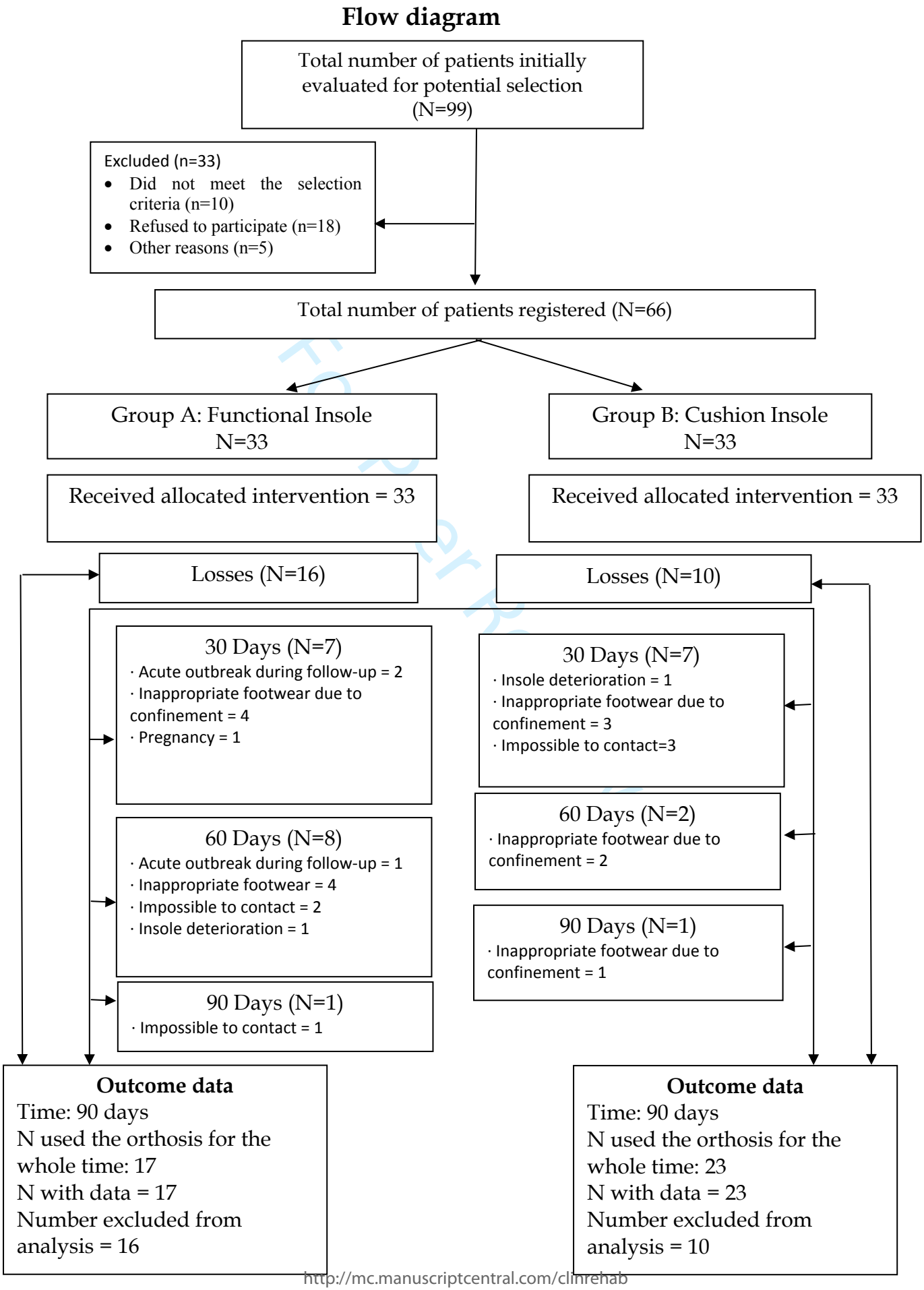
[2]Wilcoxon signed rank test

Table 4. Foot pain evolution within groups.

| | | Foot Functional Orthoses | | | | | | | | | | | | Cushioning Insoles | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | N | Mean | SD | Median | IQR | p | B-1 | B-2 | B-3 | 1-2 | 1-3 | 2-3 | N | Mean | SD | Median | IQR | p | B-1 | B-2 | B-3 | 1-2 | 1-3 | 2-3 |
| 11-NPRS | Baseline | 17 | 6.8 | 1.6 | 7 | 5.5-7.5 | 0.007 | 0.144 | 0.777 | 0.032 | >0.999 | >0.999 | >0.999 | 23 | 6.5 | 1.8 | 7 | 5-8 | 0.001 | 0.022 | 0.007 | 0.037 | >0.999 | >0.999 | >0.999 |
| | 1 month | | 4.2 | 2.9 | 5 | 1.5-6.0 | | | | | | | | | 4.3 | 3.0 | 5 | 2-7 | | | | | | | |
| | 2 months | | 4.9 | 2.5 | 5 | 3-7 | | | | | | | | | 4.0 | 3.2 | 5 | 1-7 | | | | | | | |
| | 3 months | | 4.2 | 2.9 | 5 | 2-7 | | | | | | | | | 4.7 | 3.0 | 5 | 2-7 | | | | | | | |
| Days with Pain | Baseline | 17 | 5.1 | 2.2 | 7 | 3-7 | 0.001 | 0.003 | 0.581 | 0.121 | 0.437 | >0.999 | >0.999 | 23 | 5.5 | 2.3 | 4 | 4-7 | 0.003 | 0.052 | 0.012 | 0.134 | >0.999 | >0.999 | >0.999 |
| | 1 month | | 2.2 | 2.4 | 2 | 0-3.5 | | | | | | | | | 3.0 | 2.7 | 2 | 0-5 | | | | | | | |
| | 2 months | | 3.8 | 2.9 | 4 | 1-7 | | | | | | | | | 2.6 | 2.2 | 3 | 0-4 | | | | | | | |
| | 3 months | | 3.0 | 2.6 | 3 | 0.5-5.5 | | | | | | | | | 3.6 | 2.9 | 3 | 1-7 | | | | | | | |

B-1: Baseline VS 1-month follow-up
B-2: Baseline VS 2-month follow-up
B-3: Baseline VS 3-month follow-up
1-2: 1-month follow-up VS 2-month follow-up
1-3: 1-month follow-up VS 3-month follow-up
2-3: 2-month follow-up VS 3-month follow-up

Figure 1. Flow diagram



# CONSORT 2010 checklist of information to include when reporting a randomised trial*

| Section/Topic | Item No | Checklist item | Reported on page No |
|---|---|---|---|
| **Title and abstract** | | | |
| | 1a | Identification as a randomised trial in the title | 1 |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | Independent file |
| **Introduction** | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | 1 |
| | 2b | Specific objectives or hypotheses | 2 |
| **Methods** | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | 3 and 4 |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | N/A |
| Participants | 4a | Eligibility criteria for participants | 4 |
| | 4b | Settings and locations where the data were collected | 3 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 4 to 6 |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | 6-7 |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | N/A |
| Sample size | 7a | How sample size was determined | 7 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | N/A |
| Randomisation: | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | 4 |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | 4 |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | 4 |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | 4 |

| | | | |
|---|---|---|---|
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | 6 |
| | 11b | If relevant, description of the similarity of interventions | 5 |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | 7-8 |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | N/A |
| **Results** | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | 8 |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | 8 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | 11 |
| | 14b | Why the trial ended or was stopped | N/A |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | 17 |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | 8 |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | 18 |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | N/A |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | N/A |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | N/A |
| **Discussion** | | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | 11-12 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | 11-12 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | 9-11 |
| **Other information** | | | |
| Registration | 23 | Registration number and name of trial registry | 3 |
| Protocol | 24 | Where the full trial protocol can be accessed, if available | N/A |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | 13 |

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.