Can we predict which patients with plantar heel pain are more likely to benefit from insoles? a secondary exploratory analysis of a randomized controlled trial

N. Rasenberg
    Erasmus Medical Centre: Erasmus MC

L.J.M. Dijkgraaf
    Erasmus Medical Centre: Erasmus MC

P.J. Bindels
    Erasmus Medical Centre: Erasmus MC

S.M.A. Bierma-Zeinstra
    Erasmus Medical Centre: Erasmus MC

Marienke van Middelkoop (✉ m.vanmiddelkoop@erasmusmc.nl)
    Erasmus Medical Center: Erasmus MC

Abstract

Background

Plantar heel pain (PHP) is a common cause of foot complaints, for which treatment with custom-made insoles is frequently applied. So far few studies have investigated patient characteristics that predict response to these treatments. The aim of this secondary exploratory analysis was twofold; firstly, to identify patient characteristics that predict prognosis in patients with PHP treated with insoles, and secondly to identify characteristics that might interact with treatment with insoles.

Methods

Data from a randomized trial in which participants received either custom insoles (N=70), sham insoles (N=69) or GP-led usual care (N=46) were used. At baseline, information was collected on demographics, foot symptoms, foot and ankle range of motion, navicular drop, presence of neuropathic pain, physical activity and other illnesses in the last 12 months. The primary outcome of this study was the Foot Function Index score(FFI) at 26 weeks. Multivariable linear regression models were generated to identify patients characteristics that predict the outcome for each type of intervention (i.e. insoles and GP-led usual care).

Results

We found two variables associated with a better function score at 26 weeks in patients treated with insoles, female sex (β -9.59 95%CI -17.87; -1.31) and a lower FFI score at baseline (β 0.56 95%CI 0.30; 0.82).

Conclusion

When communicating about prognosis of PHP clinicians should take sex and the amount of disability at first presentation into account. Women and people with better function scores at baseline (according to FFI) might respond better to treatment with insoles in terms of foot function.

Trial registration: NTR5346

Background

Plantar heel pain (PHP), formerly known as plantar fasciitis or plantar fasciopathy, is most commonly defined as pain located at the anteromedial part of the plantar heel during weight-bearing.[1, 2] The incidence in the Dutch general practice is estimated to be 3.83 per 1.000 person-years, where the average general practitioner (GP) sees approximately 8 new cases each year.[3] Several risk factors for developing PHP have been identified in literature, including a high BMI, limited ankle dorsiflexion, being a runner, work-related weight-bearing activities and being female.[4−8] Even though PHP is considered a self-limiting condition, with 60%-80% of cases resolving within 12−24 months [1, 9], it has a significant

negative impact on quality of life (both in terms of general and foot specific health).[10] Most reported complaints are difficulties carrying out work-related activities and sports activities.[11] Treatment strategies vary greatly among GPs and multiple interventions are often applied in patients with PHP during the course of their complaints.[3] Of the many treatments options available, orthotic devices, such as insoles, are one of the most commonly prescribed interventions by GPs.[3, 12] Though, evidence on the effectiveness of insoles in patients with PHP is conflicting.[13–15]

Little is known about factors that might predict recovery or response to treatment with insoles in patients with PHP. Only one study on this topic has been published so far. Whittaker et al. recently found that people with PHP greater ankle dorsiflexion and lower BMI, treated with insoles, experience a greater reduction of pain.[16] Though, more studies focusing on predicting response to treatment using data from high-quality studies are needed. A recent randomized controlled trial from our group found that GP-led usual care seemed to be slightly more beneficial than treatment with custom-made insoles and found no differences between custom-made insoles and sham insoles.[15] However, some patients did report an improvement after receiving insoles, while others did not. In this trial no differences were found between custom-made insoles and sham insoles and blinding between these two groups was successful. [15] This means that the context for patients in these two groups was identical and that the data from these patients is suitable to assess the prognosis of PHP in patients treated with insoles as an overall group. Therefore, the aim of this secondary exploratory analysis was twofold; firstly, to identify patients characteristics that predict the long-term complaints of patients with PHP treated with insoles, and secondly to identify characteristics that might interact with insole treatment response.

Methods

Population

For this secondary analysis, data from a previously published randomized trial investigating the effectiveness of treatment with custom-made insoles in patients with PHP were used [15]. The trial adhered to the principles of the Declaration of Helsinki and the medical ethical committee of the Erasmus Medical Centre has approved the study (MEC: 2015 – 253) and was prospectively registered at the Dutch Trial Registration (NTR5346).[17] Patients between ages 18–65 years, that presented themselves at their GP with PHP and with a minimum of 2 weeks of complaints were eligible for this trial. A total of 185 patients were included, after informed consent was received.

Interventions

Patients allocated to the custom-made insole group were referred to a podiatrist and randomly allocated to receive either a custom-made insole or a sham insole. The custom-made insole was produced according to the standard practice of their podiatrist (n = 70). The purpose of the custom-made insole was to influence the biomechanical process to reduce traction on the plantar aponeurosis and to reduce ground reaction force below the tuber calcaneus. The sham insoles were produced according to a standardized procedure, all by the same podiatrist (n = 69). The sham insoles were designed to provide as

little mechanical effect as possible, while having a visual effect similar to that of a custom insole. The patients were blinded to the type of insole they received. Patients in the GP-led usual care group were treated with usual care provided by the general practitioner (n = 46). Patients from all three groups received an information booklet containing general information on PHP including stretching and strengthening exercises targeted at PHP.(4, 16) Further details of the STAP study, and on the procedures mentioned here, are described elsewhere.[13, 15]

Measurements

At baseline, all participants filled in a questionnaire containing questions regarding demographics: age, sex, body mass index (BMI); general health status: musculoskeletal pain other than in the foot, self-reported illnesses in the last 12 months; foot complaints: affected side (right, left or bilateral), duration of complaints, pain severity (11-point numerical rating scale (NRS), including first step pain, pain in rest and during activity), neuropathic aspect of the pain according to the Doleur Neuropathique 4 (DN4 (range, 0–10))[18], the Foot Function Index (FFI (range, 0-100), higher score indicates more disability/worse function)[19] and questions regarding lifestyle factors: physical activity (Short QUestionnaire to ASsess Health enhancing physical activity (SQUASH) questionnaire)[20] and standing work for a prolonged time (4-point Likert scale). For further analysis, participants, who indicated 'bilateral' as the affected side (N = 32), were randomly assigned to either 'left' or 'right'.

Patients that were referred to a podiatrist underwent a standardized physical examination, including the range of motion in the tarsometarsal joint and the first metatarsophalangeal joint (MTP-I) as measured with a goniometer (number of degrees), the navicular drop test (millimeters)[21] and the posture of the foot using the standardized foot posture index (FPI) of both feet.[22] The podiatrist was blinded for participant allocation while performing these measurements.

At 12 and at 26 weeks participants received questionnaires containing questions on foot function (FFI), self-reported recovery (7-point Likert scale) and pain severity in rest, during activity and first step pain (11-point NRS).

Outcomes and variable selection

The FFI total score at 26 weeks was used as the primary outcome. Secondary outcomes included: the number of patients that reached a minimal important improvement in their total FFI score (an improvement of at least 6.5), the number of patients that considered themselves recovered, the first step pain according to a 11 point NRS and the number of patients that reached a minimal important improvement in their first step pain (an improvement of at least 1.9.) Potential prognostic variables were selected based on supposed clinical relevance and existing literature. The following variables were considered: age, sex, BMI, upper ankle dorsiflexion range of motion in the affected foot, MTP1 dorsiflexion range of motion in the affected foot, navicular drop (ND) in the affected foot, neuropathic pain score in the affected foot (DN4), having bilateral pain, degree of physical activity, reporting other illnesses in the last 12 months, duration of symptoms, FFI scores at baseline and the FPI.[19, 22–25] The FPI was divided into three groups. According to the criteria by Redmond et al 2006: in patients over 60

years of age, a score between 1 and 8 was considered neutral foot posture, a score below 1 was considered pronated foot posture and a score above 8 was considered supinated foot posture. In patients between 18–60 years, a score between 1 and 7 was considered normal foot posture, a score below 1 was considered pronated foot posture and a score above 7 was considered supinated foot posture. [22]

Statistical analysis

Missing values were imputed and if applicable, the minimum and maximum values were assigned as constraints by the researchers. MTP1 joint dorsiflexion (N = 12; range, 0-∞), upper ankle joint dorsiflexion (N = 12; range, 0–90), foot posture index (N = 8; range, -12 to12) and FFI total score at 26 weeks (without subscales) (N = 16; range, 0- 100) were imputed. 50 Imputations and 20 iterations using fully conditional specification (MCMC) were used.

Descriptive statistics were used to describe the selected outcome variables and to calculate to number of patients that reached an minimal important difference. Univariate and multivariate linear regression analyses with an ENTER model were performed to test the association between the selected outcomes after 26 weeks of follow-up and the selected patient characteristics in patients treated with insoles. Only data from the participants allocated to either custom-made insole or sham insole was used. The multivariate analysis performed in data from these two groups was compared to a multivariate analysis in the total population, also including data from the participants treated with GP-led usual care.

Secondly variables with a significant association with the FFI score at 26 weeks in patients treated with insoles were tested for interaction effects using linear regression, with the allocated treatment in patients treated with custom-made insoles versus sham. All analyses were performed using SPSS v25.0.

Results

The flow of patients is presented in **Fig. 1.** Baseline characteristics of the 185 included participants (sham insole group N = 69, custom insole group N = 70, GP-led usual care group N = 46) are presented in **Table 1.** **Table 2** shows the outcomes of participants at 12 and 26 weeks follow-up. Mean total FFI score at baseline was 48.7 for the total population indicating moderate disability levels. FFI scores improved during follow up (26 weeks) on average with 24 points. At 26 weeks, 79.1% of all participants reached FFI total score MID (an improvement of at least 6.5 points). Women reported higher symptom and disability scores than men at baseline .

The univariate analyses in patients treated with insoles **(Table 3)** showed that having unilateral pain (β -13.05 95%CI -22.62,-3.47), lower score on the DN4 for neuropathic pain (β 15.27 95%CI 6.75, 23.78), lower BMI (β 1.25 95%CI -0.53, 1.98), lower baseline FFI score (β .63 95%CI 0.43, 0.84) and lower baseline first step pain score (β 2.04 95%CI -0.30, 3.78) were significantly associated with lower total FFI score at 26 weeks, indicating better outcomes. In the multivariate analysis, only female sex (β -9.59 95%CI – 17.87;-1.31) and the baseline FFI score (β .56 95%CI 0.30, 0.82) were associated with lower FFI total scores at 26 weeks. **(Table 3)** A multivariate analysis in the total population (N = 185) yielded similar

results to the multivariate analysis in the patients treated with insoles. These results are presented in **Appendix 1**.

Explorative analyses in patients treated with insoles showed no significant interaction effects between the allocated treatment (custom-made versus sham) and any of the potential predictive factors (**Table 4**).

Discussion

All three treatment groups showed improvement over time when compared to baseline, according to the FFI total score, recovery rate and first step pain. Women reported higher symptom and disability scores than men at baseline. Of 16 potential characteristics analyzed in this study, female sex as well as less severe symptoms at baseline were related to better outcomes at 26 weeks follow-up in patient with PHP being treated with insoles. Of the six characteristics tested for interaction with type of treatment, none had a significant interaction. Although sex had no significant interaction with treatment effect, the confidence interval was wide and included more values on the negative side (95%CI -29.46;5.25). Given the small sample size and the exploratory nature of the present analysis, it is possible this study lacked power to demonstrate interaction effects.

The FFI total score at 26 weeks was chosen as primary outcome because of its clinical relevance and the fact that a high percentage of patients improved by at least 6.5 points (the minimal important difference) at 26 weeks when compared to baseline. The choice for this outcome may have influenced the prognostic variables. In this study the FFI total score improved significantly in both treatment groups. At 26 weeks, 79.1% of all participants reached FFI total score MID, while 55.2% self-reported to be recovered. In literature, recovery rates of 80 to 90% within 10 to 12 months are reported.[26] Follow-up in our study was relatively short at 6 months, which may explain the lower recovery rate when compared to literature. It can be noted that many patients, regardless of a meaningful improved in function, still do not consider themselves recovered.

A high BMI is a known risk factor for the development of PHP and has been found as a prognostic factor for long lasting complaints in patients treated with insoles in a previous study.[5, 16, 27] In the present study there was no significant association between BMI and the total FFI score in the multivariate model. However, BMI was associated with the FFI score in the univariate model. When adding the variables on by one to the model, the confidence interval of BMI changed the most when the baseline FFI total score was added to the model. This indicates that BMI and the FFI total score at baseline are correlated, with participants with lower BMI having lower (better) FFI scores at baseline.

PHP is more common among females, however the relationship between sex and prognosis was still unknown.[3] In the present study, both sexes showed general improvement of symptoms, as is expected in a self-limiting disease. Women reported higher symptom and disability scores than men at baseline, but reported similar scores to males at 26 weeks. In the present study sex went from being non-significant in the univariate model to being significant in the multivariate model. The significance of sex changed when the baseline FFI total score was added to the model. Indicating that when the higher score reported

by females at baseline (indicating higher disability) is taken into account, sex is a significant prognostic factor.

Strengths and limitations

To our knowledge, so far only one study has focused on patient characteristics that predict response to treatment with insoles in patients with PHP. A strength of this analysis is the fact that is based on a high-quality randomized trial where we found no differences between custom-made insoles and sham insoles while blinding between these two groups was successful. [15]This means that the context for patients in these two treatment groups was identical and that the data from both these groups is suitable to assess the prognosis of PHP in patients treated with insoles.

The main limitation of this analysis is the relatively small sample size of 139 patients. The data in the STAP study was not collected with the primary aim to perform these analyses. This limited the power and the number of potential patient characteristics that could be included. Some confidence intervals were wide and further analysis with higher power may potentially identify significant effects.

As shown in the appendix, the univariate and multivariate analysis for the entire group of patients (N = 185) included in the trial is similar to the analysis in patients treated with insoles. A separate analysis performed in only the patients who were treated with GP-led usual care, showed similar results. Since there are no studies on prognostic variables for PHP in populations with another treatment than insoles, it remains unknown, whether the prognostic variables found in this study are representative in a different context.

Furthermore, PHP is a condition that can remain symptomatic for over a year in a small percentage of patients.[28] Our follow-up was limited to 26 weeks, not allowing to measure effects on the longer term. Also, 32 participants with bilateral foot complaints were randomized into a 'left side' and 'right side' group, since data on the MTP range of motion and the navicular drop were only included of the (most) affected foot. The drawback is that for some participants we may have used measurements from the least symptomatic foot, while the FFI scores and self-reported recovery are reported for the most symptomatic foot, increasing chances for a type 2 error.

Finally, PHP is a broad term which can cover a range of different pathologies of heel pain. Given the inclusion criteria of the STAP-study, it is possible that the patients included in this study have a range of different causes of heel pain. However, exploring a wide differential diagnosis of PHP is often not indicated, since it doesn't influence clinical decision making. [2]We therefore believe the population included in this study is representative for the population presenting to the GP with PHP.

Conclusions

Female sex and less severe initial complaints, in terms of foot function, are indicative for better outcomes in patients with PHP who receive treatment with insoles. Future studies should take a difference in

response to treatment with insoles for males versus females into account in their design.

Declarations

References

1. Buchbinder R. Clinical practice. Plantar fasciitis. N Engl J Med. 2004 May;20(21):2159−66. 350(.

2. Riel H, Cotchett M, Delahunt E, Rathleff MS, Vicenzino B, Weir A, et al. Is 'plantar heel pain' a more appropriate term than 'plantar fasciitis'? Time to move on. Br J Sports Med. 2017 Nov;51(22):1576−7.

3. Rasenberg N, Bierma-Zeinstra SM, Bindels PJ, van der Lei J, van Middelkoop M. Incidence, prevalence, and management of plantar heel pain: a retrospective cohort study in Dutch primary care. Br J Gen Pract. 2019 Nov;69(688):e801-e8.

4. Martin RL, Davenport TE, Reischl SF, McPoil TG, Matheson JW, Wukich DK, et al. Heel pain-plantar fasciitis: revision 2014. J Orthop Sports Phys Ther. 2014 Nov;44(11):A1−33.

5. van Leeuwen KD, Rogers J, Winzenberg T, van Middelkoop M. Higher body mass index is associated with plantar fasciopathy/'plantar fasciitis': systematic review and meta-analysis of various clinical and imaging risk factors. Br J Sports Med. 2016 Aug;50(16):972−81.

6. Beeson P. Plantar fasciopathy: revisiting the risk factors. Foot Ankle Surg. 2014 Sep;20(3):160−5.

7. Yildiz KI, Misir A, Kizkapan TB, Cukurlu M. Changes in Rearfoot Alignment in Chronic Plantar Heel Pain. J Foot Ankle Surg. 2018 May - Jun;57(3):518–20.

8. Hansen L, Krogh TP, Ellingsen T, Bolvig L, Fredberg U. Long-Term Prognosis of Plantar Fasciitis: A 5- to 15-Year Follow-up Study of 174 Patients With Ultrasound Examination. Orthop J Sports Med. 2018 Mar;6(3):2325967118757983.

9. DiGiovanni BF, Nawoczenski DA, Malay DP, Graci PA, Williams TT, Wilding GE, et al. Plantar fascia-specific stretching exercise improves outcomes in patients with chronic plantar fasciitis - A prospective clinical trial with two-year follow-up. Journal of Bone Joint Surgery-American Volume. 2006 Aug;88A(8):1775–81.

10. Irving DB, Cook JL, Young MA, Menz HB. Impact of chronic plantar heel pain on health-related quality of life. J Am Podiatr Med Assoc. 2008 Jul-Aug;98(4):283–9.

11. Landorf KB. Plantar heel pain and plantar fasciitis. BMJ Clin Evid. 2015 Nov 25;2015.

12. Cornwall MW, McPoil TG. Plantar fasciitis: etiology and treatment. J Orthop Sports Phys Ther. 1999 Dec;29(12):756–60.

13. Rasenberg N, Fuit L, Poppe E, Kruijsen-Terpstra AJ, Gorter KJ, Rathleff MS, et al. The STAP-study: The (cost) effectiveness of custom made orthotic insoles in the treatment for plantar fasciopathy in general practice and sports medicine: design of a randomized controlled trial. BMC Musculoskelet Disord. 2016 Jan 16;17:31.

14. Whittaker GA, Munteanu SE, Menz HB, Tan JM, Rabusin CL, Landorf KB. Foot orthoses for plantar heel pain: a systematic review and meta-analysis. Br J Sports Med. 2018 Mar;52(5):322–8.

15. Rasenberg N, Bierma-Zeinstra SMA, Fuit L, Rathleff MS, Dieker A, van Veldhoven P, et al. Custom insoles versus sham and GP-led usual care in patients with plantar heel pain: results of the STAP-study - a randomised controlled trial. Br J Sports Med. 2021 Mar;55(5):272–8.

16. Whittaker GA, Landorf KB, Munteanu SE, Menz HB. Predictors of response to foot orthoses and corticosteroid injection for plantar heel pain. J Foot Ankle Res. 2020 Sep;29(1):60. 13(.

17. World Medical A. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013 Nov 27;310(20):2191–4.

18. van Seventer R, Vos C, Giezeman M, Meerding WJ, Arnould B, Regnault A, et al. Validation of the Dutch Version of the DN4 Diagnostic Questionnaire for Neuropathic Pain. Pain Practice. 2013 Jun;13(5):390–8.

19. Kuyvenhoven MM, Gorter KJ, Zuithoff P, Budiman-Mak E, Conrad KJ, Post MW. The foot function index with verbal rating scales (FFI-5pt): A clinimetric evaluation and comparison with the original FFI. J Rheumatol. 2002 May;29(5):1023–8.

20. Wendel-Vos GC, Schuit AJ, Saris WH, Kromhout D. Reproducibility and relative validity of the short questionnaire to assess health-enhancing physical activity. J Clin Epidemiol. 2003 Dec;56(12):1163–9.

21. Brody DM. Techniques in the evaluation and treatment of the injured runner. Orthop Clin North Am. 1982 Jul;13(3):541–58.

22. Redmond AC, Crosbie J, Ouvrier RA. Development and validation of a novel rating system for scoring standing foot posture: the Foot Posture Index. Clin Biomech (Bristol, Avon). 2006 Jan;21(1):89–98.

23. van Leeuwen KD, Rogers J, Winzenberg T, van Middelkoop M. Higher body mass index is associated with plantar fasciopathy/'plantar fasciitis': systematic review and meta-analysis of various clinical and imaging risk factors. Br J Sports Med. 2015 Dec 7.

24. Aranda Y, Munuera PV. Plantar fasciitis and its relationship with hallux limitus. J Am Podiatr Med Assoc. 2014 May;104(3):263–8.

25. Ribeiro AP, Sacco IC, Dinato RC, Joao SM. Relationships between static foot alignment and dynamic plantar loads in runners with acute and chronic stages of plantar fasciitis: a cross-sectional study. Braz J Phys Ther. 2016 Jan-Feb;20(1):87–95.

26. League AC. Current concepts review: plantar fasciitis. Foot Ankle Int. 2008 Mar;29(3):358–66.

27. Rano JA, Fallat LM, Savoy-Moore RT. Correlation of heel pain with body mass index and other characteristics of heel pain. J Foot Ankle Surg. 2001 Nov-Dec;40(6):351–6.

28. Digiovanni BF, Nawoczenski DA, Malay DP, Graci PA, Williams TT, Wilding GE, et al. Plantar fascia-specific stretching exercise improves outcomes in patients with chronic plantar fasciitis. A prospective clinical trial with two-year follow-up. J Bone Joint Surg Am. 2006 Aug;88(8):1775–81.

Tables

Table 1	Baseline demographics (N=185)			
	Total population N = 185 mean (SD) unless otherwise indicated	Sham insole group N = 69 mean (SD) unless otherwise indicated	Custom made insole group N = 70 mean (SD) unless otherwise indicated	Usual care group N = 46 mean (SD) unless otherwise indicated
Age, y	47.6 (10.6)	48.2 (9.4)	48.0 (11.3)	46.1 (11.4)
Sex, female, N (%)	128 (69.2)	48 (69.6)	48 (68.6)	32 (69.6)
BMI, kg/m^2	29.7 (5.3)	29.5 (4.8)	29.2 (5.8)	30.9 (5.0)
Pain history				
FFI total score (0 – 100)	48.7 (18.0)	46.1 (17.2)	50.2 (18.8)	50.3 (18.0)
FFI pain score (0 – 100)	58.7 (17.7)	55.6 (17.2)	60.0 (16.7)	61.2 (19.6)
FFI disability score (0 – 100)	39.6 (20.9)	37.3 (19.7)	41.6 (23.1)	40.1 (19.3)
First step pain score (0 – 10)	7.2 (2.3)	7.3 (2.1)	7.2 (2.4)	7.2 (2.5)
Pain at other sites than the affected foot, N (%)	78 (42.2)	32.0 (46.4)	29.0 (41.4)	17 (37.0)
DN4 score (0-10)	3.7 (2.1)	3.6 (1.8)	3.9 (2.1)	3.7 (2.3)
Localization of complaints, bilateral, N (%)	45 (24.3)	16 (23.2)	16 (22.9)	13 (28.3)
Duration of symptoms, months	6.2 (10.4)	5.1 (5.2)	7.7 (15.5)	5.4 (5.6)
Activity				
Squash questionnaire 0 – ∞	7716.7 (5270.0)	8755.3 (5747.8)	6761.3 (4525.5)	7612.6 (5398.8)
Podiatrist measurements	*Total population N = 139 mean (sd) in degrees*	*Sham insole group N = 69 mean (sd) in degrees*	*Custom insole group N = 70 mean (sd) in degrees*	*No podiatrist measurements were performed in the usual care group*
Upper ankle dorsal flexion range of motion (degrees)	16.42 (1.43)	15.52 (2.24)	17.34 (1.77)	-
MTP1 dorsal flexion range of motion (degrees)	61.38 (2.09)	61.11 (3.10)	61.65 (2.83)	-
Pronated foot posture in the affected foot according to the foot posture index, N (%)	39 (28.1)	26 (37.7)	13 (18.6)	-
Supinated foot posture in the affected foot according to the	14 (10.1)	7 (10.1)	7 (10.0)	-

foot posture index, N (%)

Outcomes at 12 weeks and 26 weeks follow-up

	Follow-up at 12 weeks			Follow-up at 26 weeks		
	Sham insole group n = 68 mean (SD) unless otherwise indicated	Custom made insole group n = 66 mean (SD) unless otherwise indicated	Usual care group N=39 mean (SD) unless otherwise indicated	Sham insole group n = 68 mean (SD) unless otherwise indicated	Custom made insole group n = 66 mean (SD) unless otherwise indicated	Usual care group N=38 mean (SD) unless otherwise indicated
total e, 0 - 00	30.3 (21.0)	30.8 (23.2)	30.2 (24.6)	24.6 (24.1)	25.0 (23.1)	22.2 (26.5)
total N (%)	48 (70.6)	45 (68.2)	27 (69.2)	53 (77.9)	53 (80.3)	30 (78.9)
ered**, (%)	25 (36.8)	24 (36.4)	15 (32.6)	39 (57.4)	35 (53.0)	21 (55.3)
step 0 - 10	5.0 (3.0)	5.0 (3.0)	4.0 (0.0)	3.0 (3.0)	4.0 (4.0)	3.0 (3.0)
step MID, N)***	38 (55.9)	39 (59.1)	23.0 (59.0)	48 (70.6)	43 (65.2)	28 (73.7)

*A patient was considered to have reached a minimal important improvement in FFI if their FFI total score at follow-up was at least 6.5 (the minimal important difference) lower than at baseline.

** A patient is defined as recovered if they answered 'the complaints have completely disappeared or they are strongly improved'.

*** A patient was considered to have reached a minimal important improvement in first step pain if their first step pain score follow-up was at least 1.9 (the minimal important difference) lower (improved) than at baseline.

Table 3	Linear regression analyses of factors associated with FFI total score at 26 weeks follow-up	
	Patients treated with insoles (custom + sham)	
	Univariate	Multivariate
Variables	Unstandardized β (95% CI)	Unstandardized β (95% CI)
Body Mass Index (kg/m^2)	1.25 (0.53, 1.98)*	0.69 (-0.05, 1.43)
Comorbidities (present)	-3.43 (-13.67, 6.81)	-3.86 (-13.87, 6.15)
Sex (female)	-0.38 (-9.05,8.29)	-9.59 (-17.87,-1.31)*
Age (years)	0.08 (-0.32, 0,47)	0.27 (-0.13, 0.67)
Bilateral pain (no)	-13.05 (-22.62, -3.47)*	-8.41 (-18.31, 1.50)
Neuropathic pain DN4 total score (0-10)	15.27 (6.75, 23.78)*	-0.21 (-2.34, 1.92)
Upper ankle joint dorsal range of motion (degrees)	-0.10 (-0.37, 0.16)	0.02 (-0.25, 0.28)
Metatarsal phalangeal joint dorsal range of motion (degrees)	0.06 (-0.13, 0,24)	0.08 (-0.08, 0.24)
Navicular drop (millimeter)	-4.73 (-14.74, 5.29)	-3.62 (-13.12, 5.87)
Activity score (SQUASH)	0.0 (0.00, 0.00)	0.00 (0.00, 0.00)
Treatment group (custom insole)	0.36 (-7.64, 8.35)	0.59 (-7.11, 8.30)
Baseline FFI total score (0 - 100)	0.63 (0.43, 0.84)*	0.56 (0.30, 0.82)*
Baseline first step pain (0 – 10)	2.04 (0.30, 3.78)*	-0.01 (-1.89, 1.70)
Duration of symptoms (months)	0.25 (-0.09, 0.59)	0.05 (-0.30, 0.40)
Foot posture index (supination)	0.05 (-13.45, 13.55)	-1.14 (-13.68, 11.39)
Foot posture index (pronation)	5.07 (-3.79, 13.93)	1.32 (-7.35, 10.00)

* p-value <0.05
In the patients treated with usual care only variables that gave a significant result in the patients treated with insoles were analyzed.

Table 4	Interaction between variables of interest and treatment with custom insoles compared to sham insoles for the total FFI score at 26-weeks follow-up	
Variables	Unstandardized β (95% CI)	Interpretation
Body Mass Index (kg/m^2)	0.49 (-1.00, 1.98)	Lower BMI gives better outcome in patients treated with custom insole *(non-significant)*
Neuropathic pain DN4 total score (0-10)	1.58 (-2.56, 5.73)	Lower score on the DN4 score for neuropathic pain gives better outcome in patients treated with custom insole *(non-significant)*
Bilateral pain (yes)	-2.16 (-21.49, 17.16)	Presence of bilateral pain gives better outcome in patients treated with custom insole *(non-significant)*
Sex (male)	-12.10 (-29.46, 5.25)	Male sex gives better outcome in patients treated with custom insole *(non-significant)*
FFI score at baseline	0.02 (-0.39, 0.43)	Lower FFI score at baseline gives better outcome in patients treated with custom insole *(non-significant)*
First step pain at baseline	0.47 (-3.07, 4.01)	Lower pain score for first step pain at baseline gives better outcome in patients treated with custom insole *(non-significant)*
Variables were multiplied with a factor indicating treatment (custom insole vs sham)		

Figures

Image not available with this version

Figure 1

Figure is not available in this version.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Appendix1.docx