OPEN ACCESS

Does a corticosteroid injection plus exercise or exercise alone add to the effect of patient advice and a heel cup for patients with plantar fasciopathy? A randomised clinical trial

Henrik Riel ,[1] Bill Vicenzino ,[2] Jens Lykkegaard Olesen,[1] Martin Bach Jensen,[1] Lars Holger Ehlers,[3] Michael Skovdal Rathleff [1,4,5]

► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/bjsports-2023-106948).

[1]Center for General Practice at Aalborg University, Aalborg University, Aalborg, Denmark
[2]The University of Queensland School of Health and Rehabilitation Sciences: Physiotherapy: Sports Injury Rehabilitation and Prevention for Health, The University of Queensland, Brisbane, Queensland, Australia
[3]Nordic Institute of Health Economics, Aarhus, Denmark
[4]Department of Health Science and Technology, Aalborg University, Aalborg, Denmark
[5]Department of Occupational Therapy and Physiotherapy, Aalborg University Hospital, Aalborg, Denmark

Correspondence to
Henrik Riel, Center for General Practice at Aalborg University, Aalborg 9220, Denmark; hriel@dcm.aau.dk

Accepted 20 June 2023
Published Online First 6 July 2023

To cite: Riel H, Vicenzino B, Olesen JL, *et al*. *Br J Sports Med* 2023;**57**:1180–1186.

ABSTRACT

Objective To compare the effectiveness of patient advice plus heel cup alone (PA) versus PA and lower limb exercise (PAX) versus PAX plus corticosteroid injection (PAXI) to improve self-reported pain in patients with plantar fasciopathy.

Methods We recruited 180 adults with plantar fasciopathy confirmed by ultrasonography for this prospectively registered three-armed, randomised, single-blinded superiority trial. Patients were randomly allocated to PA (n=62), PA plus self-dosed lower limb heavy–slow resistance training consisting of heel raises (PAX) (n=59), or PAX plus an ultrasound-guided injection of 1 mL triamcinolone 20 mg/mL (PAXI) (n=59). The primary outcome was changed in the pain domain of the Foot Health Status Questionnaire (ranging from 0 'worst' to 100 'best') from baseline to the 12-week follow-up. The minimal important difference in the pain domain is 14.1 points. The outcome was collected at baseline and at 4, 12, 26, and 52 weeks.

Results The primary analysis found a statistically significant difference between PA and PAXI after 12 weeks favouring PAXI (adjusted mean difference: −9.1 (95% CI −16.8 to −1.3; p=0.023)) and over 52 weeks (adjusted mean difference: −5.2 (95% CI −10.4 to −0.1; p=0.045)). At no follow-up did the mean difference between groups exceed the pre-specified minimal important difference. No statistically significant difference was found between PAX and PAXI or between PA and PAX at any time.

Conclusion No clinically relevant between-group differences were found after 12 weeks. The results indicate that combining a corticosteroid injection with exercise is not superior to exercise or no exercise.

Trial registration number NCT03804008.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ In clinical practice, several treatment approaches for plantar fasciopathy such as advice on physical activity, foot exercises, insoles or injections are used with no strong evidence to support the use of one treatment over another.

⇒ A corticosteroid injection as monotherapy offers short-term pain relief but is not superior compared with a placebo injection in the longer term (>8 weeks).

WHAT THIS STUDY ADDS

⇒ Combining patient advice, heel cups, exercise and a corticosteroid injection is not associated with superior outcomes compared with patient advice, heel cups and exercise, or patient advice and heel cups alone.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The findings do not support that treatments beyond simple advice on staying active, minimising pain-aggravating activities and the use of heel cups are needed initially for patients with plantar fasciopathy.

INTRODUCTION

Plantar fasciopathy (PF) is the most common musculoskeletal disorder in the foot, and in a general practice clinic with 10 000 patients, between 24 and 65 patients will present with PF each year.[1–4] Historically, the condition has been considered partially self-limiting. Yet, studies investigating treatment modalities such as stretching, mobilisation or electrophysical agents have found treatment success in as few as 48% of participants after 6 months, and 40% still had symptoms after 2 years.[5–8]

A systematic review and network meta-analysis investigated the effectiveness of different commonly used treatments for PF.[9] They could not draw firm conclusions about which treatments were the most effective. Nevertheless, corticosteroid injection and shockwave were most likely to be effective in the short term.[9] One treatment not included in the review was heavy–slow resistance training (HSR). Preliminary evidence of HSR indicates superiority to plantar fascia-specific stretching, but HSR often takes several weeks of regular exercise before patients experience pain relief.[10 11] Combining an ultrasound-guided corticosteroid injection with HSR could provide patients with superior pain reduction on both a short and long-term basis. We recently found this combination feasible.[12] The current evidence for HSR in this patient population is based on a single randomised trial. This highlights the need for larger trials to compare HSR with and without a corticosteroid injection with relatively pragmatic and simple approaches commonly used

in general practice, such as wearing insoles or advice on staying active but decreasing pain-aggravating activities.[3 10–12]

This trial aimed to compare the effectiveness of patient advice plus heel cup (PA) versus patient advice and heel cup plus HSR (PAX) versus patient advice and heel cup plus HSR plus a corticosteroid injection (PAXI) in improving the Foot Health Status Questionnaire (FHSQ) pain score after 12 weeks in patients with PF. We hypothesised that PAXI would be superior to both PA and PAX and that PAX would be superior to PA.

METHODS

Design

This randomised, single-blinded superiority trial with a three-group parallel design was prospectively registered on clinicaltrials.gov, and the trial protocol was published before the inclusion of the final participant.[13] The trial reporting follows the Consolidated Standards of Reporting Trials guidelines, TIDieR and the CHAMP statement.[14–16]

Participants

Individuals with PF were recruited from general practices of the North Denmark Region or via Facebook. The inclusion criteria were inferior heel pain ≥3 months, pain on palpation of the medial calcaneal tubercle or the proximal plantar fascia, plantar fascia thickness ≥4.0 mm measured using ultrasonography,[17] and mean heel pain of ≥30 mm on a 100 mm Visual Analogue Scale (VAS) during the previous week. Exclusion criteria were below 18 years of age; diabetes; history of inflammatory systemic diseases (eg, rheumatoid arthritis or spondyloarthritis)[18]; prior heel surgery; pregnancy or breastfeeding; corticosteroid injection specifically for PF within the previous 6 months; pain or stiffness in the first metatarsophalangeal joint to an extent where the exercises cannot be performed; known hypersensitivity to corticosteroids or local anaesthetics; skin or soft tissue infection near the injection site; received any treatment by a healthcare professional for PF within the previous 12 weeks or made any substantial changes to usual self-care of the condition in the last 4 weeks (eg, started using insoles, started performing stretching, made a substantial decrease in physical activity level). These criteria are in line with those of similar studies in this patient population.[11 18 19]

Randomisation

Potential participants underwent a telephone screening and a clinical examination by one of three project physiotherapists at Aalborg University Hospital. After baseline assessment, they were randomised, in concealed block sizes of 3 to 12 (1:1:1), into three parallel groups to receive either (1) patient advice and a heel cup (PA), (2) patient advice, a heel cup and HSR (PAX) or (3) patient advice, a heel cup, HSR and ultrasound-guided corticosteroid injection (PAXI). Randomisation was stratified by sex as men may respond better to treatment, and based on our previous studies, more than 80% of the included patients would be women.[8 11 12] The randomisation schedule was prepared at the Center for General Practice at Aalborg University by an independent researcher who generated the allocation sequence using a random number generator on www.sealedenvelope.com. The researcher placed notes revealing the randomisation in concealed envelopes at the study site. The allocation sequence and the coding of the groups were kept in a cabinet locked by a secretary.

Interventions

The patient advice consisted of both oral information and a leaflet. It was developed as a triangulation of interviews with patients and general practitioners, recommendations from clinical guidelines and a systematic review.[6 20 21] It included information about pathology, risk factors and load management.[13] Patients were asked not to seek other treatments during the trial. They were allowed to self-manage their pain if they had been doing this for at least 4 weeks before inclusion, but they were not encouraged to do so and recorded any self-treatment in a project diary. Patients were given a silicone heel cup (Medi-Dyne Healthcare Products, Colleyville, Texas) that they were advised to use whenever wearing shoes. If patients already used foot orthoses that they preferred over the heel cup, they were allowed to continue wearing these.

The HSR performed by the patients in both PAX and PAXI was a heel raise exercise standing with the forefoot on a step or a book with a rolled-up towel underneath the toes, as per Rathleff *et al*.[1010] The exercise was performed with a load as heavy as possible but no heavier than a load corresponding to 8 repetition maximum (RM) and with as many sets as possible, separated by 2 min pauses between sets.[11] If performing the exercise bilaterally was insufficient to achieve an 8RM, they were instructed to perform the exercise single limbed or by adding a load such as a backpack with books, weights or water bottles. Pain considered tolerable by the patient during exercise was allowed. The patients were asked to perform the exercise every other day until they reached a self-evaluated satisfactory result and then for an additional 4 weeks. They were instructed on how to perform the exercise by one of the physiotherapists just after randomisation and performed the exercises unsupervised throughout the trial. In PAXI, the patients were not allowed to add load to achieve an 8RM until the third week after the injection.

Patients in PAXI received an ultrasound-guided corticosteroid injection by an experienced rheumatologist at a private rheumatology clinic, preferably within 8 days but no later than 14 days after baseline. The injection consisted of 1 mL triamcinolone, 20 mg/mL (Trica, Evolan Pharma) and 1 mL lidocaine, 10 mg/mL (Xylocaine, AstraZeneca). The needle was inserted with a medial approach. The injection was distributed deep and superficially on the plantar fascia surface anterior to the insertion on the calcaneal bone in the region of maximal fascia thickness. The rheumatologist chose to distribute the injection both deep and superficially on the plantar fascia surface based on clinical experience and because there is no consensus on the best place to inject. All interventions are described in detail in the protocol.[13]

Outcome measures

Outcomes were assessed during baseline and at 4, 12, 26 and 52 weeks. Patients attended baseline and the 12-week follow-up at the hospital. In contrast, an e-mail with a link to questionnaires was sent by REDCap (Vanderbilt University, Nashville, Tennessee) for the other follow-ups.

Primary outcome and endpoint

The primary outcome was the pain domain of the FHSQ, ranging from 0 (worst possible score) to 100 (best possible score) at the 12-week follow-up to reflect patients' primary complaint of pain.[22–24] This questionnaire has been used as the primary outcome in several trials of patients with PF.[18 25–27] The minimal important difference of the pain domain is 14.1 points.[28] The primary endpoint was changed from baseline to the 12-week follow-up.

Riel H, *et al*. *Br J Sports Med* 2023;**57**:1180–1186. doi:10.1136/bjsports-2023-106948

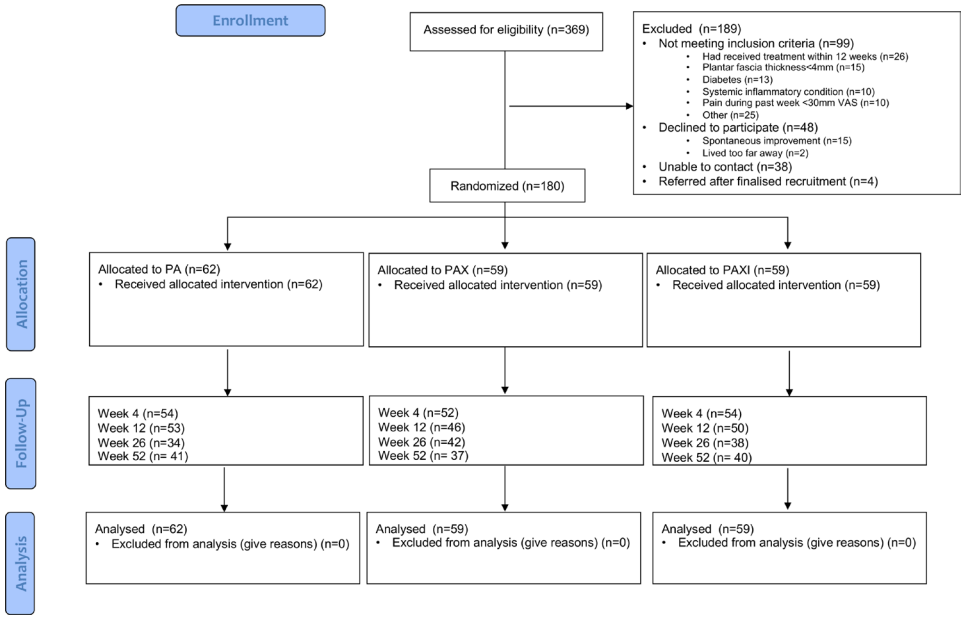

Figure 1 Flowchart of patients throughout the trial. HSR, heavy–slow resistance training; PA, patient advice plus heel cup; PAX, PA plus HSR; PAXI, PAX plus a corticosteroid injection; VAS, Visual Analogue Scale.

Secondary outcomes

Secondary outcomes were: (1) the other domains of the FHSQ (function, footwear and general foot health domains), (2) a dichotomised Global Rating of Change (GROC) to measure patients' self-reported improvement on a 7-point rank scale ranging from 'much improved' to 'much worse'. Patients were dichotomised as improved if they rated themselves as 'much improved' or 'improved' (categories 6 and 7) and categorised as not improved if they rated themselves from 'slightly improved' to 'much worse' (categories 1 to 5), (3) a dichotomised Patient Acceptable Symptom State (PASS) (yes/no) used as a measure of when patients achieved a self-evaluated satisfactory result and felt no need for further treatment, (4) the Pain Self-Efficacy Questionnaire (PSEQ) as a measure of pain self-efficacy ranging from 0 (worst) to 60 (best),[29] (5) number of training sessions performed by PAX and PAXI during the first 12 weeks and (6) the proportion of time spent sedentary and performing light, moderate, vigorous and very vigorous activities during the first valid week from weeks 1 to 3 and from weeks 13 to 15 measured by 3D accelerometry (ActiGraph wGT3X-BT (ActiGraph LLC, Pensacola, Florida)). A valid week was ≥4 days of ≥10 hours daily wear time.[13 30]

Sample size calculation

We used the software G*Power 3 (Faul, Erdfelder, Lang and Buchner, Germany) to calculate the sample size. The trial was powered to detect the minimal important difference in FHSQ pain (14.1 points). Based on an SD of 22 points,[18 26 31 32] a two-sided 5% significance level and a power of 90%, 53 participants in each group were necessary. To account for dropouts, we included 60 participants in each group.

Statistical analyses

The primary investigator, blinded to group allocation, performed the statistical analyses according to a statistical analysis plan developed in collaboration with a statistician and a biostatistician and published before the final 12-week follow-up.[33] All authors remained blinded until after the primary analysis after the 12-week follow-up had been made and the conclusions had been decided on. The analyses were conducted on 22 December 2020, and all authors made an agreement on the conclusion on 11 January 2021.

The statistical analyses were performed on an intention-to-treat basis using SPSS (IBM Corporation, New York). Q-Q plots and histograms were used to assess data normality. The primary analysis was a linear mixed effects model to test between-group differences in FHSQ pain with the participant as random effect. The baseline value, time (4, 12, 26 and 52 weeks), group allocation (PA, PAX or PAXI) and term for interaction between time and group were treated as fixed effect variables. Conclusions would only be drawn based on the primary endpoint (12 weeks). The same model was applied to investigate the other domains of the FHSQ and the PSEQ. The between-group risk of being improved according to GROC and the between-group risk of achieving PASS were calculated as risk differences. The number needed to treat (NNT) was calculated as 1/risk difference. Defined as a decrease in FHSQ pain ≥14.1 points from one follow-up to another or changing one's status from having achieved PASS to no longer having achieved PASS, a deterioration of symptoms is presented with frequencies from each group. Differences in number of training sessions performed between PAX and PAXI were explored using an unpaired t-test. Furthermore, Pearson's correlation coefficient was used to explore an association between the number of training sessions performed and change in FHSQ pain. The proportions of sedentary time and time spent performing activities of different intensities are presented descriptively.

Patient and public involvement

The patient advice used was based on the results of semistructured interviews with both patients and general practitioners. To include patients in the interpretation of the results, one woman and one man from each group were randomly selected and interviewed via single-person semistructured interviews after the trial. We presented the results of FHSQ pain, GROC and PASS after 12 weeks first and asked them how they evaluated the results,

Table 1 Baseline characteristics of patients presented by group

	PA, n=62	PAX, n=59	PAXI, n=59
Age year, mean (SD)	50.4 (10.2)	48.8 (11.3)	46.2 (11.6)
Sex, n (%) female	44 (71.0)	42 (71.2)	42 (71.2)
Height cm, mean (SD)	171.9 (8.5)	172.6 (8.3)	173.2 (8.5)
Mass kg, mean (SD)	89.8 (16.0)	88.1 (18.3)	87.8 (19.9)
Body mass index kg/m^2, mean (SD)	30.4 (5.2)	29.4 (5.2)	29.2 (6.0)
Symptom duration months, median (IQR)	7 (5–18)	7 (5–12)	6 (5–14)
Pain during past week/100, mean (SD)	65.6 (17.2)	61.7 (18.4)	68.1 (17.3)
Bilateral pain, n (%)	20 (32)	14 (24)	17 (29)
Plantar fascia thickness mm, mean (SD)	5.5 (1.2)	5.6 (1.1)	5.5 (1.2)
Comorbidities, n (%)	15 (24)	13 (22)	23 (39)
Educational level, n (%)			
No vocational education	1 (1.6)	4 (6.8)	10 (17.0)
One or more courses	1 (1.6)	2 (3.4)	3 (5.1)
Vocational education <1 year	2 (3.2)	0 (0.0)	0 (0.0)
Vocational education >1 year	33 (53.2)	34 (57.6)	28 (47.5)
Short further education 2–3 years	6 (9.7)	1 (1.7)	2 (3.4)
Medium length further education 3–4 years	13 (21.0)	18 (30.5)	11 (18.6)
Long further education >4 years	6 (9.7)	0 (0.0)	5 (8.5)
In the workforce, n (%)	47 (75.8)	53 (89.8)	49 (83.1)
Care-seeking behaviour, n (%)			
General practitioner	43 (69.4)	37 (62.7)	43 (72.9)
Physiotherapist	11 (17.7)	4 (6.8)	7 (11.9)
Medical specialist	10 (16.1)	6 (10.2)	5 (8.5)
Other	5 (8.1)	6 (10.2)	11 (18.6)
None	15 (24.2)	21 (35.6)	14 (23.7)
Previous treatment, n (%)			
No previous treatment	35 (56.5)	27 (45.8)	34 (57.6)
Foot orthoses	15 (24.2)	17 (28.8)	13 (22.0)
Exercise therapy	14 (22.6)	16 (27.1)	7 (11.9)
Electrophysical agents	13 (21.0)	9 (15.3)	7 (11.9)
Corticosteroid injection	6 (9.7)	3 (5.1)	4 (6.8)
Acupuncture	4 (6.5)	4 (6.8)	7 (11.9)
Stretching	4 (6.5)	3 (5.1	2 (3.4)
Other, for example, manual therapy, medication or tape	15 (24.2)	10 (17.0)	7 (11.9)

HSR, heavy–slow resistance training; PA, patient advice plus heel cup; PAX, PA plus HSR; PAXI, PAX plus a corticosteroid injection.

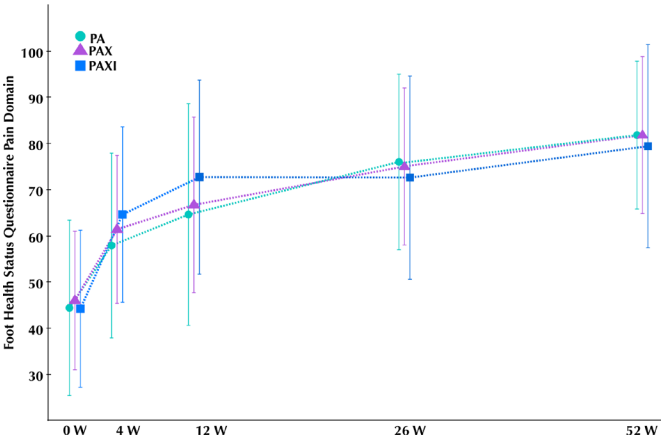

Figure 2 Foot Health Status Questionnaire Pain Domain scores at baseline and at each follow-up. Symbols present means, and error bars are SD. HSR, heavy–slow resistance training; PA, patient advice plus heel cup; PAX, PA plus HSR; PAXI, PAX plus a corticosteroid injection.

which general treatment they would recommend to a friend, and to which group they would have preferred being randomised. After this, we presented the results after 26 and 52 weeks and asked them if that would change their recommendation to others or their own preferred treatment.

Equity, diversity, and inclusion statement

The author group consists of men from different disciplines, career stages (junior and senior) and countries (Denmark and Australia). We included all eligible patients regardless of sex, race/ethnicity/culture or socioeconomic level. We did not take sex, race or socioeconomic level into account in the analyses; however, the socioeconomic level will be included in our future cost-effectiveness analyses.

Protocol deviations

(1) The analyses regarding exercise compliance were not initially planned but described in the Statistical Analysis Plan.[33] (2) To perform meaningful analyses of exercise compliance, patients who had achieved PASS were excluded from these as they were

Table 2 Outcomes and between-group comparisons

Time point	PA	PAX	PAXI	PA vs PAX	PA vs PAXI	PAX vs PAXI
Week	Mean (SD)			Adjusted mean difference (95% CI)		
FHSQ Pain (0–100)						
0	44.4 (19.0)	46.0 (15.2)	44.2 (17.4)			
4	57.9 (20.3)	61.4 (16.2)	64.6 (19.3)	−3.6 (−9.8 to 2.6)	−8.5 (−14.6 to −2.4)*	−4.9 (−11.1 to 1.3)
12	64.6 (23.8)	66.7 (19.0)	72.7 (20.7)	−2.0 (−9.9 to 5.9)	−9.1 (−16.8 to −1.3)*	−7.1 (−15.2 to 1.0)
26	76.0 (19.2)	75.1 (17.1)	72.6 (22.0)	0.9 (−7.9 to 9.8)	2.7 (−6.4 to 11.8)	1.8 (−6.8 to 10.4)
52	81.8 (16.2)	81.8 (16.5)	79.4 (21.8)	−0.3 (−8.4 to 7.9)	1.6 (−6.4 to 9.7)	1.9 (−6.4 to 10.2)
Overall				−2.4 (−7.6 to 2.8)	−5.2 (−10.4 to −0.1)*	−2.9 (−8.1 to 2.4)
FHSQ Function (0–100)						
0	60.3 (19.4)	60.0 (18.0)	56.9 (23.6)			
4	68.9 (20.0)	71.6 (17.5)	70.4 (20.7)	−3.0 (−9.2 to 3.3)	−5.2 (−11.4 to 1.1)	−2.2 (−8.5 to 4.1)
12	75.4 (19.5)	79.6 (18.0)	82.9 (20.5)	−4.9 (−11.9 to 2.0)	−9.7 (−16.6 to −2.8)*	−4.7 (−11.8 to 2.4)
26	81.4 (19.9)	85.6 (19.8)	80.3 (21.6)	−4.6 (−13.5 to 4.4)	−1.1 (−10.4 to 8.2)	3.4 (−5.4 to 12.2)
52	91.2 (12.3)	90.7 (14.3)	84.8 (22.8)	0.6 (−7.0 to 8.3)	6.0 (−1.5 to 13.5)	5.4 (−2.4 to 13.2)
Overall				−1.1 (−7.0 to 4.9)	1.0 (−4.9 to 6.9)	2.1 (−3.9 to 8.1)
FHSQ Footwear (0–100)						
0	39.9 (19.6)	39.1 (20.0)	37.4 (23.1)			
4	47.7 (23.8)	46.3 (24.2)	42.4 (26.9)	4.4 (−3.4 to 12.1)	2.3 (−5.4 to 9.9)	−2.1 (−9.9 to 5.7)
12	51.7 (26.2)	51.1 (25.3)	49.8 (28.8)	1.1 (−8.1 to 10.4)	−1.2 (−10.4 to 7.9)	−2.3 (−11.8 to 7.2)
26	57.4 (30.4)	50.2 (25.5)	48.7 (32.0)	6.1 (−5.0 to 17.2)	3.9 (−7.6 to 15.3)	−2.2 (−13.1 to 8.6)
52	52.6 (29.3)	58.8 (29.5)	52.3 (29.9)	−5.2 (−17.1 to 6.8)	−2.2 (−14.0 to 9.6)	3.0 (−9.2 to 15.1)
Overall				2.6 (−6.1 to 11.3)	3.3 (−5.3 to 11.9)	0.7 (−8.1 to 9.4)
FHSQ General Foot Health (0–100)						
0	49.0 (26.4)	45.0 (28.8)	46.4 (26.8)			
4	50.4 (28.3)	46.3 (24.9)	50.9 (25.6)	2.4 (−5.6 to 10.4)	−2.2 (−10.0 to 5.8)	−4.6 (−12.6 to 3.4)
12	55.5 (26.6)	56.1 (27.0)	59.2 (27.5)	−2.6 (−12.1 to 6.8)	−4.9 (−14.2 to 4.4)	−2.2 (−11.9 to 7.4)
26	55.7 (35.2)	58.3 (28.2)	59.5 (23.5)	−1.8 (−14.4 to 10.8)	−3.3 (−16.2 to 9.5)	−1.5 (−13.7 to 10.7)
52	60.5 (28.7)	67.9 (26.5)	56.6 (30.1)	−7.0 (−18.7 to 4.8)	1.3 (−10.2 to 12.9)	8.3 (−3.7 to 20.2)
Overall				0.4 (−8.1 to 9.0)	−0.5 (−8.9 to 8.0)	−0.9 (−9.5 to 7.7)
PSEQ (0–60)						
0	41.1 (11.0)	39.3 (12.1)	39.2 (11.2)			
4	44.9 (13.3)	45.8 (10.4)	44.5 (11.8)	−3.4 (−7.0 to 0.2)	−3.1 (−6.6 to 0.5)	0.3 (−3.3 to 3.9)
12	46.6 (12.7)	49.1 (10.4)	49.9 (11.7)	−3.0 (−7.0 to 1.0)	−5.0 (−9.0 to −1.0)*	−1.9 (−6.0 to 2.2)
26	48.8 (13.3)	51.3 (10.5)	49.9 (13.5)	−2.4 (−7.8 to 3.0)	−1.8 (−7.3 to 3.7)	0.6 (−4.7 to 5.8)
52	54.2 (8.4)	54.8 (8.9)	51.0 (13.2)	0.2 (−4.7 to 4.3)	2.1 (−2.4 to 6.5)	2.3 (−2.3 to 6.8)
Overall				−1.6 (−5.3 to 2.1)	0.1 (−3.7 to 3.5)	1.5 (−2.2 to 5.2)

*Denotes statistical significance (p<0.05).
FHSQ, Foot Health Status Questionnaire; HSR, heavy–slow resistance training; PA, patient advice plus heel cup; PAX, PA plus HSR; PAXI, PAX plus a corticosteroid injection; PSEQ, Pain Self-Efficacy Questionnaire.

allowed to stop performing exercises 4 weeks after achieving PASS. (3) Physical activity levels expressed as weekly metabolic equivalent would not allow us to explore the proportion of time spent at various intensities. Therefore, instead, we present time spent at various intensities. (4) Due to the COVID-19 restrictions, no inclusions were made between 11 March 2020 and 24 April 2020, and 12-week follow-ups were conducted electronically during this period. (5) Outcomes for the cost-effectiveness analysis will be published separately as well as the cohort of potential participants not meeting the eligibility criteria.[13]

RESULTS

Enrolment and follow-up

Of 369 individuals, 180 patients were included from February 2019 to September 2020 (figure 1). The final 12-week follow-up was conducted in December 2020, and the last 52-week follow-up was completed in September 2021. Of the 106 patients recruited from Facebook, 50 (47%) had seen their general practitioner. Baseline characteristics are displayed in table 1. One patient in PAX reported an adverse event, which did not happen in connection with the interventions. Concomitant treatments recorded are found in online supplemental file 1.

Primary outcome

The primary analysis revealed a statistically significant difference in FHSQ pain between PA and PAXI (adjusted mean difference: −9.1 (95% CI −16.8 to −1.3; p=0.023)) favouring PAXI after 12 weeks, but no significant difference was found between PAX and PAXI (adjusted mean difference: −7.1 (95% CI −15.2 to 1.0; p=0.084)) or between PA and PAX (adjusted mean difference: −2.0 (95% CI −9.9 to 5.9; p=0.625)) (figure 2). Over 52 weeks, a statistically significant difference was detected between PA and PAXI (adjusted mean difference: −5.2 (95% CI −10.4 to −0.1; p=0.045)). No difference was found between PAX and PAXI (adjusted mean difference: −2.9 (95% CI −8.1 to 2.4; p=0.279)) or between PA and PAX (adjusted mean difference:

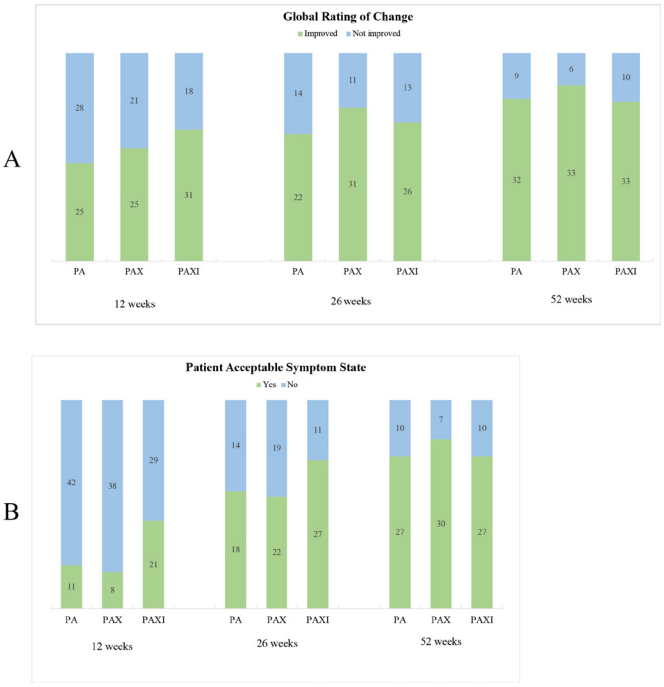

Figure 3 (A) The number of patients who were either improved or not improved according to the dichotomised Global Rating of Change. (B) The number of patients who achieved the Patient Acceptable Symptom State. HSR, heavy–slow resistance training; PA, patient advice plus heel cup; PAX, PA plus HSR; PAXI, PAX plus a corticosteroid injection.

−2.4 (95% CI −7.6 to 2.8; p=0.370)). The mean difference between PAXI and PA did not exceed the minimal important difference at any time (table 2).

Secondary outcomes

After 12 weeks, a statistically significant difference was found between PA and PAXI in the FHSQ function domain (adjusted mean difference: −9.7 (95% CI −16.6 to −2.8; p=0.006) and in the PSEQ (adjusted mean difference: −5.0 (95% CI −9.0 to −1.0; p=0.016), but no other statistically significant differences were found in the FHSQ or the PSEQ (table 2). The risk difference in GROC between PAX and PA was 0.01 (NNT=13.9, 95% CI −3.7 to 8.0), between PAXI and PA was 0.16 (NNT=6.2, 95% CI −33.5 to 2.8), and between PAXI and PAX was 0.09 (NNT=11.2, 95% CI −9.3 to 3.5) (figure 3A). PASS was achieved within the 12-week follow-up by 11 in PA, 8 in PAX and 21 patients in PAXI (figure 3B). The risk difference between PA and PAX was 0.03 (NNT=29.7, 95% CI −8.2 to 5.3), the risk difference between PAXI and PA was 0.21 (NNT=4.7, 95% CI 2.6 to 26.0) and the risk difference between PAXI and PAX was 0.25 (NNT=4.1, 95% CI 2.4 to 14.5). Patients in PAX performed 30.9 (±12.4) training sessions (74% of prescribed sessions), and patients in PAXI performed 29.9 (±10.4) training sessions (71% of prescribed sessions). No difference was detected between groups (mean difference: 1.0 sessions, 95% CI −5.9 to 7.8; p=0.779), and no association was found between the number of training sessions performed and change in FHSQ pain (r=−0.044; p=0.770). Physical activity levels and deteriorations are presented in online supplemental file 1.

Patients highlighted that the treatment choice was not important when the long-term results were the same. Complete patient interpretation is available in online supplemental file 2.

DISCUSSION

As hypothesised, a statistically significant difference was present between PAXI and PA in FHSQ pain. However, the mean between-group difference was less than the minimal important difference, which questions the clinical relevance. No other statistically significant differences in FHSQ pain were found; thus, performing HSR was no better than not performing HSR. Nor was it better to receive a corticosteroid injection and perform HSR compared with just HSR.

This was the first trial to investigate the effect of HSR versus HSR and corticosteroid injection. Johannsen *et al* have previously compared the effect of strength training plus stretching against either a corticosteroid injection alone or a combination of the two.[34] They concluded that the combination was superior to the other two groups. In contrast, PAXI was not superior to PAX, however; we used a single injection, whereas Johannsen *et al* used repeated injections. Repeated injections may add to the effect of the treatment, but every additional injection may also give an additional placebo effect, and repeated corticosteroid injections have yet to be compared with repeated placebo injections for PF.[35] It has been suggested that repeated injections may increase the risk of plantar fascia rupture as corticosteroid may affect the mechanical properties of collagen tissue, although this has not been demonstrated in a randomised trial.[34 36 37] Studies using an injection in isolation find a significant short-term improvement within 6–8 weeks with no further long-term improvements.[18 38–40] In our trial, PAXI kept improving from 4 to 12 weeks. This suggests that HSR may add to the effect of an injection.

Clinical implications

Despite the positive preliminary benefits of HSR,[10] the results of this trial do not support this as PAX was not superior to PA.[10] Although more patients in PAX achieved PASS compared with patients in our most recent trial about HSR (8/59 and 4/70, respectively), HSR in PF remains questionable.[11]

The statistically significant difference between PAXI and PA may result from the combined placebo effects of HSR and the injection.[35] Even though the difference between the two groups was statistically significant, the difference did not exceed the minimal important difference of 14.1 points.[28] A less conservative minimally important difference of FHSQ pain was calculated to be 12.5 points. Yet, this was still more than the between-group difference of 9.1 points which we found in our study.[41] One thing to consider is that the minimally important difference was calculated in a different setting and among Australians using GROC that asks participants to rate improvement compared with the start of the treatment coupled with the FHSQ that asks participants about their current symptoms. The use of GROC has been criticised for introducing recall bias. However, there is no consensus on how to best calculate a minimally important difference.[42] Although the difference between PAXI and PA not being clinically important, patients of PAXI were two times as likely to achieve PASS than patients of PA and PAX within 12 weeks with an NNT of 4.7 and 4.1, respectively, and the minimal important difference was within the 95% CI of the between-group difference. Therefore, there might be a benefit of combining an injection with HSR if patients are seeking improvement in the short term. Nevertheless, any differences diminished over time which

Riel H, *et al*. *Br J Sports Med* 2023;**57**:1180–1186. doi:10.1136/bjsports-2023-106948

should be considered in the shared decision-making process with patients.

Limitations

Due to the nature of the interventions, blinding the patients was impossible, and the patients likely perceived that recovery would be better in the groups receiving more. Almost half of the patients had experienced treatments before inclusion, and some were similar to those studied in this study. These participants may be non-responders to the trial interventions, and, thus, the overall change in outcomes observed is likely underestimated. Notwithstanding this, the frequency of these treatments was allocated similarly across groups, so their effect on between-group comparisons was minimised. Furthermore, approximately one-third of the patients did not respond to the questionnaires after 26 and 52 weeks which hampers the power of the long-term results.

CONCLUSIONS

In conclusion, all three groups had clinically meaningful improvements in the primary outcome after 12 weeks. Yet, no clinically relevant differences were found between the three treatment approaches, indicating no additional effect of exercises or injections compared with simple advice and a heel cup.

Twitter Henrik Riel @Henrik_Riel and Bill Vicenzino @Bill_Vicenzino

Contributors HR, BV, JLO, MBJ and MSR conceived the trial and developed the protocol. HR, BV, JLO, MBJ and MSR formed the steering committee with HR as chair of the committee. HR was the project manager, handled recruitment, and performed data analyses. LHE conceived the aspects of a cost-effectiveness analysis. All authors interpreted the results and read and approved the final version of this manuscript. HR acts as guarantor and takes responsibility for the integrity of the data and the accuracy of the data analysis. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Funding The trial is funded by the Independent Research Fund Denmark, the Danish General Practice Foundation, the Foundation for Professional Development in Specialty Doctoral Practices, and the Danish Committee of Multipractice Studies in General Practice.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by The Ethics Committee of North Denmark Region (N-20180066). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. The statistical analysis plan is freely available here: https://vbn.aau.dk/da/publications/statistical-analysis-plan-for-corticosteroid-injection-plus-exerc. Data will be available upon reasonable request.

ORCID iDs
Henrik Riel http://orcid.org/0000-0003-4575-6293
Bill Vicenzino http://orcid.org/0000-0003-0253-5933
Michael Skovdal Rathleff http://orcid.org/0000-0003-1173-0335

REFERENCES

1 Riel H, Lindstrøm CF, Rathleff MS, *et al*. Prevalence and incidence rate of lower-extremity tendinopathies in a Danish general practice: a registry-based study. *BMC Musculoskelet Disord* 2019;20:239.
2 Albers IS, Zwerver J, Diercks RL, *et al*. Incidence and prevalence of lower extremity tendinopathy in a Dutch general practice population: a cross sectional study. *BMC Musculoskelet Disord* 2016;17:16.
3 Rasenberg N, Bierma-Zeinstra SM, Bindels PJ, *et al*. Incidence, prevalence, and management of plantar heel pain: a retrospective cohort study in Dutch primary care. *Br J Gen Pract* 2019;69:e801–8.
4 Riel H, Cotchett M, Delahunt E, *et al*. Is "Plantar heel pain" a more appropriate term than "Plantar Fasciitis"? time to move on. *Br J Sports Med* 2017;51:1576–7.
5 Digiovanni BF, Nawoczenski DA, Malay DP, *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;88:1775–81.
6 Landorf KB. Plantar heel pain and plantar fasciitis. *BMJ Clin Evid* 2015;2015:1111.
7 Buchbinder R. Plantar fasciitis. *N Engl J Med* 2004;350:2159–66.
8 McClinton SM, Cleland JA, Flynn TW. Predictors of response to physical therapy intervention for plantar heel pain. *Foot Ankle Int* 2015;36:408–16.
9 Babatunde OO, Legha A, Littlewood C, *et al*. Comparative effectiveness of treatment options for plantar heel pain: a systematic review with network meta-analysis. *Br J Sports Med* 2019;53:182–94.
10 Rathleff MS, Mølgaard CM, Fredberg U, *et al*. High-load strength training improves outcome in patients with plantar fasciitis: a randomized controlled trial with 12-month follow-up. *Scand J Med Sci Sports* 2015;25:e292–300.
11 Riel H, Jensen MB, Olesen JL, *et al*. Self-dosed and pre-determined progressive heavy-slow resistance training have similar effects in people with plantar fasciopathy: a randomised trial. *J Physiother* 2019;65:144–51.
12 Riel H, Olesen JL, Jensen MB, *et al*. Heavy-slow resistance training in addition to an ultrasound-guided corticosteroid injection for individuals with plantar fasciopathy: a feasibility study. *Pilot Feasibility Stud* 2019;5:105.
13 Riel H, Vicenzino B, Olesen JL, *et al*. Corticosteroid injection plus exercise versus exercise, beyond advice and a heel cup for patients with plantar fasciopathy: protocol for a randomised clinical superiority trial (the FIX-heel trial). *Trials* 2020;21:5.
14 Eldridge SM, Chan CL, Campbell MJ, *et al*. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ* 2016;355:i5239.
15 Hoffmann TC, Glasziou PP, Boutron I, *et al*. Better reporting of interventions: template for intervention description and replication (Tidier) checklist and guide. *BMJ* 2014;348:g1687.
16 Mansournia MA, Collins GS, Nielsen RO, *et al*. A checklist for statistical assessment of medical papers (the CHAMP statement): explanation and elaboration. *Br J Sports Med* 2021;55:1009–17.
17 McMillan AM, Landorf KB, Barrett JT, *et al*. Diagnostic imaging for chronic plantar heel pain: a systematic review and meta-analysis. *J Foot Ankle Res* 2009;2:32.
18 McMillan AM, Landorf KB, Gilheany MF, *et al*. Ultrasound guided corticosteroid injection for plantar fasciitis: randomised controlled trial. *BMJ* 2012;344:e3260.
19 Riel H, Vicenzino B, Jensen MB, *et al*. The effect of Isometric exercise on pain in individuals with plantar fasciopathy: a randomized crossover trial. *Scand J Med Sci Sports* 2018;28:2643–50.
20 Martin RL, Davenport TE, Reischl SF, *et al*. Heel pain—plantar fasciitis: revision 2014. *J Orthop Sports Phys Ther* 2014;44:A1–33.
21 van Leeuwen KDB, Rogers J, Winzenberg T, *et al*. 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;50:972–81.
22 Bennett PJ, Patterson C, Wearing S, *et al*. Development and validation of a questionnaire designed to measure foot-health status. *J Am Podiatr Med Assoc* 1998;88:419–28.
23 Riskowski JL, Hagedorn TJ, Hannan MT, *et al*. Measures of foot function, foot health, and foot pain: American Academy of Orthopedic Surgeons lower limb outcomes assessment: foot and ankle Module (AAOS-FAM), Bristol foot score (BFS), revised foot function index (FFI-R), foot health status questionnair. *Arthritis Care Res* 2011;63:S229–39.
24 Riel H, Jensen MB, Olesen JL, *et al*. Translation and cultural adaptation of a Danish version of the foot health status questionnaire for individuals with plantar heel pain. *Foot (Edinb)* 2019;38:61–4.
25 Whittaker GA, Munteanu SE, Menz HB, *et al*. Effectiveness of foot orthoses versus corticosteroid injection for Plantar heel pain: the soothe randomized clinical trial. *J Orthop Sports Phys Ther* 2019;49:491–500.
26 Radford JA, Landorf KB, Buchbinder R, *et al*. Effectiveness of low-dye taping for the short-term treatment of plantar heel pain: a randomised trial. *BMC Musculoskelet Disord* 2006;7:64.

27 Rome K, Gray J, Stewart F, *et al*. Evaluating the clinical effectiveness and cost-effectiveness of foot orthoses in the treatment of plantar heel pain. *J Am Podiatr Med Assoc* 2004;94:229–38.
28 Landorf KB, Radford JA. Minimal important difference: values for the foot health status questionnaire, foot function index and visual analogue scale. *Foot* 2008;18:15–9.
29 Nicholas MK. The pain self-efficacy questionnaire: taking pain into account. *Eur J Pain* 2007;11:153–63.
30 Migueles JH, Cadenas-Sanchez C, Ekelund U, *et al*. Accelerometer data collection and processing criteria to assess physical activity and other outcomes: a systematic review and practical considerations. *Sports Med* 2017;47:1821–45.
31 Georgiou M, Ponte C. Editorial - introducing media, technology and the migrant family: media uses, appropriations and articulations in a culturally diverse Europe. *OBS** 2013;94:1–11.
32 Landorf KB, Keenan A-M, Herbert RD. Effectiveness of foot orthoses to treat plantar fasciitis. *Arch Intern Med* 2006;166:1305–10.
33 Riel H, Vicenzino B, Olesen JL, *et al*. Corticosteroid injection plus exercise versus exercise, beyond advice and a heel cup for patients with plantar fasciopathy: a randomised clinical superiority trial (the FIX-heel trial). *Trials* 2020;21:5.
34 Johannsen FE, Herzog RB, Malmgaard-Clausen NM, *et al*. Corticosteroid injection is the best treatment in plantar fasciitis if combined with controlled training. *Knee Surg Sports Traumatol Arthrosc* 2019;27:5–12.
35 Benedetti F, Carlino E, Pollo A. How placebos change the patient's brain. *Neuropsychopharmacology* 2011;36:339–54.
36 Dean BJF, Lostis E, Oakley T, *et al*. The risks and benefits of glucocorticoid treatment for tendinopathy: a systematic review of the effects of local glucocorticoid on tendon. *Semin Arthritis Rheum* 2014;43:570–6.
37 Acevedo JI, Beskin JL. Complications of plantar fascia rupture associated with corticosteroid injection. *Foot Ankle Int* 1998;19:91–7.
38 Ball EMA, McKeeman HMA, Patterson C, *et al*. Steroid injection for inferior heel pain: a randomised controlled trial. *Ann Rheum Dis* 2013;72:996–1002.
39 David JA, Sankarapandian V, Christopher PR, *et al*. Injected corticosteroids for treating plantar heel pain in adults. *Cochrane Database Syst Rev* 2017;6:CD009348.
40 Whittaker GA, Munteanu SE, Menz HB, *et al*. Effectiveness of foot orthoses versus corticosteroid injection for plantar heel pain: the SOOTHE randomized clinical trial. *J Orthop Sports Phys Ther* 2019;49:491–500.
41 Landorf KB, Radford JA, Hudson S. Minimal important difference (MID) of two commonly used outcome measures for foot problems. *J Foot Ankle Res* 2010;3:7.
42 Copay AG, Subach BR, Glassman SD, *et al*. Understanding the minimum clinically important difference: a review of concepts and methods. *Spine J* 2007;7:541–6.