Bijlagen bij Conceptrichtlijnmodules Fasciopathie Plantaris

Inhoudsopgave

Module 1 Lichamelijk onderzoek

Search and select

A systematic review of the literature was performed to answer the following question:
What is the diagnostic accuracy of physical examination among patients presenting with plantar heel pain (PHP), for plantar fasciopathy?

P (Patients):	Patients with plantar heel pain
I (index test):	Physical examination (any form)
C (comparator test):	Any or none
R (reference standard):	Imaging (ultrasound, MRI, X-ray)
O (outcome measure):	Sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV)
Timing and setting:	Secondary and tertiary care

Relevant outcome measures

The guideline development group considered specificity and positive predictive value as **crucial** outcome measures for decision making; and sensitivity and negative predictive value as **important** outcome measures for decision making.

A priori, the working group did not define the outcome measures listed above but used the definitions used in the studies.

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until 27th of March 2024. The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 406 hits. Studies were selected based on the following criteria:

- Systematic reviews, meta-analyses or other comparative studies (case control or cohort studies);
- Studies performed in adults, with at least 10 subjects per study arm;
- English full-text available;
- Studies according to the PICO.

Eight studies were initially selected based on title and abstract screening. After reading the full text, seven studies were excluded (see the table with reasons for exclusion under the tab Methods), and one study was included.

Results

One study was included in the analysis of the literature. Important study characteristics and results are summarized in the evidence tables. The assessment of the risk of bias is summarized in the risk of bias tables.

Data regarding the classification of cases by the index test (tenderness on palpation) compared to the reference test (imaging) were extracted from the study. Diagnostic accuracy parameters and/or 95% confidence intervals were calculated based on the extracted data, as these were not reported in the original study. In this calculation, cases classified by the index test were defined as feet tender to palpation and cases classified by the reference test were all feet with positive imaging findings of either plantar calcaneal spur on X-ray, plantar fascia thickening on ultrasound, or both.

Summary of literature

Description of studies

The cross-sectional observational study by Menz (2019) evaluated the diagnostic value of a specific clinical sign, which was 'point tenderness over the insertion of the plantar fascia into the medial tubercle of the calcaneus'. To be precise, the objective of the study was to determine whether tenderness on palpation of the heel differentiates between the presence of calcaneal spurs (determined via weight-bearing lateral foot radiograph), plantar fascia thickening (determined via ultrasound) or both these features combined. The cross-sectional analysis was performed as part of a larger population-based observational cohort study on clinical assessment of the foot, in which adults aged 50 years and older participated. For this analysis and objective, participants who reported pain in and around the foot in the past 12 months were invited for clinical assessment and imaging, resulting in 530 participants. Participants with inflammatory arthritis were excluded. If participants indicated to have experienced foot pain in the region of the plantar heel in the last month, they were documented as having plantar heel pain (PHP). Out of the 530 participants (1060 feet), 117 reported PHP in one or both feet: 51 of these patients had unilateral PHP and 66 bilateral PHP, resulting 183 feet with PHP and 877 feet without PHP at moment of inclusion.

As part of clinical assessment, the presence or absence of tenderness was determined by the assessor by applying firm pressure to the plantar-medial heel of the participant, while the first metatarsophalangeal joint was being moved into full dorsiflexion. The presence of calcaneal spurs was determined as either present or absent by a single reader on weight-bearing lateral foot radiographs, which were obtained via standardized protocol. Plantar fascia thickness was measured during sagittal ultrasound imaging of the plantar fascia by three repeated measurements, in which increased plantar fascia thickness was defined as > 4mm.

Results

In Menz (2019), cases were presented per foot and not per participant, resulting in the diagnostic outcome parameters being based on outcome per foot. Plantar fasciopathy cases were identified within the entire population of participants with foot pain in the last 12 months, as no data on classification within the PHP population was reported.

Table 1 summarizes classification of patients with foot pain according to the index test (tenderness on palpation of the heel) and reference test (presence of plantar calcaneal spurs, fascial thickening, or combination based on x-ray and ultrasound). Specificity of tenderness on clinical assessment was 83.6% (95% CI 80.1 to 86.8) and the PPV was 54.2 (95% CI 47.5 to 60.8). Sensitivity of tenderness on clinical assessment was 17.1 (95% CI was 14.1 to 20.5) and NPV was 47.1 (95% CI 45.8 to 48.5).

Table 1. Classification of patients with foot pain based on index- and reference test

	Plantar calcaneal spur and/or plantar fascia thickening	No plantar calcaneal spur or plantar fascia thickening
Tenderness	96	81
No tenderness	465	414

Additionally, the study did report that out of the 183 feet with plantar heel pain, 53 were tender to palpation and 130 feet were not tender to palpation. Finally, the study also reported that among patients not experiencing plantar heel pain (877 feet), 51.5% did also either have plantar calcaneal spur, plantar fascia thickening or both.

Level of evidence of the literature

Sensitivity

The level of evidence regarding the outcome measure sensitivity (for clinical assessment) was downgraded by four levels because of study limitations, including selection bias (-1, risk of bias), applicability, as both test-setting and reference test do not represent the setting of recommendations (-2, indirectness), and number of included patients (-1, imprecision). The final level of evidence is low.

Specificity

The level of evidence regarding the outcome measure sensitivity (for clinical assessment) was downgraded by four levels because of study limitations, including selection bias (-1, risk of bias), applicability, as both test-setting and reference test do not represent the setting of recommendations (-2, indirectness), and number of included patients (-1, imprecision). The final level of evidence is low.

Positive predictive value

The level of evidence regarding the outcome measure sensitivity (for clinical assessment) was downgraded by four levels because of study limitations, including selection bias (-1, risk of bias), applicability, as both test-setting and reference test do not represent the setting of recommendations (-2, indirectness), and number of included patients (-1, imprecision). The final level of evidence is very low.

Negative predictive value

The level of evidence regarding the outcome measure sensitivity (for clinical assessment) was downgraded by four levels because of study limitations, including selection bias (-1, risk of bias), applicability, as both test-setting and reference test do not represent the setting of recommendations (-2, indirectness), and number of included patients (-1, imprecision). The final level of evidence is very low.

Conclusions

Sensitivity

Very low GRADE	It is unclear whether the sensitivity of palpation is sufficient to confirm the diagnosis plantar fasciopathy in patients with plantar heel pain. *Menz, 2019*

Specificity

Very low GRADE	It is unclear whether the specificity of palpation is sufficient to exclude the diagnosis plantar fasciopathy in patients with plantar heel pain. *Menz, 2019*

Positive predictive value

Very low GRADE	There is a very low certainty about the positive predictive value of palpation for the diagnosis plantar fasciopathy in patients with plantar heel pain. *Menz, 2019*

Negative predictive value

Very low GRADE	There is a very low certainty about the negative predictive value of palpation for the diagnosis plantar fasciopathy in patients with plantar heel pain.

	Menz, 2019

Kennisvragen

De PICO vraag was:

What is the diagnostic accuracy of physical examination among patients presenting with plantar heel pain (PHP), for plantar fasciopathy?

P (Patients):	Patients with plantar heel pain
I (index test):	Physical examination (any form)
C (comparator test):	Any or none
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O (outcome measure):	Sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV)
Timing and setting:	Secondary and tertiary care

Voor alle uitkomstmaten (specificiteit, sensitiviteit, NPV en PPV) was de bewijskracht uit de literatuur zeer laag, waarbij de beschikbare studie de uitgangsvraag niet goed kon beantwoorden, omdat beeldvorming geen gouden standaard blijkt. Momenteel ontbreekt het ook aan bewijs over de vergelijking tussen het stellen van de diagnose fasciopathie plantaris door diverse specialisten werkzaam in de behandelzorg van blessures van het houdings-en bewegingsapparaat. Ook studies waarin inter-waarnemer correlaties bepaald worden op grond van lichamelijk onderzoek zouden informatief zijn. Dergelijke studies zijn bij de werkgroep fasciopathie plantaris niet bekend. Interessant is op grond van welke gegevens betreffende anamnese en lichamelijk onderzoek een specialist tot de diagnose besluit. Overeenkomstige diagnosestelling tussen sportarts, orthopeed en huisarts is van belang om sneller en doeltreffender behandeling in te kunnen zetten.

Literatuur

Blazina ME, Kerlan RK, Jobe FW, Carter VS, Carlson GJ. Jumper's knee. Orthop Clin North Am. 1973 Jul;4(3):665-78. PMID: 4783891.

Bolgla LA, Malone TR. Plantar fasciitis and the windlass mechanism: a biomechanical link to clinical practice. J Athl Train. 2004 Jan;39(1):77-82. PMID: 16558682; PMCID: PMC385265.

Cotchett M, Skovdal Rathleff, Dilnot M, Landorf KB, Morrissey D,Barton C Lived experience and attitudes of people with plantar heel pain: a qualitative exploration. 2020 Mar 6;13(1):12. doi: 10.1186/s13047-020-0377-3. J Foot Ankle Res. PMID: 32143679 PMCID: PMC7059663 DOI: 10.1186/s13047-020-0377-3

Mallow AJ, Debenham JR, Malliaras P, Stace R, Littlewood C. Cognitive and contextual factors to optimize clinical outcomes in tendinopathy. https://doi.org/10.1136/bjsports-2017-098064.

Menz HB, Thomas MJ, Marshall M, Rathod-Mistry T, Hall A, Chesterton LS, Peat GM, Roddy E. Coexistence of plantar calcaneal spurs and plantar fascial thickening in individuals with plantar heel pain. Rheumatology (Oxford). 2019 Feb 1;58(2):237-245. doi: 10.1093/rheumatology/key266. PMID: 30204912; PMCID: PMC6519610.

Thomas JL, Christensen JC, Kravitz SR, Mendicino RW, Schuberth JM, Vanore JV, Scott Weil Sr L, Zlotoff HJ, Bouché R, Baker J The diagnosis and treatment of heel pain: a clinical practice guideline-revision 2010. J Foot Ankle Surg. 2010 May-Jun;49(3 Suppl):S1-19. doi: 10.1053/j.jfas.2010.01.001. PMID: 20439021.

Tu P, Bytomski JR. Diagnosis of heel pain. Am Fam Physician. 2011 Oct 15;84(8):909-16. PMID: 22010770.

Vos de R-J, Vlist van der AC, Zwerver J, Meuffels DE, Smithuis F, Ingen van R, Giesen van der F, Visser E, Balemans A, Pols M, Veen N, Ouden den M, Weir A Dutch multidisciplinary guideline on Achilles tendinopathy. Br J Sports Med. 2021 Oct;55(20):1125-1134. doi: 10.1136/bjsports-2020-103867. Epub 2021 Jun 29.

5 Welck MJ, Hayes T, Pastides P, Khan W, Rudge B Stress fractures of the foot and ankle. Injury. 2017 Aug;48(8):1722-1726. doi: 10.1016/j.injury.2015.06.015. Epub 2015 Sep 15. PMID: 26412591.

Implementatietabel

Aanbeveling 1 en 2	**Aanbeveling 1** Prioriteer anamnese en lichamelijk onderzoek voor diagnosestelling van fasciopathie plantaris bij patiënten met plantaire hielpijn **Aanbeveling 2** Voor het stellen van de diagnose fasciopathie plantaris: − Lokaliseer de palpatiepijn plantair, specifieke ter hoogte van de insertie van de fascia plantaris op de mediale tuberkel van de calcaneus, eventueel met versterkte palpatiepijn door passieve dorsoflexie van de grote teen; de palpatie pijn mag ook iets meer naar anterieur zitten en enkele cm's verwijderd van de insertie. Vraag patiënt of deze de locatie van de pijn herkent;		
1. Wat was het onderliggende probleem om deze uitgangsvraag uit te werken?	□ **Ongewenste praktijkvariatie**		
2. Maak een inschatting over hoeveel patiënten het ongeveer gaat waar de aanbeveling betrekking op heeft?	*x* **5000-40.000 (ruwe schatting 20000?) (Volgens Crawford et al. (2000) wordt 10% van de bevolking in hun leven geconfronteerd met pijn aan de hiel).**		
3. Maakt de aanbeveling deel uit van een set van interventies voor hetzelfde probleem?	**Er zijn meerdere aanbevelingen binnen deze module geformuleerd. De eerste en derde aanbeveling zijn beiden sterk geformuleerd.**		
4. Belemmeringen en kansen op verschillende niveaus voor landelijke toepassing van de aanbeveling:	***Voorbeelden***	**Wat zijn mogelijke belemmerende factoren?**	**Wat zijn mogelijke bevorderende factoren?**
a) **Richtlijn/ klinisch traject (innovatie)**	*Voortschrijding/vooruitgang in de praktijk, haalbaarheid, geloofwaardigheid, toegankelijkheid, aantrekkelijkheid*	*Onenigheid tussen beroepsgroepen: radiologen/sportartsen/orthopeden/huisartsen.* *Zorgverleners die te veel vertrouwen/steunen op aanvullende diagnostiek.*	*Autoriteitsdragende instituten (academische centra bijvoorbeeld) die de richtlijn publiek steunen. Publicatie in vakbladen.*
b) **Zorgverleners (artsen en verpleegkundigen)**	*Bewustzijn, kennis, houding, motivatie om te veranderen, gedragsroutines*	*Onenigheid tussen beroepsgroepen: radiologen/sportartsen/orthopeden/huisartsen.*	*Publicatie in vakbladen specialisten.*

		Zorgverleners die te veel vertrouwen/steunen op aanvullende diagnostiek. *Weerstand tegen verandering.* *Gebrek aan kennis en training.*	*Organisatie symposia/congressen* *Autoriteitsdragende instituten (academische centra bijvoorbeeld) die de richtlijn publiek steunen.*
c) **Patiënt/ cliënt (naasten)**	*Kennis, vaardigheden, houding, compliance*	*Onenigheid tussen beroepsgroepen: radiologen/sportartsen/orthopeden/huisartsen.* *Er is geen voldoende patiënteninformatie hoe het onderzoek er nu uit ziet.*	*Publicatie van streven naar uniformiteit (via multidisciplinaire richtlijn) in diagnose en behandeling tussen (para)medici in een blad voor leken.*
d) **Sociale context**	*Mening van collega's, cultuur van het netwerk, samenwerking, leiderschap*	*Oudere (para)medici die al jaren monodisciplinar werken, en weinig met anderen samenwerken.* *(Para)medici die overtuigd zijn van eigen gelijk.*	*Netwerk met (para)medici die veelvuldig congressen/symposia bezoeken, intercollegiale toetsingsbijeenkomsten hebben.*
e) **Organisatorische context**	*Organisatie van zorgprocessen, personeel, capaciteiten, middelen, structuren*	*Te weinig tijd ingeruimd voor intercollegiale toetsing of overlegmomenten.* *Te weinig tijd om richtlijnen te leren en toe te passen.*	*Tijd voor intercollegiale toetsing en multidisciplinair overleg op de werkvloer.*
f) **Economische en politieke context**	*Financiële regelingen, regelgeving, beleid (vergoede zorg, betaaltitel)*	*Niet van toepassing*	*Niet van toepassing*
5. Welke personen/partijen zijn van belang bij het toepassen van de aanbeveling in de praktijk?		**x** Professional x Beroepsvereniging x Ziekenhuis(bestuurder)	

6. Wat zouden deze personen/ partijen moeten veranderen in hun gedrag of organisatie om de aanbeveling toe te passen?	*De professional moet openstaan voor de aanbevelingen van de rchtlijn en deze willen toepassen.* *De Beroepsvereniging zal de professionals in moeten lichten via publicatie avn de richtlijn.* *Het Ziekenhuisbestuur dient de productiviteit van een afdeling met professionals niet dermate te prioriteren dat dat ten koste gaat van pverlegtijd en mogelijkheden voor intercollegiale toetsing maar ook spreekuurtijd.*
7. Binnen welk tijdsbestek moet de aanbeveling zijn geïmplementeerd?	< 2 jaar
Conclusie: is er extra aandacht nodig voor implementatie van de aanbeveling (anders dan publicatie van deze richtlijnmodule)?	**X Ja*** **Toelichting:** Mogelijk is het ook nuttig om via meerdere platformen deze nieuwe richtlijn te communiceren. Hierbij is het belangrijk dat alle partijen die hier belang bij hebben juist geïnformeerd worden.

Aanbeveling 3	**Aanbeveling 3** Voor differentiaal-diagnostische overwegingen: − Inspecteer de voet op zwellingen en roodheid op overige plekken op de voet voor differentiatie, (insertie tendinopathie achillespees, retrocalcaneaire bursitis); − Onderzoek drukpijn aan plantaire zijde, meer naar achteren dan de mediale tuberkel (fatpad-irritatie); − Onderzoek drukpijn aan achterzijde/rondom de hiel (Onderste spronggewricht dysfunctie, insertie tendinopathie achillespees); − Onderzoek pijn bij palpatie middenvoetsbeentjes, met eventuele zwelling (stressfractuur); − Onderzoek pijn bij palpatie plantaire zijde onder bal van de voet (Morton's Neuroom); Onderzoek pijn bij palpatie aan achterzijde van de mediale malleolus (Tarsaal Tunnelsyndroom		
1. Wat was het onderliggende probleem om deze uitgangsvraag uit te werken?	□ **Ongewenste praktijkvariatie** **Toelichting:** Veel patiënten komen bij de orthopedisch chirurg terwijl ze op dat moment niet voor tenminste een jaar lang adequaat conservatief behandeld zijn. De werkgroep is van mening dat een jaar lang adequaat behandelen de standaard moet zijn, evenals het bespreken van de relatieve effecten van operatief ingrijpen ten opzichte van andere conservatieve behandelingen.		
2. Maak een inschatting over hoeveel patiënten het ongeveer gaat waar de aanbeveling betrekking op heeft?	*x* **5000-40.000 (zie eerder).**		
3. Maakt de aanbeveling deel uit van een set van interventies voor hetzelfde probleem?	**Er zijn meerdere aanbevelingen binnen deze module geformuleerd. De eerste en derde aanbeveling zijn beiden sterk geformuleerd.**		
4. Belemmeringen en kansen op verschillende niveaus voor landelijke toepassing van de aanbeveling:	***Voorbeelden***	**Wat zijn mogelijke belemmerende factoren?**	**Wat zijn mogelijke bevorderende factoren?**
g) **Richtlijn/ klinisch traject (innovatie)**	*Voortschrijding/vooruitgang in de praktijk, haalbaarheid, geloofwaardigheid, toegankelijkheid, aantrekkelijkheid*	*Onenigheid tussen beroepsgroepen: radiologen/sportartsen/orthopeden/huis artsen.*	*Autoriteitsdragende instituten (academische centra bijvoorbeeld) die de richtlijn publiek steunen. Publicatie in vakbladen.*

h) **Zorgverleners (artsen en verpleegkundigen)**	*Bewustzijn, kennis, houding, motivatie om te veranderen, gedragsroutines*	*Onenigheid tussen beroepsgroepen: radiologen/sportartsen/orthopeden/huis artsen.* *Zorgverleners die te veel vertrouwen/steunen op aanvullende diagnostiek.* *Weerstand tegen verandering.* *Gebrek aan kennis en training.*	*Autoriteitsdragende instituten (academische centra bijvoorbeeld) die de richtlijn publiek steunen. Publicatie in vakbladen.*
i) **Patiënt/ cliënt (naasten)**	*Kennis, vaardigheden, houding, compliance*	*Onenigheid tussen beroepsgroepen: radiologen/sportartsen/orthopeden/huis artsen.*	*Publicatie van streven naar uniformiteit (via multidisciplinaire richtlijn) in diagnose en behandeling tussen (para)medici in een blad voor leken. Zorgen dat er in dit stadium voldoende patiënteninformatie voor handen is over hoe het lichamelijk onderzoek er uit ziet. bijvoorbeeld via Thuisarts.nl.*
j) **Sociale context**	*Mening van collega's, cultuur van het netwerk, samenwerking, leiderschap*	*Oudere (para)medici die al jaren monodisciplinar werken, en weinig met anderen samenwerken.* *(Para)medici die overtuigd zijn van eigen gelijk.*	*Netwerk met (para)medici die veelvuldig congressen/symposia bezoeken, intercollegiale toetsingsbijeenkomsten hebben.*
k) **Organisatorische context**	*Organisatie van zorgprocessen, personeel, capaciteiten, middelen, structuren*	*Te weinig tijd ingeruimd voor intercollegiale toetsing of overlegmomenten.*	*Tijd voor intercollegiale toetsing en multidisciplinair overleg op de werkvloer.*

		Te weinig tijd om richtlijnen te leren en toe te passen.	
l) **Economische en politieke context**	*Financiële regelingen, regelgeving, beleid (vergoede zorg, betaaltitel)*	*Niet van toepassing.*	*Minder kosten ten gevolge van overbodige aanvullende diagnostiek.*
5. Welke personen/partijen zijn van belang bij het toepassen van de aanbeveling in de praktijk?		**x** Professional x Beroepsvereniging x Ziekenhuis(bestuurder)	
6. Wat zouden deze personen/ partijen moeten veranderen in hun gedrag of organisatie om de aanbeveling toe te passen?		*De professional moet openstaan voor de aanbevelingen van de rchtlijn en deze willen toepassen.* *De Beroepsvereniging zal de professionals in moeten lichten via publicatie van de richtlijn.* *Het Ziekenhuisbestuur dient de productiviteit van een afdeling met professionals niet dermate te prioriteren dat dat ten koste gaat van overlegtijd en mogelijkheden voor intercollegiale toetsing maar ook spreekuurtijd.*	
7. Binnen welk tijdsbestek moet de aanbeveling zijn geïmplementeerd?		< 3 jaar	
Conclusie: is er extra aandacht nodig voor implementatie van de aanbeveling (anders dan publicatie van deze richtlijnmodule)?		**x Ja*** **Toelichting:** Mogelijk is het ook nuttig om via meerdere platformen deze nieuwe richtlijn te communiceren. Hierbij is het belangrijk dat alle partijen die hier belang bij hebben juist geïnformeerd worden.	

Evidence-tabellen

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
Menz, 2019	Type of study: Cross-sectional observational study Setting and country: Within population-based cohort, United Kingdom Funding and conflicts of interest: Study was supported by an Arthritis Research UK Programme Grant (18174) and service support through the West Midlands North CLRN. The authors have declared no conflicts of interest.	Inclusion criteria: Adults aged 50 years and over registered with four general practices, who reported pain in and around the foot in the past 12 months and provided written consent Exclusion criteria: Participants with inflammatory arthritis were excluded. N= 530 (1060 feet), Prevalence: Not reported Mean age ± SD: 64.9 [8.4] years Sex 56% Female Other important characteristics:	Describe index test: Clinical assessment: As part of clinical assessment, tenderness was determined by the assessor by applying firm pressure to the plantar-medial heel of the participant, while the first metatarsophalangeal joint was being moved into full dorsiflexion Cut-off point(s): No cut-off point Comparator test: No comparator	Describe reference test: presence of either/both calcaneal spurs (determined via weight-bearing lateral foot radiograph) and plantar fascia thickening (determined via ultrasound) Cut-off point(s): Plantar fascia thickness: Mean of > 4mm on sagittal ultrasound imaging of the plantar fascia in three repeated measurements	Time between the index test en reference test: All tests undertaken during research clinic (same day) For how many participants were no complete outcome data available? Of 1635 consenting individuals, only 530 attended the research assessment clinic. Reasons for incomplete outcome data described? Not reported	Outcome measures and effect size (include 95%CI and p-value if available)[4]: Calculated based on 4x4 table, baseline prevalence not reported: Specificity: 83.6% (95% CI 80.1 to 86.8) PPV: 54.2 (95% CI 47.5 to 60.8). Sensitivity: 17.1 (95% CI 14.1 to 20.5) NPV: 47.1 (95% CI 45.8 to 48.5).	Baseline prevalence was unknown. Study (mistakenly?) provided a comparison of palpation with imaging in the group of people with foot pain in the last 12 months, instead of subgroup of people with plantar heel pain within the last month, even though title of table states otherwise (samples don't match).

Risk of bias assessment diagnostic accuracy studies (QUADAS II, 2011)

Study reference	Patient selection	Index test	Reference standard	Flow and timing	Comments with respect to applicability
Menz, 2019	Was a consecutive or random sample of patients enrolled? No Was a case-control design avoided? Yes Did the study avoid inappropriate exclusions? Unclear Bias could be introduced by assessing separate feet instead of participants.	Were the index test results interpreted without knowledge of the results of the reference standard? Yes If a threshold was used, was it pre-specified? n/a	Is the reference standard likely to correctly classify the target condition? No Were the reference standard results interpreted without knowledge of the results of the index test? Yes	Was there an appropriate interval between index test(s) and reference standard? Yes (during research clinic) Did all patients receive a reference standard? Yes (but was inclusion criterium) Did patients receive the same reference standard? Yes Were all patients included in the analysis? No	Are there concerns that the included patients do not match the review question? Yes Are there concerns that the index test, its conduct, or interpretation differ from the review question? No Are there concerns that the target condition as defined by the reference standard does not match the review question? Yes
	CONCLUSION: Could the selection of patients have introduced bias? **RISK: HIGH**	CONCLUSION: Could the conduct or interpretation of the index test have introduced bias? **RISK: LOW**	CONCLUSION: Could the reference standard, its conduct, or its interpretation have introduced bias? **RISK: HIGH**	CONCLUSION Could the patient flow have introduced bias? **RISK: UNCLEAR**	

Table of excluded studies

Reference	Reason for exclusion
Wang X, Xu L, Hu X, Zhao H, Yin J. Musculoskeletal Ultrasound for the Diagnosis of Plantar Fasciitis: An Accuracy and Diagnostic Yield Study. Int J Gen Med. 2023 Oct 25;16:4765-4771. doi: 10.2147/IJGM.S434182. PMID: 37904905; PMCID: PMC10613412.	Wrong population. Population selected based on physical examination, no comparison could be made.
De Garceau D, Dean D, Requejo SM, Thordarson DB. The association between diagnosis of plantar fasciitis and Windlass test results. Foot Ankle Int. 2003 Mar;24(3):251-5. doi: 10.1177/107110070302400309. PMID: 12793489.	Wrong outcomes. Did not assess diagnostic accuracy of physical examination.
Maatallah K, Triki W, Riahi H, Ferjani H, Salem FB, Kaffel D, et al. Plantar fascia enthesitis: Clinical, radiographic and ultrasound findings in patients with axial spondyloarthritis. The Egyptian Rheumatologist. 2020 Oct;42(4):267–70. doi:10.1016/j.ejr.2020.07.011	Wrong outcomes, did not assess diagnostic accuracy of physical examination.
Drake C, Whittaker GA, Kaminski MR, Chen J, Keenan A, Rathleff MS, et al. Medical Imaging for Plantar heel pain: A systematic review and meta-analysis. Journal of Foot and Ankle Research. 2022 Jan;15(1). doi:10.1186/s13047-021-00507-2	Wrong population. Population selected based on physical examination, no comparison could be made.
Tsai WC, Hsu CC, Chen CP, Chen MJ, Yu TY, Chen YJ. Plantar fasciitis treated with local steroid injection: comparison between sonographic and palpation guidance. J Clin Ultrasound. 2006 Jan;34(1):12-6. doi: 10.1002/jcu.20177. PMID: 16353228.	Wrong population. Population selected based on physical examination, no comparison could be made.
Kane D, Greaney T, Shanahan M, Duffy G, Bresnihan B, Gibney R, FitzGerald O. The role of ultrasonography in the diagnosis and management of idiopathic plantar fasciitis. Rheumatology (Oxford). 2001 Sep;40(9):1002-8. doi: 10.1093/rheumatology/40.9.1002. PMID: 11561110.	Wrong population. Population selected based on physical examination, no comparison could be made.
Saba EK, El-Sherif SM. Ultrasound-guided versus palpation-guided local corticosteroid injection therapy for treatment of plantar fasciitis. The Egyptian Rheumatologist. 2016 Apr;38(2):123–31. doi:10.1016/j.ejr.2015.06.005	No diagnostic accuracy study.
1. Cetin A, Sivri A, Dincer F, Kiratli P, Ceylan E. Evaluation of chronic plantar fasciitis by scintigraphy and relation to clinical parameters. Journal of Musculoskeletal Pain. 2001 Jan;9(4):55–61. doi:10.1300/j094v09n04_06	No comparisons made.

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Fasciopathie Plantaris – UV1 Lichamelijk onderzoek	
Uitgangsvraag/modules: Hoe wordt de diagnose fasciopathie plantaris gesteld?	
Database(s): Embase.com, Ovid/Medline	Datum: 27 maart 2024
Periode: vanaf 2000	Talen: geen restrictie
Literatuurspecialist: Esther van der Bijl	Rayyan review: https://rayyan.ai/reviews/972986
BMI-zoekblokken: voor verschillende opdrachten wordt (deels) gebruik gemaakt van de zoekblokken van BMI-Online https://blocks.bmi-online.nl/ Bij gebruikmaking van een volledig zoekblok zal naar de betreffende link op de website worden verwezen.	
Toelichting: Voor deze vraag is gezocht op de elementen fasciopathie plantaris EN lichamelijk onderzoek EN diagnostisch filter. → Zoals besproken wordt het sleutelartikel PMID28717618 niet gevonden met deze search.	
Te gebruiken voor richtlijntekst: In de databases Embase.com en Ovid/Medline is op 27 maart 2024 systematisch gezocht naar systematische reviews en observationele studies over lichamelijk onderzoek bij patiënten met plantaire hielpijn. De literatuurzoekactie leverde 406 unieke treffers op.	

5

Zoekopbrengst 27-3-2024

	EMBASE	OVID/MEDLINE	Ontdubbeld
SR	27	10	34
RCT	129	30	150
Observationeel	201	48	222
Totaal	357	88	**406***

in Rayyan

Embase.com 27-3-2024

No.	Query	Results
#1	'plantar fasciitis'/exp OR 'plantar fasciopathy'/exp OR 'heel spur'/exp OR 'policeman heel'/exp OR (((calcane* OR heel* OR subcalcane*) NEAR/3 (spur* OR exostos* OR pain* OR policeman* OR jogger*)):ti,ab,kw) OR ((plant* NEAR/3 (fasciitis OR fasciopath* OR fascios* OR inflam*)):ti,ab,kw) OR (((baxter* OR plant* OR calcane* OR heel) NEAR/3 neuropath*):ti,ab,kw) OR calcaneodyn*:ti,ab,kw OR 'calcane* periostitis':ti,ab,kw	6372
#2	'physical examination'/exp OR 'palpation'/exp OR 'percussion'/exp OR 'inspection'/exp OR 'foot posture index'/exp OR 'ankle dorsiflexion angle'/exp OR 'eversion'/exp OR 'body mass'/exp OR ((diagnostic NEAR/3 (method* OR procedure* OR technique*)):ti,ab,kw) OR ((physical* NEAR/3 (exam* OR assessment* OR check* OR inspect* OR test*)):ti,ab,kw) OR (((foot OR heel) NEAR/3 palpat*):ti,ab,kw) OR 'windlass':ti,ab,kw OR 'foot posture index score*':ti,ab,kw OR 'dorsiflexion*':ti,ab,kw OR 'eversion*':ti,ab,kw OR bmi:ti,ab,kw OR 'body mass index*':ti,ab,kw	1379249
#3	'diagnostic procedure'/exp OR 'sensitivity and specificity'/de OR sensitivity:ab,ti OR specificity:ab,ti OR predict*:ab,ti OR 'roc curve':ab,ti OR 'receiver operator':ab,ti OR 'receiver operators':ab,ti OR likelihood:ab,ti OR 'diagnostic error'/exp OR 'diagnostic accuracy'/exp OR 'diagnostic test accuracy study'/exp OR 'inter observer':ab,ti OR 'intra observer':ab,ti OR interobserver:ab,ti OR intraobserver:ab,ti OR validity:ab,ti OR kappa:ab,ti OR reliability:ab,ti OR reproducibility:ab,ti OR ((test NEAR/2 're-test'):ab,ti) OR ((test NEAR/2 'retest'):ab,ti) OR 'reproducibility'/exp OR accuracy:ab,ti OR 'differential diagnosis'/exp OR 'validation study'/de OR 'measurement precision'/exp OR 'diagnostic value'/exp OR 'reliability'/exp OR 'predictive value'/exp OR ppv:ti,ab,kw OR npv:ti,ab,kw OR (((false OR true) NEAR/3 (negative OR positive)):ti,ab) OR diagnos*:ti,ab	24874822
#4	#1 AND #2 AND #3	801
#5	#4 AND [2000-2024]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	577
#6	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	1014403
#7	'clinical trial'/exp OR 'randomization'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR 'placebo'/exp OR 'prospective	4001180

	study'/exp OR rct:ab,ti OR random*:ab,ti OR 'single blind':ab,ti OR 'randomised controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti	
#8	'major clinical study'/de OR 'clinical study'/de OR 'case control study'/de OR 'family study'/de OR 'longitudinal study'/de OR 'retrospective study'/de OR 'prospective study'/de OR 'comparative study'/de OR 'cohort analysis'/de OR ((cohort NEAR/1 (study OR studies)):ab,ti) OR (('case control' NEAR/1 (study OR studies)):ab,ti) OR (('follow up' NEAR/1 (study OR studies)):ab,ti) OR (observational NEAR/1 (study OR studies)) OR ((epidemiologic NEAR/1 (study OR studies)):ab,ti) OR (('cross sectional' NEAR/1 (study OR studies)):ab,ti)	6767914
#9	'case control study'/de OR 'comparative study'/exp OR 'control group'/de OR 'controlled study'/de OR 'controlled clinical trial'/de OR 'crossover procedure'/de OR 'double blind procedure'/de OR 'phase 2 clinical trial'/de OR 'phase 3 clinical trial'/de OR 'phase 4 clinical trial'/de OR 'pretest posttest design'/de OR 'pretest posttest control group design'/de OR 'quasi experimental study'/de OR 'single blind procedure'/de OR 'triple blind procedure'/de OR (((control OR controlled) NEAR/6 trial):ti,ab,kw) OR (((control OR controlled) NEAR/6 (study OR studies)):ti,ab,kw) OR (((control OR controlled) NEAR/1 active):ti,ab,kw) OR 'open label*':ti,ab,kw OR (((double OR two OR three OR multi OR trial) NEAR/1 (arm OR arms)):ti,ab,kw) OR ((allocat* NEAR/10 (arm OR arms)):ti,ab,kw) OR placebo*:ti,ab,kw OR 'sham-control*':ti,ab,kw OR (((single OR double OR triple OR assessor) NEAR/1 (blind* OR masked)):ti,ab,kw) OR nonrandom*:ti,ab,kw OR 'non-random*':ti,ab,kw OR 'quasi-experiment*':ti,ab,kw OR crossover:ti,ab,kw OR 'cross over':ti,ab,kw OR 'parallel group*':ti,ab,kw OR 'factorial trial':ti,ab,kw OR ((phase NEAR/5 (study OR trial)):ti,ab,kw) OR ((case* NEAR/6 (matched OR control*)):ti,ab,kw) OR ((match* NEAR/6 (pair OR pairs OR cohort* OR control* OR group* OR healthy OR age OR sex OR gender OR patient* OR subject* OR participant*)):ti,ab,kw) OR ((propensity NEAR/6 (scor* OR match*)):ti,ab,kw) OR versus:ti OR vs:ti OR compar*:ti OR ((compar* NEAR/1 study):ti,ab,kw) OR (('major clinical study'/de OR 'clinical study'/de OR 'cohort analysis'/de OR 'observational study'/de OR 'cross-sectional study'/de OR 'multicenter study'/de OR 'correlational study'/de OR 'follow up'/de OR cohort*:ti,ab,kw OR 'follow up':ti,ab,kw OR followup:ti,ab,kw OR longitudinal*:ti,ab,kw OR prospective*:ti,ab,kw OR retrospective*:ti,ab,kw OR observational*:ti,ab,kw OR 'cross sectional*':ti,ab,kw OR cross?ectional*:ti,ab,kw OR multicent*:ti,ab,kw OR 'multi-cent*':ti,ab,kw OR consecutive*:ti,ab,kw) AND (group:ti,ab,kw OR groups:ti,ab,kw OR subgroup*:ti,ab,kw OR versus:ti,ab,kw OR vs:ti,ab,kw OR compar*:ti,ab,kw OR 'odds ratio*':ab OR 'relative odds':ab OR 'risk ratio*':ab OR 'relative risk*':ab OR 'rate ratio':ab OR aor:ab OR arr:ab OR rrr:ab OR ((('or' OR 'rr') NEAR/6 ci):ab)))	14947963
#10	#5 AND #6 **– SR's**	27
#11	#5 AND #7 NOT #10 **– RCT's**	129
#12	#5 AND (#8 OR #9) NOT (#10 OR #11) **– Observationele studies**	201
#13	#10 OR #11 OR #12	357

Ovid/Medline 27-3-2024

#	Searches	Results
1	exp Fasciitis, Plantar/ or exp Heel Spur/ or ((calcane* or heel* or subcalcane*) adj3 (spur* or exostos* or pain* or policeman* or jogger*)).ti,ab,kf. or (plant* adj3 (fasciitis or fasciopath* or fascios* or inflam*)).ti,ab,kf. or ((baxter* or plant* or calcane* or heel) adj3 neuropath*).ti,ab,kf. or calcaneodyn*.ti,ab,kf. or calcane* periostitis.ti,ab,kf.	4416
2	exp Physical Examination/ or exp Palpation/ or exp Percussion/ or exp Body Mass Index/ or (diagnostic adj3 (method* or procedure* or technique*)).ti,ab,kf. or (physical* adj3 (exam* or assessment* or check* or inspect* or test*)).ti,ab,kf. or ((foot or heel) adj3 palpat*).ti,ab,kf. or windlass.ti,ab,kf. or foot posture index score*.ti,ab,kf. or dorsiflexion*.ti,ab,kf. or eversion*.ti,ab,kf. or bmi.ti,ab,kf. or body mass index*.ti,ab,kf.	1765391

3	exp "Sensitivity and Specificity"/ or (sensitivity or specificity).ti,ab. or (predict* or ROC-curve or receiver-operator*).ti,ab. or (likelihood or LR*).ti,ab. or exp Diagnostic Errors/ or (inter-observer or intra-observer or interobserver or intraobserver or validity or kappa or reliability).ti,ab. or reproducibility.ti,ab. or (test adj2 (re-test or retest)).ti,ab. or "Reproducibility of Results"/ or accuracy.ti,ab. or Diagnosis, Differential/ or Validation Study/ or ((false or true) adj3 (negative or positive)).ti,ab.	5046071
4	1 and 2 and 3	155
5	limit 4 to yr="2000 -Current"	142
6	5 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	141
7	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	735423
8	exp clinical trial/ or randomized controlled trial/ or exp clinical trials as topic/ or randomized controlled trials as topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial or multicenter study or clinical trial).pt. or random*.ti,ab. or (clinic* adj trial*).tw. or ((singl* or doubl* or treb* or tripl*) adj (blind$3 or mask$3)).tw. or Placebos/ or placebo*.tw.	2706308
9	Epidemiologic studies/ or case control studies/ or exp cohort studies/ or Controlled Before-After Studies/ or Case control.tw. or cohort.tw. or Cohort analy$.tw. or (Follow up adj (study or studies)).tw. or (observational adj (study or studies)).tw. or Longitudinal.tw. or Retrospective*.tw. or prospective*.tw. or consecutive*.tw. or Cross sectional.tw. or Cross-sectional studies/ or historically controlled study/ or interrupted time series analysis/ [Onder exp cohort studies vallen ook longitudinale, prospectieve en retrospectieve studies]	4685975
10	Case-control Studies/ or clinical trial, phase ii/ or clinical trial, phase iii/ or clinical trial, phase iv/ or comparative study/ or control groups/ or controlled before-after studies/ or controlled clinical trial/ or double-blind method/ or historically controlled study/ or matched-pair analysis/ or single-blind method/ or (((control or controlled) adj6 (study or studies or trial)) or (compar* adj (study or studies)) or ((control or controlled) adj1 active) or "open label*" or ((double or two or three or multi or trial) adj (arm or arms)) or (allocat* adj10 (arm or arms)) or placebo* or "sham-control*" or ((single or double or triple or assessor) adj1 (blind* or masked)) or nonrandom* or "non-random*" or "quasi-experiment*" or "parallel group*" or "factorial trial" or "pretest posttest" or (phase adj5 (study or trial)) or (case* adj6 (matched or control*)) or (match* adj6 (pair or pairs or cohort* or control* or group* or healthy or age or sex or gender or patient* or subject* or participant*)) or (propensity adj6 (scor* or match*))).ti,ab,kf. or (confounding adj6 adjust*).ti,ab. or (versus or vs or compar*).ti. or ((exp cohort studies/ or epidemiologic studies/ or multicenter study/ or observational study/ or seroepidemiologic studies/ or (cohort* or 'follow up' or followup or longitudinal* or prospective* or retrospective* or observational* or multicent* or 'multi-cent*' or consecutive*).ti,ab,kf.) and ((group or groups or subgroup* or versus or vs or compar*).ti,ab,kf. or ('odds ratio*' or 'relative odds' or 'risk ratio*' or 'relative risk*' or aor or arr or rrr).ab. or (("OR" or "RR") adj6 CI).ab.))	5653155
11	6 and 7 **– SR's**	10
12	(6 and 8) not 11 **– RCT's**	30
13	(6 and (9 or 10)) not (11 or 12) **– Observationele studies**	48
14	11 or 12 or 13	88

Module 2 Beeldvorming

Search and select

A systematic review of the literature was performed to answer the following question:

What is the diagnostic accuracy of ultrasound or conventional radiography compared to MRI for diagnosing plantar fasciopathy in patients suspected of having plantar fasciopathy?

Table 1. PICROTS

Patients	Patients with suspected plantar fasciopathy
Index test	Ultrasound, X-ray
Comparator	-
Reference	MRI
Outcomes	Sensitivity, specificity, negative predictive value, positive predictive value
Timing/Setting	Secondary and tertiary care (hospital)
Other selection criteria	Study design: systematic reviews, randomized controlled trials, other comparative studies

Relevant outcome measures

The guideline development group considered specificity and negative predictive value a **crucial** outcome measure for decision making; and sensitivity and positive predictive value as an **important** outcome measure for decision making.

Outcome	Consequence
Sensitivity	The tests' ability to designate a patient with plantar fasciopathy as positive
Specificity	The tests' ability to designate a patient without plantar fasciopathy as negative
Negative predictive value (NPV)	The proportion of the cases with a negative test result who truly don't have plantar fasciopathy
Positive predictive value (PV)	The proportion of the cases with a positive test result who truly have plantar fasciopathy

A priori, the working group did not define the outcome measures listed above but used the definitions used in the studies.

Search and select (Methods)

A systematic literature search was performed by a medical information specialist using the following bibliographic databases: Embase.com and Ovid/Medline. Both databases were searched from 2000 to 2 May 2024 for systematic reviews, RCTs and observational studies. Systematic searches were completed using a combination of controlled vocabulary/subject headings (e.g., Emtree-terms, MeSH) wherever they were available and natural language keywords. The overall search strategy was derived from 3 primary search concepts: (1) Plantar fasciopathy (2) ultrasound; (3) radiography. Duplicates were removed using EndNote software. After deduplication a total of 886 records were imported for title/abstract screening. Initially, eight studies were selected based on title and abstract screening. After reading the full text, all eight studies were excluded (see the exclusion table under the tab 'Evidence tabellen'), and no studies were included.

Summary of literature

Description of studies

No studies were included in the analysis of the literature.

Results

No results are presented as there were no studies included in the analysis of the literature.

Outcome	Study results and measurements	Absolute effect estimates	Certainty of evidence (GRADE)	Conclusions
Sensitivity	No studies	-	**No GRADE**	No evidence was found regarding the sensitivity of ultrasound when compared to MRI in patients with suspected plantar fasciopathy
			No GRADE	No evidence was found regarding the sensitivity of X-ray when compared to MRI in patients with suspected plantar fasciopathy
Specificity	No studies	-	**No GRADE**	No evidence was found regarding the specificity of ultrasound when compared to MRI in patients with suspected plantar fasciopathy
			No GRADE	No evidence was found regarding the specificity of X-ray when compared to MRI in patients with suspected plantar fasciopathy
Positive predictive value	No studies	-	**No GRADE**	No evidence was found regarding the positive predictive value of ultrasound when compared to MRI in patients with suspected plantar fasciopathy
			No GRADE	No evidence was found regarding the positive predictive value of X-ray when compared to MRI in patients with suspected plantar fasciopathy
Negative predictive value	No studies	-	**No GRADE**	No evidence was found regarding the negative predictive value of ultrasound when compared to MRI in patients with suspected plantar fasciopathy
			No GRADE	No evidence was found regarding the negative predictive value of X-ray when compared to MRI in patients with suspected plantar fasciopathy

Kennisvragen

Tijdens de ontwikkeling van deze module is systematisch naar onderzoeken gezocht die de zoekvraag kunnen beantwoorden. Door gebruik te maken van een systematische literatuuranalyse met beoordeling van de bewijskracht is duidelijk geworden dat er binnen deze module nog kennisvragen bestaan. De werkgroep meent dat (vervolg)onderzoek wenselijk is om in de toekomst een duidelijker antwoord te kunnen geven op vragen uit de praktijk.

Kennisvraag:

What is the diagnostic accuracy of ultrasound or conventional radiography compared to MRI for diagnosing plantar fasciopathy in patients suspected of having plantar fasciopathy?

Zoekvraag: wat zijn de normwaarden voor dikte van de fascia plantaris en hoe kan dit worden gestandaardiseerd voor patient/individuele karakteristieken (lengte, gewicht)

PICROTS:

Patients	Patients with suspected plantar fasciopathy
Index test	Ultrasound, X-ray

Comparator	-
Reference	MRI
Outcomes	Sensitivity, specificity, negative predictive value, positive predictive value
Timing/Setting	Secondary and tertiary care (hospital)
Other selection criteria	Study design: systematic reviews, randomized controlled trials, other comparative studies

Toelichting:
Wegens het ontbreken van beschikbare literatuur voor de hier onderzochte zoekvraag is er op dit vlak nog sprake van een kennislacune.

Literatuur

Draghi F, Gitto S, Bortolotto C, Draghi AG, Ori Belometti G. Imaging of plantar fascia disorders: findings on plain radiography, ultrasound and magnetic resonance imaging. Insights Imaging. 2017 Feb;8(1):69-78. doi: 10.1007/s13244-016-0533-2. Epub 2016 Dec 12. PMID: 27957702; PMCID: PMC5265197.

Drake C, Whittaker GA, Kaminski MR, Chen J, Keenan AM, Rathleff MS, Robinson P, Landorf KB. Medical imaging for plantar heel pain: a systematic review and meta-analysis. J Foot Ankle Res. 2022 Jan 22;15(1):4. doi: 10.1186/s13047-021-00507-2. PMID: 35065676; PMCID: PMC8783477.

McMillan AM, Landorf KB, Gregg JM, De Luca J, Cotchett MP, Menz HB. Hyperemia in plantar fasciitis determined by power Doppler ultrasound. J Orthop Sports Phys Ther. 2013 Dec;43(12):875-80. doi: 10.2519/jospt.2013.4810. Epub 2013 Oct 11. PMID: 24175601.

Park YH, Kim HJ, Kim W, Choi JW. Reliability of Ultrasound Measurement of Plantar Fascia Thickness: A Systematic Review. J Am Podiatr Med Assoc. 2023 Jul-Aug;113(4):21-024. doi: 10.7547/21-024. PMID: 37715979.

Zhou B, Zhou Y, Tao X, Yuan C, Tang K. Classification of Calcaneal Spurs and Their Relationship With Plantar Fasciitis. J Foot Ankle Surg. 2015 Jul-Aug;54(4):594-600. doi: 10.1053/j.jfas.2014.11.009. Epub 2015 Mar 11. PMID: 25771476.

Aggarwal P, Jirankali V, Garg SK. Evaluation of plantar fascia using high-resolution ultrasonography in clinically diagnosed cases of plantar fasciitis. Pol J Radiol. 2020 Jul 24;85:e375-e380. doi: 10.5114/pjr.2020.97955. PMID: 32817771; PMCID: PMC7425221.

Implementatietabel

Aanbeveling 1: Overweeg beeldvorming bij diagnostische twijfel of indien de patiënt onvoldoende reageert op eerder ingestelde therapie. Echografie is de beeldvorming van eerste keuze.	Op basis van de beschikbare evidentie en ervaring uit de praktijk kon er onvoldoende richting aan de besluitvorming worden gegeven. Om die reden is er geen beschrijving van belemmeringen en kansen voor implementatie van de aanbeveling toegevoegd. Disseminatie van de kennis in deze module verloopt via de standaard route. De module wordt gepubliceerd op de Richtlijnendatabase.
Sub-aanbeveling 1 Overweeg een MRI-onderzoek alleen indien: • er discrepantie is tussen de uitslag van echografie en de klinische bevindingen; • een bijkomende specifieke diagnose wordt verwacht die niet middels echografie of een röntgenfoto te detecteren is; • er een operatieve ingreep wordt overwogen.	
Sub-aanbeveling 2 Overweeg een conventionele röntgenfoto alleen wanneer er een klinisch vermoeden is op een afwijking met andere etiologie (bijvoorbeeld een (stress)fractuur). • Voer geen conventionele röntgenfoto uit om een enthesofyt aan te tonen.	

Table of excluded studies

Reference	Reason for exclusion
ABDEL-WAHAB, N., Fathi, S., AL-EMADI, S., & Mahdi, S. (2008). High-resolution ultrasonographic diagnosis of plantar fasciopathy: a correlation of ultrasound and magnetic resonance imaging. International Journal of Rheumatic Diseases, 11(3), 279-286.	Wrong design (construct validity instead of case validity study)
Chithiravelu, S., Guhan, S. T., Aiyappan, S. K., Sai, D. R., & Mittal, H. (2023). Diagnostic Accuracy of Ultrasonography in Patients with Plantar Fasciitis: A Cross-sectional Study. *JOURNAL OF CLINICAL AND DIAGNOSTIC RESEARCH*, *17*(5), TC16-TC20.	Wrong population, inclusion based on plantar fascia thickness
Sabir N, Demirlenk S, Yagci B, Karabulut N, Cubukcu S. Clinical utility of sonography in diagnosing plantar fasciitis. J Ultrasound Med. 2005 Aug;24(8):1041-8. doi: 10.7863/jum.2005.24.8.1041. PMID: 16040817.	Wrong population, study inclusion based on positive MRI results
Fazal MA, Tsekes D, Baloch I. Is There a Role for MRI in Plantar Heel Pain. Foot Ankle Spec. 2018 Jun;11(3):242-245. doi: 10.1177/1938640017729493. Epub 2017 Sep 6. PMID: 28877593.	No comparator
Wu, J., Zhang, Yz., Gao, Y. et al. Assessment the reliability of ultrasonography in the imaging of the plantar fascia: a comparative study. BMC Med Imaging 19, 62 (2019). https://doi.org/10.1186/s12880-019-0361-1	Wrong population (healthy individuals)
Cheng JW, Tsai WC, Yu TY, Huang KY. Reproducibility of sonographic measurement of thickness and echogenicity of the plantar fascia. J Clin Ultrasound. 2012 Jan;40(1):14-9. doi: 10.1002/jcu.20903. Epub 2011 Nov 22. PMID: 22109854.	No comparator
Schneider HP, Baca JM, Carpenter BB, Dayton PD, Fleischer AE, Sachs BD. American College of Foot and Ankle Surgeons Clinical Consensus Statement: Diagnosis and Treatment of Adult Acquired Infracalcaneal Heel Pain. J Foot Ankle Surg. 2018 Mar-Apr;57(2):370-381. doi: 10.1053/j.jfas.2017.10.018. Epub 2017 Dec 25. PMID: 29284574.	Wrong study design (consensus statement
Şerban O, Fodor D, Papp I, Micu MC, Duma DG, Csutak C, Lenghel M, Bădărînză M, Albu A. Reasons for discordances between ultrasonography and magnetic resonance imaging in the evaluation of the ankle, hindfoot and heel of the patients with rheumatoid arthritis. Med Ultrason. 2019 Nov 24;21(4):405-413. doi: 10.11152/mu-2304. PMID: 31765448.	Wrong population

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Fasciopathie Plantaris - UV2 Beeldvorming	
Uitgangsvraag/modules: Welke plaats heeft beeldvorming (echografie of röntgenfoto) in het diagnostisch traject van patiënten met fasciopathie plantaris?	
Database(s): Embase.com, Ovid/Medline	Datum: 2 mei 2024
Periode: vanaf 2000	Talen: geen restrictie
Literatuurspecialist: Esther van der Bijl	Rayyan review: https://rayyan.ai/reviews/1019232
BMI-zoekblokken: voor verschillende opdrachten wordt (deels) gebruik gemaakt van de zoekblokken van BMI-Online https://blocks.bmi-online.nl/ Bij gebruikmaking van een volledig zoekblok zal naar de betreffende link op de website worden verwezen.	
Toelichting: Voor deze vraag is gezocht op de elementen fasciopathie plantaris EN (echografie OF röntgenfoto). → De volgende sleutelartikelen worden gevonden met deze search: • Drake C, Whittaker GA, Kaminski MR, Chen J, Keenan AM, Rathleff MS, Robinson P, Landorf KB. Medical imaging for plantar heel pain: a systematic review and meta-analysis. J Foot Ankle Res. 2022 Jan 22;15(1):4. doi: 10.1186/s13047-021-00507-2. PMID: 35065676; PMCID: PMC8783477 • Granado MJ, Lohman EB 3rd, Daher NS, Gordon KE. Effect of Gender, Toe Extension Position, and Plantar Fasciitis on Plantar Fascia Thickness. Foot Ankle Int. 2019 Apr;40(4):439-446. doi: 10.1177/1071100718811631. Epub 2018 Nov 9. PMID: 30413134. → Het volgende sleutelartikel valt uit op de P: er wordt in titel, abstract of keywords niet gesproken over het ziektebeeld, slechts over de plantaire facia.	

• Narindra LHRNO, Herinirina NF, Rakotonirina H, Andrianah GE, Ranoharison HD, Randriamboavonjy R, Ahmad A. Thickness of the Plantar Fascia in Asymptomatic Subjects. J Med Ultrasound. 2019 Feb 26;27(3):121-123. doi: 10.4103/JMU.JMU_72_18. PMID: 31867173; PMCID: PMC6905272. Valt uit op P: en diagnostisch filter in Embase
Te gebruiken voor richtlijntekst: In de databases Embase.com en Ovid/Medline is op 2 mei 2024 systematisch gezocht naar systematische reviews, RCTs en observationele studies over de plaats van beeldvorming (echografie of röntgenfoto) in het diagnostisch traject van patiënten met fasciopathie plantaris. De literatuurzoekactie leverde 886 unieke treffers op.

Zoekopbrengst 2 mei 2024

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	80	48	88
RCT	310	183	343
Observationeel	390	294	455
Totaal	780	525	**886***

****in Rayyan***

5 ***Zoekstrategie Embase.com 2 mei 2024***

No.	Query	Results
#1	'plantar fasciitis'/exp OR 'plantar fasciitis'/exp OR 'heel spur'/exp OR 'policeman heel'/exp OR (((calcane* OR heel* OR subcalcane*) NEAR/3 (spur* OR exostos* OR pain* OR policeman* OR jogger*)):ti,ab,kw) OR ((plant* NEAR/3 (fasciitis OR fasciopath* OR fascios* OR inflam*)):ti,ab,kw) OR (((baxter* OR plant* OR calcane* OR heel) NEAR/3 neuropath*):ti,ab,kw) OR calcaneodyn*:ti,ab,kw OR 'calcane* periostitis':ti,ab,kw	6416
#2	'ultrasound'/exp OR 'ultrasound scanner'/exp OR 'echography'/exp OR 'muscle ultrasonography'/exp OR 'muscle ultrasound'/exp OR ultraso*:ti,ab,kw OR sonograph*:ti,ab,kw OR echograph*:ti,ab,kw OR sonogram*:ti,ab,kw OR 'ultra so*':ti,ab,kw	1492041
#3	'x ray'/exp OR 'radiodiagnosis'/exp OR 'radiology'/exp OR 'radiography'/exp OR 'radiography device'/exp OR 'foot radiography'/exp OR ((bone* NEAR/3 (scan* OR imag*)):ti,ab,kw) OR 'x ray*':ti,ab,kw OR 'x foot':ti,ab,kw OR 'x feet':ti,ab,kw OR rontgen*:ti,ab,kw OR roentgen*:ti,ab,kw OR radiograph*:ti,ab,kw OR 'radiodiagnos*':ti,ab,kw OR radiolog*:ti,ab,kw	4444174
#4	#2 OR #3	5324373
#5	#1 AND #4	2074
#6	#5 AND [2000-2024]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	1412
#7	'meta-analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	1023902
#8	'clinical trial'/exp OR 'randomization'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR 'placebo'/exp OR 'prospective	4021209

	study'/exp OR rct:ab,ti OR random*:ab,ti OR 'single blind':ab,ti OR 'randomised controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti	
#9	'major clinical study'/de OR 'clinical study'/de OR 'case control study'/de OR 'family study'/de OR 'longitudinal study'/de OR 'retrospective study'/de OR 'prospective study'/de OR 'comparative study'/de OR 'cohort analysis'/de OR ((cohort NEAR/1 (study OR studies)):ab,ti) OR (('case control' NEAR/1 (study OR studies)):ab,ti) OR (('follow up' NEAR/1 (study OR studies)):ab,ti) OR (observational NEAR/1 (study OR studies)) OR ((epidemiologic NEAR/1 (study OR studies)):ab,ti) OR (('cross sectional' NEAR/1 (study OR studies)):ab,ti)	8196967
#10	'case control study'/de OR 'comparative study'/exp OR 'control group'/de OR 'controlled study'/de OR 'controlled clinical trial'/de OR 'crossover procedure'/de OR 'double blind procedure'/de OR 'phase 2 clinical trial'/de OR 'phase 3 clinical trial'/de OR 'phase 4 clinical trial'/de OR 'pretest posttest design'/de OR 'pretest posttest control group design'/de OR 'quasi experimental study'/de OR 'single blind procedure'/de OR 'triple blind procedure'/de OR (((control OR controlled) NEAR/6 trial):ti,ab,kw) OR (((control OR controlled) NEAR/6 (study OR studies)):ti,ab,kw) OR (((control OR controlled) NEAR/1 active):ti,ab,kw) OR 'open label*':ti,ab,kw OR (((double OR two OR three OR multi OR trial) NEAR/1 (arm OR arms)):ti,ab,kw) OR ((allocat* NEAR/10 (arm OR arms)):ti,ab,kw) OR placebo*:ti,ab,kw OR 'sham-control*':ti,ab,kw OR (((single OR double OR triple OR assessor) NEAR/1 (blind* OR masked)):ti,ab,kw) OR nonrandom*:ti,ab,kw OR 'non-random*':ti,ab,kw OR 'quasi-experiment*':ti,ab,kw OR crossover:ti,ab,kw OR 'cross over':ti,ab,kw OR 'parallel group*':ti,ab,kw OR 'factorial trial':ti,ab,kw OR ((phase NEAR/5 (study OR trial)):ti,ab,kw) OR ((case* NEAR/6 (matched OR control*)):ti,ab,kw) OR ((match* NEAR/6 (pair OR pairs OR cohort* OR control* OR group* OR healthy OR age OR sex OR gender OR patient* OR subject* OR participant*)):ti,ab,kw) OR ((propensity NEAR/6 (scor* OR match*)):ti,ab,kw) OR versus:ti OR vs:ti OR compar*:ti OR ((compar* NEAR/1 study):ti,ab,kw) OR (('major clinical study'/de OR 'clinical study'/de OR 'cohort analysis'/de OR 'observational study'/de OR 'cross-sectional study'/de OR 'multicenter study'/de OR 'correlational study'/de OR 'follow up'/de OR cohort*:ti,ab,kw OR 'follow up':ti,ab,kw OR followup:ti,ab,kw OR longitudinal*:ti,ab,kw OR prospective*:ti,ab,kw OR retrospective*:ti,ab,kw OR observational*:ti,ab,kw OR 'cross sectional*':ti,ab,kw OR cross?ectional*:ti,ab,kw OR multicent*:ti,ab,kw OR 'multi-cent*':ti,ab,kw OR consecutive*:ti,ab,kw) AND (group:ti,ab,kw OR groups:ti,ab,kw OR subgroup*:ti,ab,kw OR versus:ti,ab,kw OR vs:ti,ab,kw OR compar*:ti,ab,kw OR 'odds ratio*':ab OR 'relative odds':ab OR 'risk ratio*':ab OR 'relative risk*':ab OR 'rate ratio':ab OR aor:ab OR arr:ab OR rrr:ab OR ((('or' OR 'rr') NEAR/6 ci):ab)))	15035668
#11	#6 AND #7 – **SR's**	80
#12	#6 AND #8 NOT #11 – **RCT's**	310
#13	#6 AND (#9 OR #10) NOT (#11 OR #12) – **Observationele studies**	390
#14	#11 OR #12 OR #13	780

Zoekstrategie Ovid/Medline 2 mei 2024

#	Searches	Results
1	exp Fasciitis, Plantar/ or exp Heel Spur/ or ((calcane* or heel* or subcalcane*) adj3 (spur* or exostos* or pain* or policeman* or jogger*)).ti,ab,kf. or (plant* adj3 (fasciitis or fasciopath* or fascios* or inflam*)).ti,ab,kf. or ((baxter* or plant* or calcane* or heel) adj3 neuropath*).ti,ab,kf. or calcaneodyn*.ti,ab,kf. or calcane* periostitis.ti,ab,kf.	4448
2	exp Ultrasonography/ or exp Ultrasonics/ or exp Endosonography/ or ultraso*.ti,ab,kf. or sonograph*.ti,ab,kf. or echograph*.ti,ab,kf. or sonogram*.ti,ab,kf.	774922
3	exp X-Rays/ or exp Radiography/ or exp Radiology/ or (bone* adj3 (scan* or imag*)).ti,ab,kf. or x ray*.ti,ab,kf. or x foot.ti,ab,kf. or x feet.ti,ab,kf. or rontgen*.ti,ab,kf. or roentgen*.ti,ab,kf. or radiograph*.ti,ab,kf. or radiodiagnos*.ti,ab,kf. or radiolog*.ti,ab,kf.	1958457
4	2 or 3	2575211
5	1 and 4	1062
6	limit 5 to yr="2000 -Current"	880
7	6 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	850
8	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or	743109

	((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	
9	exp clinical trial/ or randomized controlled trial/ or exp clinical trials as topic/ or randomized controlled trials as topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial or multicenter study or clinical trial).pt. or random*.ti,ab. or (clinic* adj trial*).tw. or ((singl* or doubl* or treb* or tripl*) adj (blind$3 or mask$3)).tw. or Placebos/ or placebo*.tw.	2720194
10	Epidemiologic studies/ or case control studies/ or exp cohort studies/ or Controlled Before-After Studies/ or Case control.tw. or cohort.tw. or Cohort analy$.tw. or (Follow up adj (study or studies)).tw. or (observational adj (study or studies)).tw. or Longitudinal.tw. or Retrospective*.tw. or prospective*.tw. or consecutive*.tw. or Cross sectional.tw. or Cross-sectional studies/ or historically controlled study/ or interrupted time series analysis/ [Onder exp cohort studies vallen ook longitudinale, prospectieve en retrospectieve studies]	4714854
11	Case-control Studies/ or clinical trial, phase ii/ or clinical trial, phase iii/ or clinical trial, phase iv/ or comparative study/ or control groups/ or controlled before-after studies/ or controlled clinical trial/ or double-blind method/ or historically controlled study/ or matched-pair analysis/ or single-blind method/ or (((control or controlled) adj6 (study or studies or trial)) or (compar* adj (study or studies)) or ((control or controlled) adj1 active) or "open label*" or ((double or two or three or multi or trial) adj (arm or arms)) or (allocat* adj10 (arm or arms)) or placebo* or "sham-control*" or ((single or double or triple or assessor) adj1 (blind* or masked)) or nonrandom* or "non-random*" or "quasi-experiment*" or "parallel group*" or "factorial trial" or "pretest posttest" or (phase adj5 (study or trial)) or (case* adj6 (matched or control*)) or (match* adj6 (pair or pairs or cohort* or control* or group* or healthy or age or sex or gender or patient* or subject* or participant*)) or (propensity adj6 (scor* or match*))).ti,ab,kf. or (confounding adj6 adjust*).ti,ab. or (versus or vs or compar*).ti. or ((exp cohort studies/ or epidemiologic studies/ or multicenter study/ or observational study/ or seroepidemiologic studies/ or (cohort* or 'follow up' or followup or longitudinal* or prospective* or retrospective* or observational* or multicent* or 'multi-cent*' or consecutive*).ti,ab,kf.) and ((group or groups or subgroup* or versus or vs or compar*).ti,ab,kf. or ('odds ratio*' or 'relative odds' or 'risk ratio*' or 'relative risk*' or aor or arr or rrr).ab. or (("OR" or "RR") adj6 CI).ab.))	5679784
12	7 and 8 **– SR's**	48
13	(7 and 9) not 12 **– RCT's**	183
14	(7 and (10 or 11)) not (12 or 13) **– Observationele studies**	294
15	12 or 13 or 14	525

Module 3 Educatie

Search and select

A systematic review of the literature was performed to answer the following question:

Wat is de effectiviteit van het geven van educatie (bijvoorbeeld informatieverstrekking over de aandoening, prognose, leefstijladviezen) aan patiënten met fasciopathie plantaris?

Table 1. PICO

Patients	Patients with plantar fasciopathy
Intervention	Education (e.g. providing information on the disease, prognosis, lifestyle advise)
Comparator	Wait and see, placebo, other therapies
Outcomes	Function (e.g. disability index, FHSq, FADI) crucial, pain (e.g. VAS, BPI, NRS) (crucial), quality of life (e.g. EQ5D) (important), return to sport (important)

Relevant outcome measures

The guideline development group considered Function and pain as a **crucial** outcome measure for decision making; and quality of life and return to sport as an **important** outcome measure for decision making.

A priori, the working group did not define the outcome measures listed above but used the definitions used in the studies.

The working group defined a 10% difference for both continuous outcome measures and dichotomous outcome measures informing on relative risk (RR ≤ 0.91 and ≥ 1.1).

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until March 14th, 2024. The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 830 hits. Studies were selected based on the following criteria:

- Systematic Reviews (searched in at least two databases, and detailed search strategy, risk of bias assessment and results of individual studies available), randomized controlled trial, or observational comparative studies
- Full-text English language publication
- Studies including ≥ 20 (ten in each study arm) patients; and
- Studies according to the PICO.

Based on titles and abstracts, 24 studies were selected. After reading the full text, 23 studies were excluded (see the table with reasons for exclusion under the tab Methods), and one study was included.

Results

The assessment of the risk of bias is summarized in the risk of bias tables.

Reinstein (2024) included people with persistent heel pain (>12 months), but not necessarily diagnosed with plantar fasciitis. Participants were aged between 18 and 70 years, with a localized pain felt on the bottom of the heel, pain during first steps in the morning and a decrease in pain when no weight bearing. Patients were randomly allocated to either

barefoot walking or shod walking treatment sessions, which included by-weekly sessions of treadmill-walking and therapeutic ultrasound, supervised by a physical therapist.

Results

1. Function (crucial)

Reinstein (2024) measured function with the SF-36 using the function subscale (0-100, with higher scores indicating better function. They reported a mean difference post intervention of 9.10 (95% CI-0.56 to 18.76) and after 4 weeks 16.80 (95% CI 6.85 to 26.75) both favoring barefoot walking. However, only the difference after 4 weeks was clinically relevant.

2. Pain (crucial)

Reinstein (2024) reported on pain using a VAS (0-10). VAS mean difference post intervention was -1.30 (95% CI -2.42 to -0.18) and after 4 weeks -2 (-3.25 to -0.75) both favoring barefoot walking and clinically relevant.

3. Quality of life (important)

Reinstein (2024) reported on quality of life using different subscales of the SF-36. However, no overall score or mental/physical component score was reported.

4. Return to sport (important)

Reinstein (2024) did not report on return to sport.

Summary of literature

Description of studies

Study (year) **Study type**	**Intervention (26)**	**Characteristics**	**Control (26)**	**Characteristics**	**Outcomes of interest reported**	**FU**	**RoB**	**Considerations**
Reinstein, 2024	Barefoot walking	Age: mean 48 (range 31-67) %female: 76.9% VAS (0-10): 6.8 (2)	Shod walking	Age: mean 55 (range 30-69) %female: 73.1% VAS (0-10): 6.6 (1.9)	Pain	Post intervention and 4 weeks	Some concerns	-
Abbreviations: FFI: Foot Function Index, NR: Not reported, SD: standard deviation, VAS: visual analogue scale for pain (first step in the morning)								

Summary of Findings table: Education for plantar fasciopathy

Population: Patients with plantar fasciopathy

Intervention: Education

Comparator: Any

Outcome	**Study results and measurements**	**Absolute effect estimates**		**Certainty of the Evidence** (Quality of evidence)	**Conclusions**
		Placebo	Education		
Function (critical)	SF-36 function subscale (0-100, higher scores indicating better functioning) (Reinstein (2024) Based on data from 52 participants in 1 study	Reinstein (2024): mean difference post intervention: 9.10 (95% CI-0.56 to 18.76) and after 4 weeks 16.80 (95% CI 6.85 to 26.75) both favoring barefoot walking.		**Very low** Due to risk of bias[1] Due to indirectness[2] Due to imprecision[3]	The evidence is very uncertain about the effect of barefoot walking on pain when compared with shod walking in patients with plantar fasciopathy. *(Reinstein, 2024)*
Pain (critical)	VAS (0-10) post treatment and 4 weeks follow up (Reinstein, 2024). Based on data from 52 participants in 1 study	Reinstein (2024): VAS mean difference post intervention: -1.30 (95% CI -2.42 to -0.18) and after 4 weeks -2 (-3.25 to -0.75) both favoring barefoot walking.		**Very low** Due to risk of bias[1] Due to indirectness[2] Due to imprecision[4]	The evidence is very uncertain about the effect of barefoot walking on pain when compared with shod walking in patients with plantar fasciopathy. *(Reinstein, 2024)*
Quality of life (important)	-	-		**No GRADE** (no evidence was found)	No evidence was found regarding the effect of education when compared with wait-list or any intervention in patients with plantar fasciopathy.

Return to sport (important)	-	-	**No GRADE** (no evidence was found)	No evidence was found regarding the effect of education when compared with wait-list or any intervention in patients with plantar fasciopathy.

1. Since this was a patient reported outcome-measure, the fact that patients were not blinded in this study increases the risk of bias (-1, risk of bias)
2. Population in Reinstein (2024) with heel pain but not necessarily with the diagnosis plantar fasciitis (-1, indirectness).
3. At post intervention upper border of confidence interval overlaps with MCID, after 4 weeks the lower border of the confidence interval overlaps with MCID (-1, imprecision)
4. Upper level of 95% confidence interval overlapping with border MCID (-1, imprecision)

Kennisvragen

Wat is de effectiviteit van het geven van educatie (bijvoorbeeld informatieverstrekking over de aandoening, prognose, leefstijladviezen) aan patiënten met fasciopathie plantaris?

P	**(Patients)**	= Patients with plantar fasciopathy
I	**(Intervention)**	= Education (e.g. providing information on the disease, prognosis, lifestyle advise)
C	**(Comparison)**	= Wait and see, placebo, other therapies
O	**(Outcomes)**	= Function (e.g. disability index, FHSq, FADI) crucial, pain (e.g. VAS, BPI, NRS) (crucial), quality of life (e.g. EQ5D) (important), return to sport (important)

Literatuur

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Implementatietabel

<table>
<tr><td colspan="4">Aanbeveling – 1 Start bij de behandeling van patiënten met fasciopathie plantaris met educatie en personaliseer de inhoud van de educatie op basis van de patiënt:
1. Uitleg over de aandoening;
2. Uitleg over de prognose;
3. Geef uitleg over langdurige pijn (afwezigheid relatie weefselschade en mate van pijn, invloed van gedrag op pijn, effect van psychosociale factoren op pijn);
4. Geef belastingadviezen volgens het pain-monitoring model
5. Personaliseer het type schoeisel</td></tr>
<tr><td>1. Wat was het onderliggende probleem om deze uitgangsvraag uit te werken?</td><td colspan="3">▪ Ongewenste praktijkvariatie

Toelichting:
De werkgroepleden identificeren dat er inconsistentie is in de informatie die patiënten krijgen over fasciopathie plantaris. Deze variatie kan leiden tot verwarring, uiteenlopende adviezen van zorgverleners en verminderde effectiviteit van de behandeling. Een gestandaardiseerde educatieve aanpak zorgt ervoor dat patiënten eenduidige en betrouwbare informatie ontvangen, wat helpt bij het managen van verwachtingen en het optimaliseren van zelfmanagement.</td></tr>
<tr><td>2. Maak een inschatting over hoeveel patiënten het ongeveer gaat waar de aanbeveling betrekking op heeft?</td><td colspan="3">▪ 5000-40.000
□ > 40.000</td></tr>
<tr><td>3. Maakt de aanbeveling deel uit van een set van interventies voor hetzelfde probleem?</td><td colspan="3">▪ Ja:

hoe verhoudt deze aanbeveling zich tot de andere aanbevelingen uit deze module/ richtlijn of uit andere richtlijnen(modules)? Dient hier rekening mee gehouden te worden bij de implementatie of kan dit worden gezien als een losstaande aanbeveling?

Toelichting: Educatie is een essentieel onderdeel van de algehele behandelaanpak van fasciopathie plantaris. Het is geen op zichzelf staande behandeling, maar wordt in de praktijk vaak gecombineerd met andere conservatieve maatregelen, zoals oefenprogramma’s, steunzolen, ESWT, en injectie therapieën.

□ Nee</td></tr>
<tr><td>4. Belemmeringen en kansen op verschillende niveaus voor landelijke toepassing van de aanbeveling:</td><td>Voorbeelden</td><td>Wat zijn mogelijke belemmerende factoren?</td><td>Wat zijn mogelijke bevorderende factoren?</td></tr>
</table>

a) **Richtlijn/ klinisch traject (innovatie)**	*Voortschrijding/vooruitgang in de praktijk, haalbaarheid, geloofwaardigheid, toegankelijkheid, aantrekkelijkheid*	*Gebrek aan gestandaardiseerde educatiematerialen*	*Richtlijnondersteuning verhoogt de geloofwaardigheid van educatie*
b) **Zorgverleners (artsen en verpleegkundigen)**	*Bewustzijn, kennis, houding, motivatie om te veranderen, gedragsroutines*	*Beperkte consulttijd voor educatie*	*Bij- en nascholing voor zorgprofessionals*
c) **Patiënt/ cliënt (naasten)**	*Kennis, vaardigheden, houding, compliance*	*Lage gezondheidsvaardigheden bij een subgroep van patiënten*	*Beschikbaarheid van een breed pallet aan digitale educatiematerialen (bijvoorbeeld video's, brochures, apps) die zijn ontwikkeld in samenwerking met communicatie experts*
d) **Sociale context**	*Mening van collega's, cultuur van het netwerk, samenwerking, leiderschap*	*Tegenstrijdige adviezen van verschillende zorgverleners en vanuit het sociale netwerk van patiënten*	*Interdisciplinaire samenwerking voor uniforme educatie*
e) **Organisatorische context**	*Organisatie van zorgprocessen, personeel, capaciteiten, middelen, structuren*	*Beperkte middelen in de eerste- en tweede lijn zorg voor uitgebreide educatie*	*Opname in standaardzorgpaden in zowel de eerste als tweede lijn, zodat educatie structureel wordt aangeboden*
f) **Economische en politieke context**	*Financiële regelingen, regelgeving, beleid (vergoede zorg, betaaltitel)*	*Educatie is niet een losstaande interventie die wordt vergoed door zorgverzekeraars*	*Potentiële kostenbesparing op lange termijn door minder onnodige interventies*

5. Welke personen/partijen zijn van belang bij het toepassen van de aanbeveling in de praktijk?	■ Patiënt/ cliënt (naaste) ■ Professional ■ Beroepsvereniging ■ Ziekenhuis(bestuurder) ■ Zorgverzekeraars/ NZa ■ Zorginstituut [duiding nodig]
6. Wat zouden deze personen/ partijen moeten veranderen in hun gedrag of organisatie om de aanbeveling toe te passen?	*Patiënten dienen actief betrokken te worden bij zelfmanagement met toegankelijke materialen (bijvoorbeeld door ontwikkeling van standaard patiënt informatie materiaal).* *Zorgverleners moeten gestructureerde educatie opnemen in hun consultaties.* *Beroepsverenigingen moeten samen met de zorgverleners het initiatief nemen om betrouwbare en passende gestandaardiseerde educatiematerialen te ontwikkelen.* *Ziekenhuizen en praktijken moeten gestandaardiseerde educatiematerialen (geprint, online of video) integreren in de patiëntenzorg.* *Zorgverzekeraars zouden vergoeding van gestructureerde educatiesessies kunnen overwegen om therapietrouw te stimuleren en in de toekomst onnodige behandelingen te voorkomen.*
7. Binnen welk tijdsbestek moet de aanbeveling zijn geïmplementeerd?	■ < 3 jaar Scholing van zorgverleners om consistente educatie te bieden, dient binnen een jaar prioriteit te krijgen. De ontwikkeling en implementatie van standaard educatie materiaal (bijv. patiëntenbrochures, digitale materialen) zal meer tijd nodig hebben omdat er meerdere partijen bij betrokken moeten worden.
8. Conclusie: is er extra aandacht nodig voor implementatie van de aanbeveling (anders dan publicatie van deze richtlijnmodule)?	■ **Ja*** □ **Nee** **Toelichting:** Ontwikkeling van gestandaardiseerde educatiematerialen (zoals folders, video's, digitale tools) door zorgverleners, patiënten en communicatie experts. Stimuleren van interdisciplinaire samenwerking om consistente patiëntenvoorlichting te waarborgen.

	Evalueren van patiëntbegrip en therapietrouw en de impact daarvan op behandeluitkomsten en zorgconsumptie. Integratie in klinische werkprocessen, zodat educatie structureel onderdeel wordt van het zorgtraject.

**Deze aanbeveling komt in aanmerking voor plaatsing op de Implementatie Agenda van het programma Zorg Evaluatie & Gepast Gebruik (ZE&GG). In het programma ZE&GG werken patiënten, zorgverleners, zorgaanbieders, zorgverzekeraars en overheid samen aan de bewezen beste zorg voor de patiënt. Daarmee is ZE&GG een programma van alle betrokken partijen in de Medisch Specialistische Zorg. FMS is één van deze betrokken partijen.*

De implementatieagenda van ZE&GG bevat onderwerpen over wat de bewezen beste zorg is en die in de dagelijkse zorgpraktijk geïmplementeerd zouden moeten worden. Zorgverzekeraars Nederland (ZN) en de Nederlandse Vereniging voor Ziekenhuizen (NVZ) hebben landelijke afspraken gemaakt over de implementatie van de onderwerpen van de implementatieagenda. Deze afspraken zijn onderdeel van de zorginkoopafspraken tussen zorgverzekeraars en zorgaanbieders.

Vanuit FMS worden sterke, goed onderbouwde aanbevelingen, getoetst op de behoefte aan een implementatie impuls aangedragen. Voor de beoordeling van onderwerpen uit richtlijnen wordt gekeken naar bovenstaande tabel voor een inschatting van de implementatie impuls. Met de ingevulde implementatietabel kunnen we vanuit FMS de andere HLA-MSZ partijen goed informeren om zo samen te beslissen of de aanbeveling daadwerkelijk op de implementatie agenda zal worden geplaatst.

Risk of bias table

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?**	**Was the allocation adequately concealed?**	**Blinding: Was knowledge of the allocated interventions adequately prevented?**	**Was loss to follow-up (missing outcome data) infrequent?**	**Are reports of the study free of selective outcome reporting?**	**Was the study apparently free of other problems that could put it at a risk of bias?**	**Overall risk of bias** **If applicable/necessary, per outcome measure**
Reinstein, 2024	Probably yes, since envelopes were sealed and the trial assessor was blind for allocation, allocation could not be predicted	Definitely yes, concealed envelopes were used	The assessor was blinded, due to the nature of the intervention, patients and healthcare providers could not be blinded.	An intention to treat analysis was used, lost to follow-up was balanced between the groups. LOCF analysis was used.	All predefined outcomes were reported	No other sources of bias were found.	**LOW**

Table of excluded studies

Reference	Reason for exclusion
Schneider, H. P. and Baca, J. M. and Carpenter, B. B. and Dayton, P. D. and Fleischer, A. E. and Sachs, B. D.	Wrong study design, narrative review
Babatunde, O. O. and Legha, A. and Littlewood, C. and Chesterton, L. S. and Thomas, M. J. and Menz, H. B. and van der Windt, D. and Roddy, E.	NMA without education arm
Salvioli, S. and Guidi, M. and Marcotulli, G.	No education in individual studies (intervention or control)
Schuitema, D. and Greve, C. and Postema, K. and Dekker, R. and Hijmans, J. M.	No suitable outcome-measures reported
Heide, M. and Mørk, M. and Røe, C. and Brox, J. I. and Fenne Hoksrud, A.	Study protocol, no results
Guimarães, J. S. and Arcanjo, F. L. and Leporace, G. and Metsavaht, L. F. and Conceição, C. S. and Moreno, M. V. M. G. and Vieira, T. E. M. and Moraes, C. C. and Gomes Neto, M.	No studies matching with PICO, except for a possible match Ryan (2009) already found in search
Lourenço, B. M. and Campos, M. G. M. and Maia, L. and Castro, B. and Trede, R. G. and Oliveira, V. C.	No education in non-farmacological studies
Morrissey, D. and Cotchett, M. and Said J'Bari, A. and Prior, T. and Griffiths, I. B. and Rathleff, M. S. and Gulle, H. and Vicenzino, B. and Barton, C. J.	No education in individual studies (intervention or control)
Chesterton, L. S. and Thomas, M. J. and Hendry, G. and Chen, Y. and Goddin, D. and Halliday, N. and Lawton, S. A. and Lewis, M. and Mallen, C. D. and Menz, H. B. and Foster, N. E. and Roddy, E.	In all intervention-arms the self-management advice (SMA) booklet was provided, thus removing the effect of SMA out of the equation (between-group effects)
Rhim, Hye Chang and Kwon, Jangwon and Park, Jewel and Borg-Stein, Joanne and Tenforde, Adam S.	No education in individual studies (intervention or control)
Akter, S. and Hossain, M. S. and Hossain, K. M. A. and Uddin, Z. and Hossain, M. A. and Alom, F. and Kabir, M. F. and Walton, L. M. and Raigangar, V.	No education:the SDM approach included dorsiflexion strain and mobilization, the release of myofascial trigger points of the gastrocnemius and soleus.
Stuber, Kent and Kristmanson, Kevyn	Narrative review
Rasenberg, N. and Bierma-Zeinstra, S. M. A. and Fuit, L. and Rathleff, M. S. and Dieker, A. and van Veldhoven, P. and Bindels, P. J. E. and van Middelkoop, M.	The controlgroup included a non-surgical approach and any intervention the physician considered to be necessary for each particular patient. Included corticosteroid injection, or biomechanical interventions (heel cups)
Riel, H. and Vicenzino, B. and Olesen, J. L. and Bach Jensen, M. and Ehlers, L. H. and Rathleff, M. S.	In all intervention-arms the patients were provided with oral information and a leaflet, thus removing the effect of advice out of the equation (between-group effects)
Naruseviciute, D. and Kubilius, R.	Both interventions contained a single session of education, removing the possibility to compare the groups for effects of education
Ribeiro, A. P. and João, S. M. A.	Custom inlay sole compared to no inlay sole. Control-group was not randomized.
Çil, E. T. and Serif, T. and Şaylı, U. and Subaşı, F.	Patient education was received by both groups, removing the possibility to compare the groups for effects of education
Kamalakannan, M. and Earnest Philemon Dass, D.	Barefoot versus common footwear exercise, no education-intervention
Ryan, M. and Fraser, S. and McDonald, K. and Taunton, J.	Controlgroup <10 participants, study too small
Vicenzino, B. and McPoil, T. G. and Stephenson, A. and Paul, S. K.	Contoured sandal versus flip-flops versus contoured shoe inserts (foot-orthoses), no lifestyle advices or education
Çil, E. T. and Şaylı, U. and Subaşı, F.	Patient education was received by both groups, removing the possibility to compare the groups for effects of education
Crawford, F.	No mention of education/lifestyle advise
DiGiovanni, B. F. and Nawoczensk, D. A. and Lintal, M. E. and Moore, E. A. and Murray, J. C. and Wilding, G. E. and Baumhauer, J. F.	Patient education was received by both groups, removing the possibility to compare the groups for effects of education

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Fasciopathie Plantaris - UV3 Educatie	
Uitgangsvraag/modules: Wat is de plaats van educatie bij de behandeling van patiënten met fasciopathie plantaris?	
Database(s): Embase.com, Ovid/Medline	Datum: 14 maart 2024
Periode: vanaf 2000	Talen: geen restrictie
Literatuurspecialist: Esther van der Bijl	Rayyan review: https://rayyan.ai/reviews/964040
BMI-zoekblokken: voor verschillende opdrachten wordt (deels) gebruik gemaakt van de zoekblokken van BMI-Online https://blocks.bmi-online.nl/ Bij gebruikmaking van een volledig zoekblok zal naar de betreffende link op de website worden verwezen.	
Toelichting: Voor deze vraag is gezocht op de elementen fasciopathie plantaris EN educatie. → De sleutelartikelen PMID29954828, PMID37414460 en PMID33785535 worden gevonden met deze search.	
Te gebruiken voor richtlijntekst: In de databases Embase.com en Ovid/Medline is op 14 maart 2024 systematisch gezocht naar systematische reviews en RCTs over educatie bij de behandeling van patiënten met fasciopathie plantaris. De literatuurzoekactie leverde 830 unieke treffers op.	

Zoekopbrengst 14-3-2024

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	303	182	328
RCT	461	246	502
~~Observationeel~~			
Totaal	764	428	**830***

in Rayyan

Zoekstrategie Embase.com 14-3-2024

No.	Query	Results
#1	'plantar fasciitis'/exp OR 'plantar fasciopathy'/exp OR 'heel spur'/exp OR 'policeman heel'/exp OR (((calcane* OR heel* OR subcalcane*) NEAR/3 (spur* OR exostos* OR pain* OR policeman* OR jogger*)):ti,ab,kw) OR ((plant* NEAR/3 (fasciitis OR fasciopath* OR fascios* OR inflam*)):ti,ab,kw) OR (((baxter* OR plant* OR calcane* OR heel) NEAR/3 neuropath*):ti,ab,kw) OR calcaneodyn*:ti,ab,kw OR 'calcane* periostitis':ti,ab,kw	6351
#2	'disease management'/exp OR 'education'/exp OR 'health education'/exp OR 'patient education'/exp OR 'consumer health information'/exp OR 'medical information'/exp OR 'patient information'/exp OR 'self care'/exp OR 'prevention and control'/exp OR 'shoe'/exp OR (((disease* OR health* OR medical* OR patient* OR treatm*) NEAR/3 advice*):ti,ab,kw) OR management*:ti,ab,kw OR 'educat*':ti,ab,kw OR 'inform*':ti,ab,kw OR 'selfcare':ti,ab,kw OR 'selfmanag*':ti,ab,kw OR 'selftreatm*':ti,ab,kw OR 'self treatm*':ti,ab,kw OR prevent*:ti,ab,kw OR 'foot wear*':ti,ab,kw OR 'footwear*':ti,ab,kw OR 'shoe*':ti,ab,kw	12490812
#3	#1 AND #2	3018
#4	#3 AND [2000-2024]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	2128
#5	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR	1009552

	'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	
#6	'randomized controlled trial'/exp OR random*:ti,ab OR (((pragmatic OR practical) NEAR/1 'clinical trial*'):ti,ab) OR ((('non inferiority' OR noninferiority OR superiority OR equivalence) NEAR/3 trial*):ti,ab) OR rct:ti,ab,kw	2171445
#7	#4 AND #5 **– SR's**	303
#8	#4 AND #6 NOT #7 **– RCT's**	461
#9	#7 OR #8	764

Zoekstrategie Ovid/Medline 14-3-2024

#	Searches	Results
1	exp Fasciitis, Plantar/ or exp Heel Spur/ or ((calcane* or heel* or subcalcane*) adj3 (spur* or exostos* or pain* or policeman* or jogger*)).ti,ab,kf. or (plant* adj3 (fasciitis or fasciopath* or fascios* or inflam*)).ti,ab,kf. or ((baxter* or plant* or calcane* or heel) adj3 neuropath*).ti,ab,kf. or calcaneodyn*.ti,ab,kf. or calcane* periostitis.ti,ab,kf.	4405
2	exp Disease Management/ or exp Patient Education Handout/ or exp Health Education/ or exp "Patient Education as Topic"/ or exp Consumer Health Information/ or exp Self Care/ or exp Primary Prevention/ or exp Secondary Prevention/ or exp Tertiary Prevention/ or exp Shoes/ or ((disease* or health* or medical* or patient* or treatm*) adj3 advice*).ti,ab,kf. or management*.ti,ab,kf. or educat*.ti,ab,kf. or inform*.ti,ab,kf. or selfcare.ti,ab,kf. or selfmanag*.ti,ab,kf. or selftreatm*.ti,ab,kf. or self treatm*.ti,ab,kf. or prevent*.ti,ab,kf. or foot wear*.ti,ab,kf. or footwear*.ti,ab,kf. or shoe*.ti,ab,kf.	5734155
3	1 and 2	1414
4	limit 3 to yr="2000 -Current"	1238
5	4 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	1171
6	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	732357
7	exp randomized controlled trial/ or randomized controlled trials as topic/ or random*.ti,ab. or rct?.ti,ab. or ((pragmatic or practical) adj "clinical trial*").ti,ab,kf. or ((non-inferiority or noninferiority or superiority or equivalence) adj3 trial*).ti,ab,kf.	1696577
8	5 and 6 **– SR's**	182
9	(5 and 7) not 8 **– RCT's**	246
10	8 or 9	428

Module 4 Oefentherapie

Search and select

A systematic review of the literature was performed to answer the following question(s):

What is the effectiveness of strength and stretching related exercise therapy compared to placebo/ wait and see in patients with plantar fasciopathy?

Table 1. PICO

Patients	Patients with plantar fasciopathy
Intervention	Strength related exercise therapy and stretching related exercise therapy
Control	Placebo, wait and see
Outcomes	Pain (crucial), function (crucial), adverse events (crucial), return to sport (important), return to play (important)
Other selection criteria	Study design: systematic reviews, meta-analyses and randomized controlled trials

Relevant outcome measures

The guideline panel considered function, pain and adverse events as a **crucial** outcome measure for decision making; and return to sport / play as an **important** outcome measure for decision making.

A priori, the guideline panel did not define the outcome measures listed above but used the definitions used in the studies. The guideline panel was interested in a preferred follow-up period of at least 3 months.

The guideline panel defined 10% as a minimal clinically important difference for both continuous as well as dichotomous outcome measures. This includes a 10% difference on the outcome measurement on both a continuous scale or a Relative Risk (RR ≤ 0 .90 and ≥ 1.1).

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until 28 March2024. The detailed search strategy is listed under the tab 'Literature search strategy'. The systematic literature search resulted in 265 hits. Studies were selected based on the following criteria:

- Randomized controlled trials (RCTs), systematic reviews and/or meta-analyses;
- Studies according to the PICO;
- Studies including a minimum of 20 patients (10 patients per study arm);
- Full text English language publication.

Initially 26 studies were selected based on title and abstract screening. After reading the full text, 24 studies were excluded (see the exclusion table under the tab 'Bijlagen bij module 4'), and 2 RCTs were included.

Summary of literature

Description of studies

A total of 2 RCTs were included in the analysis of the literature. Radford (2007) Hyland (2006) Both studies assessed outcomes on pain and function for a stretching related exercise therapy vs placebo. Important study characteristics and results of the individual studies are

summarized in table 1. The assessment of the risk of bias is summarized in the risk of bias table (under the tab 'Bijlagen bij module 4').

Radford (2007) performed an RCT comparing calf muscle stretching and sham ultrasound as placebo in plantar fasciopathy. A total of 92 patients (46 per arm) of 18 years or older with plantar heel pain (localized pain at plantar heel which was worst when first standing or walking and that improved after first standing but worsened with increasing activity) having symptoms for ≥ 4 weeks, were included. Exclusion criteria were a history of any inflammatory, osseous, metabolic or neurological abnormalities or if they had received a corticosteroid injection within the past three months. Patients were recruited through local community newspaper advertisements (Campbelltown, Sydney Australia). Relevant outcome measures included pain (VAS score) and function (Foot Health Status Questionnaire (FHSQ); which measures function as interference with daily activities, foot condition, footwear and pain) at baseline and 2 weeks follow up.

Hyland (2006) performed an RCT comparing plantar fascia stretching and calcaneal taping, sham taping or no treatment in plantar fasciopathy. A total of 40 patients (10 per arm) with plantar heel pain (pain located at the heel or plantar surface of midfoot that occurred with first steps upon waking and presence of an everted calcaneus ≥2°) were included. Patients were excluded in case of previous surgery or treatment for plantar fasciopathy in the previous 6 months (including pain or anti-inflammatory medication), history of ankle or foot fracture, congenital deformity of the foot or ankle, spasticity throughout the lower extremity, use of assistive device for ambulation, having bilateral plantar heel pain or when they refused to participate in the study. Patients were recruited via fliers placed in local gymnasiums and physician offices (Manhattan, New Your, USA). Relevant outcome measures included pain (VAS score) and function (Patient Specific Functional Scale (PSFS); which measures ability to perform activities) at baseline and 1 week follow up. The calcaneal taping and sham taping groups were excluded and only the 'no treatment' group was included in the literature analysis.

Table 1. Characteristics of included studies

RCT (author, year, country)	Intervention	Participants (number, age, sex, duration of symptoms) Results	Control	Participants (number, age, sex, duration of symptoms)	Outcome measures	Follow-up	Risk of bias (per outcome measure)*	Remarks
Radford (2007) Australia	Calf stretching in standing on a wooden stretching wedge, at least 5 min a day for 14 days with sham ultrasound	N at baseline: 46 Age (mean ± sd) 50.7 ± 11.8 Sex: 32.6% male Duration of symptoms: (median; range) 13; 4 to 61 months	Placebo (sham ultrasound)	N at baseline: 46 Age (mean ± sd) 50.1 ± 11.0 Sex: 45.7% male Duration of symptoms: (median; range) 13; 3 to 121 months	Pain (VAS); scale 0–100 Function (FHSQ); scale 0-100	Baseline, 2 weeks	Some concerns (all outcome measures)	10 participants in the stretching group experienced advers events (mostly mild to moderate and short-lived)
Hyland (2006) USA	Passive calf and plantar fascia stretching, 30 s for 3 times. 2 sessions in 4 days	N at baseline:10 Age (mean ± sd) 34.1 ± 5.9 Sex: 80% male Duration of symptoms: not reported	Placebo (no treatment)	N at baseline: 10 Age (mean ± sd) 37.6 ± 10.1 Sex: 30% male Duration of symptoms: not reported	Pain (VAS); scale 0-10 Function (PSFS): scale 0-10	Baseline, 1 week	Some concerns (all outcome measures)	Additional arms (calcaneal taping & sham taping) not included

*For further details, see risk of bias table in the appendix

Results

1. Pain (crucial)

Both studies reported on pain using the VAS (Visual Analogue Score). Higher scores indicated more pain. The studies Radford (2007) and Hyland (2006) included a total of 56 patients in the stretching related exercise group and 56 patients in the placebo (sham ultrasound or no treatment) group. As Radford (2007) assessed pain on a 100-point VAS, these results were divided by 10 to pool the results. Results are summarized and pooled in figure 1 and are presented in a Summary of Findings table, including the level of evidence, using GRADE (table 4). This is a clinically relevant difference in favor of stretching related exercise.

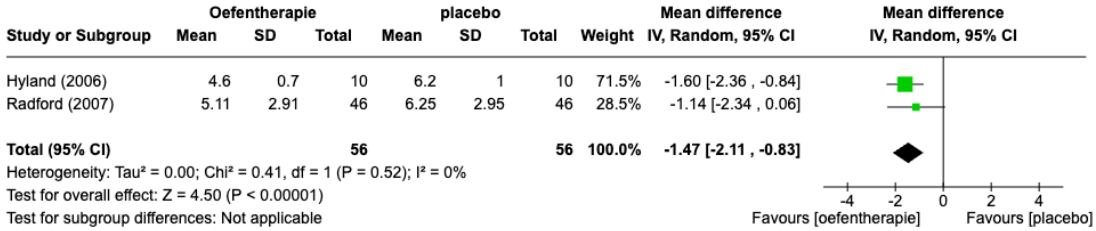


Figure 1. pooled effect difference in pain between stretching related exercise and placebo

2. Function (crucial)

Both studies used different scales to report on function: the FHSQ (Foot Health Status Questionnaire on foot function) and the PSFS (Patient specific functional scale). Higher scores indicated better function. The studies Radford (2007) and Hyland (2006) included a total of 56 patients in the stretching related exercise group and 56 patients in the placebo (sham ultrasound or no treatment) group. Due to the limited number of studies and use of different measurement scales, data were not pooled. Results are summarized and pooled using a standardized mean difference (SMD) in figure 2 and are presented in a Summary of Findings table, including the level of evidence, using GRADE (table 4).

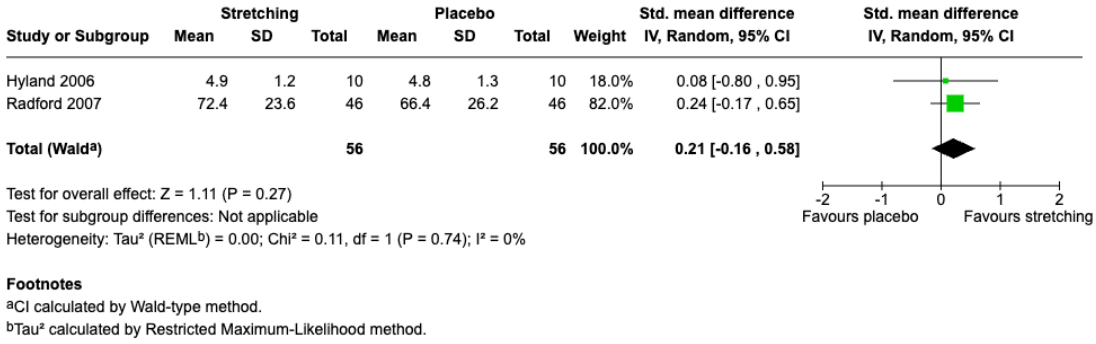


Figure 2. pooled effect difference in function between stretching related exercise and placebo

3. Adverse events (crucial)

Radford (2007) described the occurrence of adverse events in 22% (10 patients) in the stretching group. This was defined as an increase in pain but were recorded as mostly mild to moderate and mostly short lived. One participant discontinued treatment (stretching) due to severe pain after which the adverse events resolved. With no adverse events in the control group. Hyland (2006) didn't report any adverse events.

4. Return to sport/return to play (important)

No studies reported on the effect of strength or stretching related exercises on return to sport or return to play.

Summary of Findings

Table 4: Summary of findings table including GRADE

Outcome	Study results and measurements	Absolute effect estimates*		Certainty of evidence (GRADE)	Conclusions
		Stretching related exercise	Placebo		
Pain (crucial)	Measured by VAS on a 0-10 scale or 0-100 scale. Lower better Based on 2 studies including data from 112 patients	Radford (2007), VAS 0-100 scale, reported a mean difference of -11.40 (95% CI: -23.37 lower to 0.57 higher) Hyland (2006), VAS 0-10 scale, reported a mean difference of -1.60(95% CI: -2.36 lower to -0.84 lower) All results were in favor of the stretching related exercise group.		**VERY LOW** Due to risk of bias, due to indirectness, due to imprecision[1]	The evidence is very uncertain about the effect of stretching related exercises on pain when compared with placebo in patients with plantar fasciopathy. Radford (2007), Hyland (2006)
Function (crucial)	Measured by FHSQ (0-100 scale) or PSFS scores (0-10 scale) – higher better Based on 2 studies including data from 112 patients	Difference: **SMD 0.21 higher** (CI 95% 0.16 lower - 0.58 higher) All results were in favor of the stretching related exercise group.		**VERY LOW** Due to risk of bias, due to indirectness, due to serious imprecision[2]	The evidence is very uncertain about the effect of stretching related exercises on function when compared with placebo in patients with plantar fasciopathy. Radford (2007), Hyland (2006)
Adverse events (crucial)	Radford	Radford (2007) reported the occurrence of increased pain in 22% of patients in the exercise treatment group and none in the placebo group.		**No GRADE**	No evidence was found regarding the effect of strength or stretching related exercises on adverse events when compared with placebo in patients with plantar fasciopathy.
Return to sport/play (important)	No studies	-		**No GRADE**	No evidence was found regarding the effect of strength or stretching related exercises on return to sport/play when compared with placebo in patients with plantar fasciopathy.

Reasons for downgrading certainty of evidence (levels of downgrading -1 or -2)

1. Risk of Bias: Potential roB, mainly due to lack of detailed information on allocation, blinding (-1 level)
   Indirectness: downgraded due to indirectness caused by short follow-up. Follow-up is 1-2 weeks instead of at least 8 weeks (-1 level)
   Imprecision: serious imprecision: due to overlap of the 95% CI with the minimal clinically important difference, i.e. not showing clear and/ or meaningful clinical benefits or harms (-1 level)
2. Risk of Bias: Potential roB, mainly due to lack of detailed information on allocation, blinding (-1 level)
   Indirectness: downgraded due to indirectness caused by short follow-up. Follow-up is 1-2 weeks instead of at least 8 weeks (-1 level)
   Imprecision: serious imprecision: due to overlap of the 95% CI with the minimal clinically important difference, i.e. not showing clear and/ or meaningful clinical benefits or harms and small study sizes (-2 levels)

Kennisvragen

Tijdens de ontwikkeling van deze module is systematisch naar onderzoeken gezocht die de zoekvraag kunnen beantwoorden. Door gebruik te maken van een systematische literatuuranalyse met beoordeling van de bewijskracht is duidelijk geworden dat er binnen deze module nog kennisvragen bestaan. De werkgroep meent dat (vervolg)onderzoek wenselijk is om in de toekomst een duidelijker antwoord te kunnen geven op vragen uit de praktijk.

Kennisvraag:

What is the effectiveness of strength and stretching related exercise therapy compared to placebo/ wait and see in patients with plantar fasciopathy?

Table 1. PICO

Patients	Patients with plantar fasciopathy
Intervention	Strength related exercise therapy and stretching related exercise therapy
Control	Placebo, wait and see
Outcomes	Pain, function, adverse events, return to sport , return to play, return to work

Literatuur

Bassett S. The assessment of patient adherence to physiotherapy rehabilitation. N Z J Physiother. 2003;31:60-66.

Digiovanni BF, Nawoczenski DA, Malay DP, Graci PA, Williams TT, Wilding GE, Baumhauer JF. 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. doi: 10.2106/JBJS.E.01281. PMID: 16882901.

Hyland MR, Webber-Gaffney A, Cohen L, Lichtman PT. Randomized controlled trial of calcaneal taping, sham taping, and plantar fascia stretching for the short-term management of plantar heel pain. J Orthop Sports Phys Ther. 2006 Jun;36(6):364-71. doi: 10.2519/jospt.2006.2078. PMID: 16776486.

Jack K, McLean SM, Moffett JK, Gardiner E. Barriers to treatment adherence in physiotherapy outpatient clinics: a systematic review. Man Ther. 2010 Jun;15(3):220-8. doi: 10.1016/j.math.2009.12.004. Epub 2010 Feb 16. PMID: 20163979; PMCID: PMC2923776.

Koc TA Jr, Bise CG, Neville C, Carreira D, Martin RL, McDonough CM. Heel Pain - Plantar Fasciitis: Revision 2023. J Orthop Sports Phys Ther. 2023 Dec;53(12):CPG1-CPG39. doi: 10.2519/jospt.2023.0303. PMID: 38037331.

Morrissey D, Cotchett M, Said J'Bari A, Prior T, Griffiths IB, Rathleff MS, Gulle H, Vicenzino B, Barton CJ. Management of plantar heel pain: a best practice guide informed by a systematic review, expert clinical reasoning and patient values. Br J Sports Med. 2021 Oct;55(19):1106-1118. doi: 10.1136/bjsports-2019-101970. Epub 2021 Mar 30. PMID: 33785535; PMCID: PMC8458083.

Radford JA, Landorf KB, Buchbinder R, Cook C. Effectiveness of calf muscle stretching for the short-term treatment of plantar heel pain: a randomised trial. BMC Musculoskelet Disord. 2007 Apr 19;8:36. doi: 10.1186/1471-2474-8-36. PMID: 17442119; PMCID: PMC1867816.

Riel H, Griffiths I, Heide M, Morrissey D, Mørk M, Prior T, Rathleff MS. Reinterpreting the Clinical Practice Guidelines for Plantar Heel Pain Through an International Lens. J Orthop Sports Phys Ther. 2025 Jan;55(1):72-73. doi: 10.2519/jospt.2025.0202. PMID: 39741456.

Siriphorn A, Eksakulkla S. Calf stretching and plantar fascia-specific stretching for plantar fasciitis: A systematic review and meta-analysis. J Bodyw Mov Ther. 2020 Oct;24(4):222-232. doi: 10.1016/j.jbmt.2020.06.013. Epub 2020 Jul 30. PMID: 33218515.

Implementatietabel

Aanbeveling – 1	Adviseer patiënten met fasciopathie plantaris ofwel dagelijkse rekoefeningen of opbouwende krachtoefeningen (om de dag) als onderdeel van de conservatieve behandeling voor tenminste 12 weken. Maak de keuze voor rekoefeningen of krachtoefeningen door de voorkeuren, doelen, verwachte therapietrouw en dagelijkse activiteiten van de patiënt gezamenlijk in kaart te brengen. Bespreek met de patiënt de mogelijkheden om de motivatie voor het uit blijven voeren van de oefeningen hoog te houden. Dit kan door de patiënt een dagboek te laten bijhouden, gebruik te maken van ondersteunende e-health applicaties of door begeleiding van een zorgverlener. Bespreek dat de patiënt vermindering in pijn en verbetering in functie kan verwachten binnen 12 weken, maar dat het grootste deel van de patiënten in deze periode nog niet volledig klachtenvrij is.
1. Wat was het onderliggende probleem om deze uitgangsvraag uit te werken?	**X Ongewenste praktijkvariatie** □ **Nieuwe evidentie** □ **Anders** **Toelichting:** De werkgroepleden identificeren dat er inconsistentie is in de wijze waarop rek- en krachtoefeningen worden verstrekt. Deze variatie kan leiden tot suboptimale behandelresultaten.
2. Maak een inschatting over hoeveel patiënten het ongeveer gaat waar de aanbeveling betrekking op heeft?	□ **< 1000** □ **< 5000** *X* **5000-40.000** □ **> 40.000**
3. Maakt de aanbeveling deel uit van een set van interventies voor hetzelfde probleem?	**X Ja**: **Toelichting:** Rek- en krachtoefeningen zijn laagdrempelig en worden vaak in combinatie met andere therapievormen meegegeven. □ **Nee**

4. Belemmeringen en kansen op verschillende niveaus voor landelijke toepassing van de aanbeveling:	***Voorbeelden***	**Wat zijn mogelijke belemmerende factoren?**	**Wat zijn mogelijke bevorderende factoren?**
a) **Richtlijn/ klinisch traject (innovatie)**	*Voortschrijding/vooruitgang in de praktijk, haalbaarheid, geloofwaardigheid, toegankelijkheid, aantrekkelijkheid*	*Gebrek aan gestandaardiseerde hulpmiddelen zoals instructievideo's.*	*Richtlijnondersteuning verhoogt de geloofwaardigheid van oefentherapie*
b) **Zorgverleners (artsen en verpleegkundigen)**	*Bewustzijn, kennis, houding, motivatie om te veranderen, gedragsroutines*	*Beperkte consulttijd om de oefeningen goed uit te leggen en uitvoering te controleren.*	*Bij- en nascholing voor zorgprofessionals*
c) **Patiënt/ cliënt (naasten)**	*Kennis, vaardigheden, houding, compliance*	*Gebrek aan discipline om 12 weken oefeningen uit te voeren.*	*Eenduidigheid in adviezen.*
d) **Sociale context**	*Mening van collega's, cultuur van het netwerk, samenwerking, leiderschap*	*Bij eerder gefaalde oefentherapie in de eerstelijn wellicht lastig om patiënt te overtuigen weer 12 weken te gaan oefenen.*	*Interdisciplinaire samenwerking voor uniform voorschrijven oefentherapie.*
e) **Organisatorische context**	*Organisatie van zorgprocessen, personeel, capaciteiten, middelen, structuren*	*Beperkte educatieve middelen voor hulp bij uitvoering van oefeningen.*	*Opname in standaardzorgpaden in zowel de eerste als tweede lijn, zodat oefentherapie structureel wordt aangeboden*
f) **Economische en politieke context**	*Financiële regelingen, regelgeving, beleid (vergoede zorg, betaaltitel)*	*Wanneer het gewenst is om oefentherapie onder supervisie uit te laten voeren dan komen daar kosten bij voor de patiënt.*	*Potentiële kostenbesparing op lange termijn door minder onnodige interventies*

5. Welke personen/partijen zijn van belang bij het toepassen van de aanbeveling in de praktijk?	■ Patiënt/ cliënt (naaste) ■ Professional ■ Beroepsvereniging ■ Ziekenhuis(bestuurder) ■ Zorgverzekeraars/ NZa ■ Zorginstituut [duiding nodig]
6. Wat zouden deze personen/ partijen moeten veranderen in hun gedrag of organisatie om de aanbeveling toe te passen?	*Patiënten dienen actief betrokken te worden bij zelfmanagement met toegankelijke materialen (bijvoorbeeld door ontwikkeling van standaard patiënt informatie materiaal).* *Zorgverleners moeten oefentherapie in hun consultaties opnemen, ook al heeft eerdere oefentherapie in de eerstelijns praktijk geen effect gehad.* *Beroepsverenigingen moeten samen met de zorgverleners het initiatief nemen om betrouwbare en passende gestandaardiseerde hulpmiddelen (video instructies) te ontwikkelen.* *Ziekenhuizen en praktijken moeten gestandaardiseerde educatiematerialen (geprint, online of video) t.a.v. oefentherapie integreren in de patiëntenzorg.* *Zorgverzekeraars zouden vergoeding van gestructureerde gesuperviseerde oefentherapie kunnen overwegen om therapietrouw te stimuleren en in de toekomst onnodige behandelingen te voorkomen.*
7. Binnen welk tijdsbestek moet de aanbeveling zijn geïmplementeerd?	☐ < 1 jaar ☐ < 2 jaar X < 3 jaar
8. Conclusie: is er extra aandacht nodig voor implementatie van de aanbeveling (anders dan publicatie van deze richtlijnmodule)?	☐ **Ja*** ☐ **Nee** **Toelichting:** Ontwikkeling van gestandaardiseerde materialen (zoals folders, video's, digitale tools) door zorgverleners. Stimuleren van interdisciplinaire samenwerking om consistente patiëntenvoorlichting te waarborgen. Evalueren van patiëntbegrip en therapietrouw en de impact daarvan op behandeluitkomsten en zorgconsumptie.

**Deze aanbeveling komt in aanmerking voor plaatsing op de Implementatie Agenda van het programma Zorg Evaluatie & Gepast Gebruik (ZE&GG). In het programma ZE&GG werken patiënten, zorgverleners, zorgaanbieders, zorgverzekeraars en overheid samen aan de bewezen beste zorg voor de patiënt. Daarmee is ZE&GG een programma van alle betrokken partijen in de Medisch Specialistische Zorg. FMS is één van deze betrokken partijen.*

De implementatieagenda van ZE&GG bevat onderwerpen over wat de bewezen beste zorg is en die in de dagelijkse zorgpraktijk geïmplementeerd zouden moeten worden. Zorgverzekeraars Nederland (ZN) en de Nederlandse Vereniging voor Ziekenhuizen (NVZ) hebben landelijke afspraken gemaakt over de implementatie van de onderwerpen van de implementatieagenda. Deze afspraken zijn onderdeel van de zorginkoopafspraken tussen zorgverzekeraars en zorgaanbieders.

Vanuit FMS worden sterke, goed onderbouwde aanbevelingen, getoetst op de behoefte aan een implementatie impuls aangedragen. Voor de beoordeling van onderwerpen uit richtlijnen wordt gekeken naar bovenstaande tabel voor een inschatting van de implementatie impuls. Met de ingevulde implementatietabel kunnen we vanuit FMS de andere HLA-MSZ partijen goed informeren om zo samen te beslissen of de aanbeveling daadwerkelijk op de implementatie agenda zal worden geplaatst.

Risk of Bias tables

Table 5: Risk of bias table for intervention studies (randomized controlled trials; based on Cochrane risk of bias tool and suggestions by the CLARITY Group at McMaster University)

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?**	**Was the allocation adequately concealed?**	**Blinding: Was knowledge of the allocated interventions adequately prevented? |Were patients blinded? | Were healthcare providers blinded? | Were data collectors blinded? | Were outcome assessors blinded? | Were data analysts blinded?**	**Was loss to follow-up (missing outcome data) infrequent?**	**Are reports of the study free of selective outcome reporting?**	**Was the study apparently free of other problems that could put it at a risk of bias?**	**Overall risk of bias** **If applicable/necessary, per outcome measure** **LOW/Some concerns/ HIGH**
Radford (2007)	Definitely yes Reason: random allocation generated using computer programming	Definitely yes Reason: allocation with sealed envelopes	Probably no Reason: patients blinded but high rate identified their group status, researchers not blinded and data collectors an outcome assessor partly	Probably yes Reason: there were no patients lost to follow up, yet 1 patient discontinued treatment	Definitely yes, Reason: all relevant outcomes were reported	Probably no Reason: 22% of patients in intervention group experienced adverse events	Some concerns (all outcome measures) Reason: no adequate blinding and adverse events in the intervention group
Hyland (2006)	Probably yes	Probably no	Definitely no	Probably yes	Probably yes,	Probably yes	Some concerns (all outcome measures)

	Reason: patients randomly assigned using a random number table	Reason: no information provided on allocation concealment	Reason: only patients in the calcaneal and sham taping group were blinded, no other description of blinding	Reason: there was no report on loss to follow up, 1 patient dropped out, however no details presented	Reason: all relevant outcomes were reported but no detailed information provided in methodology	Reason: seems no other risks of biases but detailed information is lacking	Reason: Unclear allocation concealment and no blinding procedure

Table of excluded studies

Reference	Reason for exclusion
Siriphorn A, Eksakulkla S. Calf stretching and plantar fascia-specific stretching for plantar fasciitis: A systematic review and meta-analysis. J Bodyw Mov Ther. 2020 Oct;24(4):222-232. doi: 10.1016/j.jbmt.2020.06.013. Epub 2020 Jul 30. PMID: 33218515.	Systematic review that included the same RCTs that were already included, additional RCTS assessed wrong comparison
Sweeting D, Parish B, Hooper L, Chester R. The effectiveness of manual stretching in the treatment of plantar heel pain: a systematic review. J Foot Ankle Res. 2011 Jun 25;4:19. doi: 10.1186/1757-1146-4-19. PMID: 21703003; PMCID: PMC3150253.	Systematic review that included the same RCTs that were already included, additional RCTS assessed wrong comparison
Salvioli S, Guidi M, Marcotulli G. The effectiveness of conservative, non-pharmacological treatment, of plantar heel pain: A systematic review with meta-analysis. Foot (Edinb). 2017 Dec;33:57-67. doi: 10.1016/j.foot.2017.05.004. Epub 2017 Jun 15. PMID: 29126045.	Systematic review that included the same RCTs that were already included, additional RCTS assessed wrong comparison
Babatunde OO, Legha A, Littlewood C, Chesterton LS, Thomas MJ, Menz HB, van der Windt D, Roddy E. Comparative effectiveness of treatment options for plantar heel pain: a systematic review with network meta-analysis. Br J Sports Med. 2019 Feb;53(3):182-194. doi: 10.1136/bjsports-2017-098998. Epub 2018 Jun 28. PMID: 29954828.	Wrong Intervention (different types/combinations)
Rhim HC, Kwon J, Park J, Borg-Stein J, Tenforde AS. A Systematic Review of Systematic Reviews on the Epidemiology, Evaluation, and Treatment of Plantar Fasciitis. Life (Basel). 2021 Nov 24;11(12):1287. doi: 10.3390/life11121287. PMID: 34947818; PMCID: PMC8705263.	Wrong design (assessment of risk factors)
Landorf KB, Menz HB. Plantar heel pain and fasciitis. BMJ Clin Evid. 2008 Feb 5;2008:1111. PMID: 19450330; PMCID: PMC2907928.	Wrong intervention ((different types/combinations)
Landorf KB. Plantar heel pain and plantar fasciitis. BMJ Clin Evid. 2015 Nov 25;2015:1111. PMID: 26609884; PMCID: PMC4661045.	Wrong intervention (different types/combinations)
Morrissey D, Cotchett M, Said J'Bari A, Prior T, Griffiths IB, Rathleff MS, Gulle H, Vicenzino B, Barton CJ. Management of plantar heel pain: a best practice guide informed by a systematic review, expert clinical reasoning and patient values. Br J Sports Med. 2021 Oct;55(19):1106-1118. doi: 10.1136/bjsports-2019-101970. Epub 2021 Mar 30. PMID: 33785535; PMCID: PMC8458083.	Wrong intervention (different types /combinations)
Guimarães JS, Arcanjo FL, Leporace G, Metsavaht LF, Conceição CS, Moreno MVMG, Vieira TEM, Moraes CC, Gomes Neto M. Effects of therapeutic interventions on pain due to plantar fasciitis: A systematic review and meta-analysis. Clin Rehabil. 2023 Jun;37(6):727-746. doi: 10.1177/02692155221143865. Epub 2022 Dec 26. PMID: 36571559.	Wrong intervention (different types /combinations)
Boob MA Jr, Phansopkar P, Somaiya KJ. Physiotherapeutic Interventions for Individuals Suffering From Plantar Fasciitis: A Systematic Review. Cureus. 2023 Jul 31;15(7):e42740. doi: 10.7759/cureus.42740. PMID: 37654968; PMCID: PMC10467524.	Wrong intervention (different types /combinations)
Huffer D, Hing W, Newton R, Clair M. Strength training for plantar fasciitis and the intrinsic foot musculature: A systematic review. Phys Ther Sport. 2017 Mar;24:44-52. doi: 10.1016/j.ptsp.2016.08.008. Epub 2016 Aug 18. PMID: 27692740.	Wrong intervention (different types /combinations)
Cole C, Seto C, Gazewood J. Plantar fasciitis: evidence-based review of diagnosis and therapy. Am Fam Physician. 2005 Dec 1;72(11):2237-42. PMID: 16342847.	Wrong design (narrative review)
Assad S, Ahmad A, Kiani I, Ghani U, Wadhera V, Tom TN. Novel and Conservative Approaches Towards Effective Management of Plantar Fasciitis. Cureus. 2016 Dec 5;8(12):e913. doi: 10.7759/cureus.913. PMID: 28083457; PMCID: PMC5215813.	Wrong design (narrative review)
Cutts S, Obi N, Pasapula C, Chan W. Plantar fasciitis. Ann R Coll Surg Engl. 2012 Nov;94(8):539-42. doi: 10.1308/003588412X13171221592456. PMID: 23131221; PMCID: PMC3954277.	Wrong design (narrative review)

Stuber K, Kristmanson K. Conservative therapy for plantar fasciitis: a narrative review of randomized controlled trials. J Can Chiropr Assoc. 2006 Jun;50(2):118-33. PMID: 17549177; PMCID: PMC1839987.	Wrong design (narrative review)
Crawford F, Thomson C. Interventions for treating plantar heel pain. Cochrane Database Syst Rev. 2003;(3):CD000416. doi: 10.1002/14651858.CD000416. Update in: Cochrane Database Syst Rev. 2010 Jan 20;(1):CD000416. doi: 10.1002/14651858.CD000416.pub2. PMID: 12917892	Study rejected
Díaz López AM, Guzmán Carrasco P. Efectividad de distintas terapias físicas en el tratamiento conservador de la fascitis plantar: revisión sistemática [Effectiveness of different physical therapy in conservative treatment of plantar fasciitis: systematic review]. Rev Esp Salud Publica. 2014 Jan-Feb;88(1):157-78. Spanish. doi: 10.4321/S1135-57272014000100010. PMID: 24728397.	Wrong language (Spanish)
Lafuente Guijosa A, O'mullony Muñoz I, de La Fuente ME, Cura-Ituarte P. Fascitis plantar: revisión del tratamiento basado en la evidencia [Plantar fascitis: evidence-based review of treatment]. Reumatol Clin. 2007 Jul;3(4):159-65. Spanish. doi: 10.1016/S1699-258X(07)73614-8. Epub 2008 Nov 13. PMID: 21794421.	Wrong language (Spanish)
Kamonseki DH, Gonçalves GA, Yi LC, Júnior IL. Effect of stretching with and without muscle strengthening exercises for the foot and hip in patients with plantar fasciitis: A randomized controlled single-blind clinical trial. Man Ther. 2016 Jun;23:76-82. doi: 10.1016/j.math.2015.10.006. Epub 2015 Oct 30. PMID: 26654252.	Wrong control group (no comparison group)
Rompe JD, Furia J, Cacchio A, Schmitz C, Maffulli N. Radial shock wave treatment alone is less efficient than radial shock wave treatment combined with tissue-specific plantar fascia-stretching in patients with chronic plantar heel pain. Int J Surg. 2015 Dec;24(Pt B):135-42. doi: 10.1016/j.ijsu.2015.04.082. Epub 2015 May 1. PMID: 25940060.	Wrong intervention (different types /combinations)
Franettovich Smith MM, Collins NJ, Mellor R, Grimaldi A, Elliott J, Hoggarth M, Weber Ii KA, Vicenzino B. Foot exercise plus education versus wait and see for the treatment of plantar heel pain (FEET trial): a protocol for a feasibility study. J Foot Ankle Res. 2020 May 8;13(1):20. doi: 10.1186/s13047-020-00384-1. PMID: 32384905; PMCID: PMC7206811.	Wrong study design (feasibility study) and wrong intervention (different types /combinations)
Kaiser PB, Keyser C, Crawford AM, Bluman EM, Smith JT, Chiodo CP. A Prospective Randomized Controlled Trial Comparing Physical Therapy With Independent Home Stretching for Plantar Fasciitis. J Am Acad Orthop Surg. 2022 Jul 15;30(14):682-689. doi: 10.5435/JAAOS-D-21-00009. PMID: 35797682.	Wrong control group (no placebo or wait and see)
Yildiz S, Sumer E, Zengin HY, Bek N. Intensive physiotherapy versus home-based exercise and custom-made orthotic insoles in patients with plantar fasciitis: Pilot study. Foot (Edinb). 2022 May;51:101906. doi: 10.1016/j.foot.2022.101906. Epub 2022 Jan 7. PMID: 35255402.	Wrong control group (no comparison group)
Thong-On S, Bovonsunthonchai S, Vachalathiti R, Intiravoranont W, Suwannarat S, Smith R. Effects of Strengthening and Stretching Exercises on the Temporospatial Gait Parameters in Patients With Plantar Fasciitis: A Randomized Controlled Trial. Ann Rehabil Med. 2019 Dec;43(6):662-676. doi: 10.5535/arm.2019.43.6.662. Epub 2019 Dec 31. PMID: 31918529; PMCID: PMC6960082.	Wrong control group (no comparison group)

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Fasciopathie Plantaris - UV4 Oefentherapie	
Uitgangsvraag/modules: Wat is de rol van oefentherapie bij de behandeling van patiënten met fasciopathie plantaris?	
Database(s): Embase.com, Ovid/Medline	Datum: 28-3-2024
Periode: vanaf 2000	Talen: geen restrictie

Literatuurspecialist: Esther van der Bijl	Rayyan review: https://rayyan.ai/reviews/980177
BMI-zoekblokken: voor verschillende opdrachten wordt (deels) gebruik gemaakt van de zoekblokken van BMI-Online https://blocks.bmi-online.nl/ Bij gebruikmaking van een volledig zoekblok zal naar de betreffende link op de website worden verwezen.	
Toelichting: Voor deze vraag is gezocht op de elementen oefentherapie EN fasciopathie plantaris. → De sleutelartikelen worden gevonden met deze search.	
Te gebruiken voor richtlijntekst: In de databases Embase.com en Ovid/Medline is op 28 maart 2024 systematisch gezocht naar systematische reviews en RCTs over de rol van oefentherapie bij de behandeling van patiënten met fasciopathie plantaris. De literatuurzoekactie leverde 265 unieke treffers op.	

Zoekopbrengst

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	86	60	97
RCT	152	115	168
~~Observationeel~~			
Totaal	238	175	**265***

****in Rayyan***

5 ***Zoekstrategie Embase.com***

No.	Query	Results
#1	'plantar fasciitis'/exp OR 'plantar fasciopathy'/exp OR 'heel spur'/exp OR 'policeman heel'/exp OR (((calcane* OR heel* OR subcalcane*) NEAR/3 (spur* OR exostos* OR pain* OR policeman* OR jogger*)):ti,ab,kw) OR ((plant* NEAR/3 (fasciitis OR fasciopath* OR fascios* OR inflam*)):ti,ab,kw) OR (((baxter* OR plant* OR calcane* OR heel) NEAR/3 neuropath*):ti,ab,kw) OR calcaneodyn*:ti,ab,kw OR 'calcane* periostitis':ti,ab,kw	6372
#2	'kinesiotherapy'/exp OR 'resistance training'/exp OR 'stretching exercise'/exp OR 'muscle stretching'/exp OR 'stretching'/exp OR 'strength'/exp OR 'muscle strength'/exp OR ((exercis* NEAR/3 (therap* OR program*)):ti,ab,kw) OR strength*:ti,ab,kw OR stretch*:ti,ab,kw OR kinesiotherap*:ti,ab,kw OR kinesitherap*:ti,ab,kw	955569
#3	#1 AND #2	779
#4	#3 AND [2000-2024]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	592
#5	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	1014761
#6	'randomized controlled trial'/exp OR random*:ti,ab OR (((pragmatic OR practical) NEAR/1 'clinical trial*'):ti,ab) OR ((('non inferiority' OR noninferiority OR superiority OR equivalence) NEAR/3 trial*):ti,ab) OR rct:ti,ab,kw	2178974
#7	#4 AND #5 **– SR's**	86
#8	#4 AND #6 NOT #7 **– RCT's**	152
#9	#7 OR #8	238

Zoekstrategie Ovid/Medline

#	Searches	Results
1	exp Fasciitis, Plantar/ or exp Heel Spur/ or ((calcane* or heel* or subcalcane*) adj3 (spur* or exostos* or pain* or policeman* or jogger*)).ti,ab,kf. or (plant* adj3 (fasciitis or fasciopath* or fascios* or inflam*)).ti,ab,kf. or ((baxter* or plant* or calcane* or heel) adj3 neuropath*).ti,ab,kf. or calcaneodyn*.ti,ab,kf. or calcane* periostitis.ti,ab,kf.	4416
2	exp Exercise Therapy/ or exp Resistance Training/ or exp Muscle Stretching Exercises/ or exp Muscle Strength/ or (exercis* adj3 (therap* or program*)).ti,ab,kf. or strength*.ti,ab,kf. or stretch*.ti,ab,kf. or kinesiotherap*.ti,ab,kf. or kinesitherap*.ti,ab,kf.	744929
3	1 and 2	435
4	limit 3 to yr="2000 -Current"	402
5	4 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	388
6	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	735289
7	exp randomized controlled trial/ or randomized controlled trials as topic/ or random*.ti,ab. or rct?.ti,ab. or ((pragmatic or practical) adj "clinical trial*").ti,ab,kf. or ((non-inferiority or noninferiority or superiority or equivalence) adj3 trial*).ti,ab,kf.	1700385
8	5 and 6 **– SR's**	60
9	(5 and 7) not 8 **– RCT's**	115
10	8 or 9	175

Module 5 Op maat gemaakte zolen

Search and select

A systematic review of the literature was performed to answer the following question(s):

Wat is de effectiviteit van op maat gemaakte op maat gemaakte zolen in vergelijking met sham/placebo als behandeling van patiënten met fasciopathie plantaris?

Table 1. PICO

Patients	Patients with plantar fasciopathy, with abnormal foot posture and/or gait pattern
Intervention	Custom-made insoles
Control	Placebo / sham
Outcomes	Critical: pain, function Important: return to sport, patient satisfaction, quality of life
Other selection criteria	Study design: systematic reviews or randomized controlled trials From 2000

Relevant outcome measures

The guideline panel considered pain and function as a **crucial** outcome measure for decision making; and return to sport, patient satisfaction and quality of life as an **important** outcome measure for decision making.

The guideline panel defined 10% as a minimal clinically important difference for both continuous as well as dichotomous outcome measures. This includes a 10% difference on the outcome measurement on a continuous scale or a Relative Risk (RR ≤ 0 .90 and ≥ 1.1). In case a standardized mean difference was reported, the previously used GRADE default was used, ≤-0.5 SMD ≥ 0.5 as minimal clinically (patient) important differences.

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until 23 May 2024. The detailed search strategy is listed under the tab 'Literature search strategy'. The systematic literature search resulted in 382 hits. Studies were selected based on the PICO criteria. 15 studies were initially selected based on title and abstract screening. After reading the full text, 13 studies were excluded (see the exclusion table under the tab 'Evidence tabellen') and two studies were included.

Summary of literature

Description of studies

A total of two studies (one systematic review and one RCT) were included in the analysis of the literature (one systematic review and one randomized controlled trial) . Important study characteristics are summarized in table 2. The assessment of the risk of bias is summarized in the risk of bias tables (under the tab 'Evidence tabellen').

Rasenberg (2018) performed a systematic review with meta-analysis to assess the effect of different foot orthoses on pain, function, and self-reported recovery in participants with plantar heel pain and compare them with other conservative interventions. Twenty studies were included in the review covering data of a total of 1756 participants. Eight different types of foot orthoses were investigated. Three studies compared a custom-made orthosis with a sham orthosis in a randomized controlled setting and were included in this summary

of literature (Landorf 2006, Oliveira 2015, Wrobel 2015). These three studies had a low risk of bias and covered data of 207 participants. Short-term pain and short-term function were reported in all three studies. Midterm pain and function were reported in one study (Oliveira 2015) and long-term pain and function were reported in another study (Landorf 2006). Wrobel (2015) also assessed quality of life.

Rasenberg (2021) performed a double-blind three-armed randomized controlled trial in the Netherlands, to compare custom-made insoles to sham insoles and usual care in terms of pain at rest and during activity. In this study, 185 participants with a clinical diagnosis of plantar heel plain for two weeks to two years were randomized into the custom-made insole group (n=70), sham insole (n=69) or usual care (n=46). Duration of follow-up was six months. The primary study outcome was pain severity at 12 weeks of follow-up. The risk of bias for this study was considered low as randomization and blinding were performed accurately, there were no conflicts of interest reported, and the funder had no role in any part of the study.

Table 2. Characteristics of included studies

Study	Participants	Comparison	Follow-up	Outcome measures	Comments	Risk of bias
Included in systematic review of Rasenberg, 2018 and meeting the PICO						
Landorf, 2006	N at baseline: 136 Intervention: 46 Control: 46 (44 in arm not of interest) Age (mean (SD)) I: 49.2 (12.0) C: 48.5 (9.6) Sex (% female) I: 74 C: 67 All patients were diagnosed with plantar fasciitis.	Intervention: Customized foot orthosis fabricated in a commercial orthotic laboratory providing significant support and influencing the position of the foot relative to the leg. Control: Sham foot orthosis providing minimal structural support. 3rd group was allocated to prefabricated foot orthosis (excluded here)	12 months	- pain - function Both measured with the FSHQ	Setting: university podiatry clinic in Australia.	Low[1]
Oliveira, 2015	N at baseline: 74 Intervention: 37 Control: 37 Age (mean (SD)) I: 48 (10.1) C: 52 (10.8) Sex (% female) I: 81 C: 97	Intervention: Customized total contact insoles for daily use for 6 months. Control: Flat insole (sham) for daily use for 6 months.	6 months	- pain measured on VAS and FHSQ	Setting: Outpatient clinic in Brazil.	Low[1]

	All patients were diagnosed with plantar fasciitis.					
Wrobel, 2015	N at baseline: 77 Intervention: 25 Control: 23 (21 in arm not of interest) Age (mean (SD)): 49.6 (12.1) Sex (% female): 63 All patients were diagnosed with plantar fasciitis.	Intervention: Customized foot orthosis with providing neutral calcaneal stance position. Control: Sham foot orthosis. 3r group was allocated to prefabricated foot orthosis (excluded here)	12 weeks	- pain measured on FFI-R and VAS - quality of life measured with SF-36	Setting: 3 foot and ankle centers in Chicago, USA.	Low[1]
Individual studies						
Rasenberg, 2021	N at baseline: 185 Intervention: 70 Control: 69 (46 in arm not of interest) Age (mean (SD)) I: 48.0 (11.3) C: 48.2 (9.4) Sex (% female) I: 68.8 C: 69.6 All patients had plantar heel pain.	Intervention: Custom-made insole made by a podiatrist based on a 3D imprint of the participants' feet reducing traction on the plantar aponeurosis and ground reaction force below the calcaneal tuberosity. Control: Sham insole made by a podiatrist based on a 3D imprint of the participants' feet providing as little mechanical effect as possible. 3r group was allocated to usual care (excluded here)	6 months	- Pain severity measured on 11-point NRS and FFI - patient satisfaction - quality of life measured with SF-12	Study acronym: STAP Setting: primary care setting in the Netherlands.	Low[2]

[1]Assessed by the authors of the systematic review.
[2] For further details, see risk of bias table in the appendix.

Abbreviations: FFI(-R): Foot Function Index(-Revised). FSHP: Foot Health Status Questionnaire. NRS: Numeric Rating Scale. SF-36 / SF-12: Short Form Health Survey with 36 or 12 items. VAS: Visual Analogue Scale.

Results

1. Pain (crucial)

All four studies assessed pain scores. Landorf (2006) and Oliveira (2015) measured it with the pain domains of the Foot Health Status Questionnaire which ranges from 0 to 100 and a higher score indicates better foot status. Rasenberg (2021) and Wrobel (2015) used the pain subscale of the (Revised) Foot Function Index which ranges from 0 to 100, a higher score indicates a worse foot status. Because of differences in directionality of the outcomes (e.g., higher scores reflecting better or worse outcomes), the data of Landorf (2006) and Oliveira (2015) were inversed in order to set to the same direction.

In addition, the Visual Analogue Scale (VAS) was used by Oliveira (2015) and Wrobel (2015) and the Numerical Rating Scale (NRS) was by used Rasenberg (2021). These scales range from 0 to 10 and a higher score indicates more pain.

1.1 Short-term (at 3 months)

All studies assessed pain after three months of follow-up including data of 346 participants. Based on the pain scores measured with the FHSQ or FFI-(R) questionnaire, the standardized mean difference for short-term pain when comparing custom-made insoles to sham insoles was -0.14 (95% CI -0.35 to 0.07), in favor of custom-made insoles (figure 1). This difference is not considered clinically relevant.

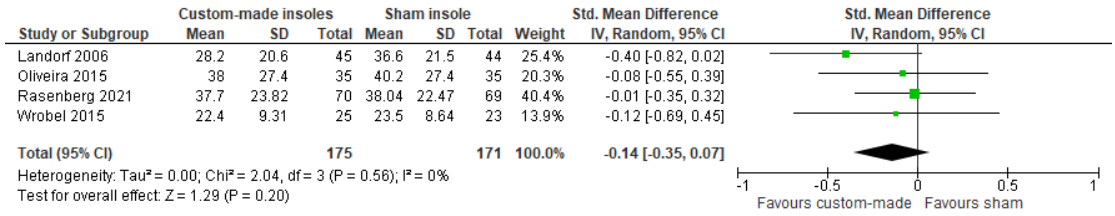


Figure 1. Forest plot of short-term pain measured with the pain domains of the FHSQ or FFI(-R) questionnaires in the comparison of custom-made insoles versus sham insoles among participants with plantar heel pain.

When analyzing pain in rest on the VAS or NRS scale (both scales range 0-10), the mean difference for short-term pain was -0.10 (95% CI -0.75 to 0.55), in favor of custom-made insoles (figure 2). This difference is not considered clinically relevant.

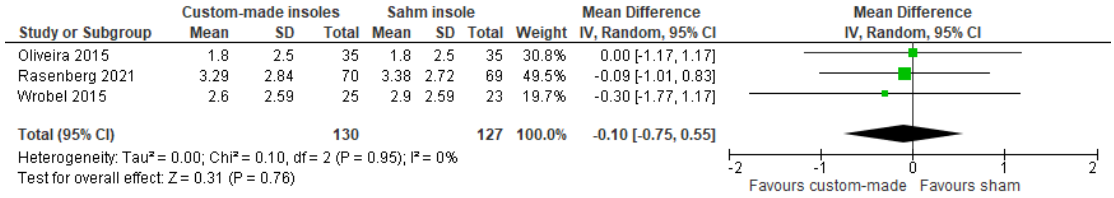


Figure 2. Forest plot of short-term pain in rest measured with the VAS or NRS scale in the comparison of custom-made insoles versus sham insoles among participants with plantar heel pain.

1.2 Mid-term (6 months)

Pain at 6 months was assessed in two studies with data of 210 participants (Oliveira 2015, Rasenberg 2021). Based on the pain scores measured with the FHSQ or FFI questionnaire, the standardized mean difference for mid-term pain when comparing custom-made insoles to sham insoles was -0.04 (95% CI -0.31 to 0.23), in favor of custom-made insoles (figure 3). This difference is not considered clinically relevant.

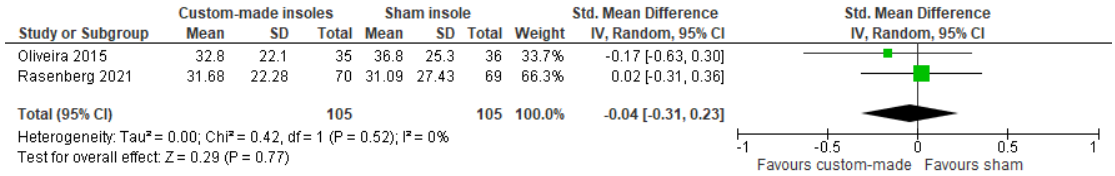


Figure 3. Forest plot of short-term pain measured with the pain domains of the FHSQ or FFI questionnaires in the comparison of custom-made insoles versus sham insoles among participants with plantar heel pain.

When analyzing pain in rest on the VAS or NRS scale, the mean difference for mid-term pain was -0.14 (95% CI -0.84 to 0.57), in favor of custom-made insoles (figure 4). This difference is not considered clinically relevant.

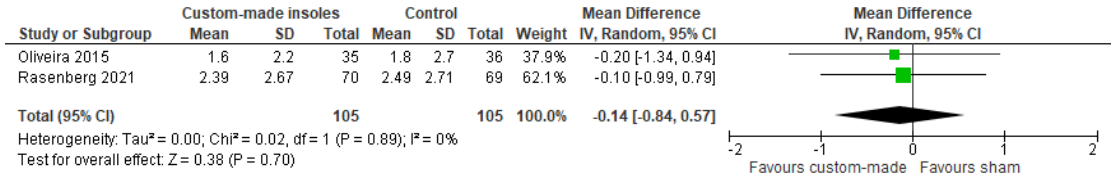


Figure 4. Forest plot of mid-term pain in rest measured with the VAS or NRS scale in the comparison of custom-made insoles versus sham insoles among participants with plantar heel pain.

1.3 Long-term (12 months)

Pain at 12 months was reported by Landorf (2006). The adjusted estimate of effect was -0.1 (95% CI -7.8 to 7.7) in favor of sham insoles. It was reported to not be statistically significantly different. The effect was not clinically relevant.

2. Function (crucial)

All four studies assessed function scores. Landorf (2006) and Oliveira (2015) measured it with the function domains of the Foot Health Status Questionnaire which ranges from 0 to 100 and a higher score indicates better foot status. Rasenberg (2021) used the function subscale of the Foot Function Index which ranges from 0 to 100, a higher score indicates a worse foot status. Wrobel (2015) only reported the total Foot Function Index-Revised score and not the score of the function subscale. Therefore, data of Wrobel (2015) could not be pooled. Because of differences in directionality of the outcomes (e.g., higher scores reflecting better or worse outcomes), the data of Landorf (2006) and Oliveira (2015) were inversed in order to set to the same direction.

2.1 Short-term (at 3 months)

All studies assessed function after three months of follow-up. Based on three studies with 298 participants, the standardized mean difference for short-term pain when comparing custom-made insoles to sham insoles was -0.12 (95% CI -0.37 to 0.12), in favor of custom-made insoles (figure 5). This difference is not considered clinically relevant.

Wrobel (2015) reported no statistically significant differences in total FFI-R score.

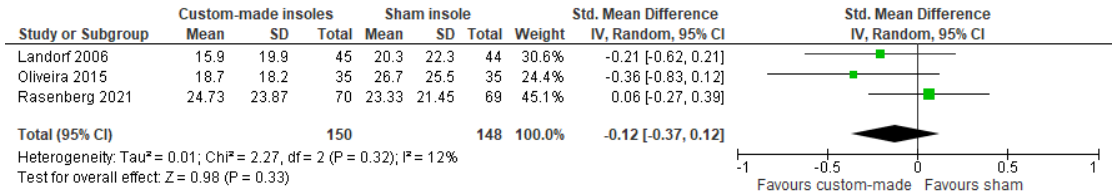


Figure 5. Forest plot of short-term function measured with the function domains of the FHSQ or FFI questionnaire in the comparison of custom-made insoles versus sham insoles among participants with plantar heel pain.

2.2 Mid-term (6 months)

Function at 6 months was assessed in two studies (Oliveira 2015, Rasenberg 2021). The standardized mean difference for mid-term pain when comparing custom-made insoles to sham insoles was -0.10 (95% CI -0.42 to 0.22), in favor of custom-made insoles (figure 6). This difference is not considered clinically relevant.

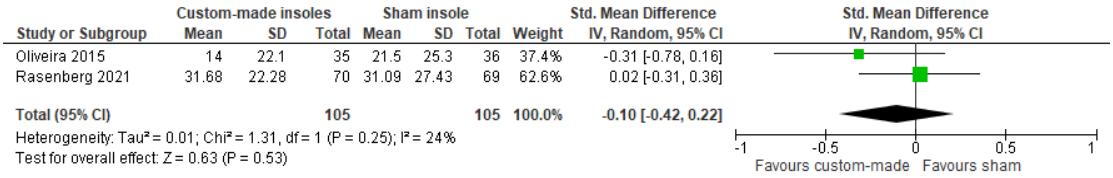


Figure 6. Forest plot of short-term function measured with the function domains of the FHSQ or FFI questionnaire in the comparison of custom-made insoles versus sham insoles among participants with plantar heel pain.

2.3 Long-term (12 months)

Function at 12 months was reported by Landorf (2006). They reported no statistically significant difference between the custom-made and sham orthosis group: the adjusted estimate of effect was 4.3 (95% CI -3.0 to 11.6), in favor of custom-made insoles.

3. Return to sport (important)

None of the studies reported on the outcome return to sport.

4. Patient satisfaction (important)

Patient satisfaction was reported by Rasenberg (2021). Discomfort when wearing the insoles was reported by 23 out of 70 participants in the custom-made insole group (32.9%) and by 8 out of 69 participants in the sham insole group (11.6%). This resulted in a risk difference of 0.21 (95% CI 0.08 to 0.35) favoring the sham insole group. The risk ratio was 2.83 (95% CI 1.36 to 5.90).

5. Quality of life (important)

Quality of life was assessed in two studies (Rasenberg 2021, Wrobel 2015). Rasenberg (2021) used the SF-12 questionnaire which is a short version of the Short Form Health Survey with 36, which was used by Wrobel (2015). The questionnaire has a physical and a mental health component. The total score ranges from 0 to 100 and a higher score reflects better quality of life.

Rasenberg (2021) reported at 3 months of follow-up no statistically significant differences between the custom-made group and the sham group in physical health: mean difference 2.13 (95% CI -0.28 to 4.55). After 6 months of follow-up, the mean difference in physical health was 1.62 (95% CI -0.79 to 4.03) which was reported to not be statistically significantly different. Regarding mental health, both after 3 and 6 months of follow-up the mean difference were -3.70 (95% CI -6.49 to 0.92) and -3.00 (95% CI -5.71 to 0.29), respectively; both in favor of the sham insole.

Wrobel (2015) reported the total score at 3 months of follow-up. The score was 103.2 in the custom-made insole group and 99.9 in the sham group. This was reported to not be statistically significantly different between the groups (no confidence intervals or standard deviations were reported). This result was therefore not evaluated using the GRADE method.

Summary of Findings

Custom-made insoles as treatment for plantar fasciopathy?

Population: Patients with plantar fasciopathy

Intervention: Custom-made insoles

Comparison: Placebo / sham

Outcome		Study results and measurements	Absolute effect estimates		Certainty of the Evidence (Quality of evidence)	Summary
			Sham	Custom-made		
Pain (critical)	Short-term (3 months)	Measured by FHSQ or FFI(-R) Lower is better Based on data of 346 participants in 4 studies	Standardized mean difference: **0.14 lower** (95% CI 0.35 lower - 0.07 higher)		**Low** Due to serious imprecision, due to serious indirectness[1]	Custom-made insoles may result in little to no difference in short-term pain when compared with sham or placebo in patients with plantar fasciopathy. *(Landorf 2006, Oliveira 2015, Rasenberg 2021, Wrobel 2015)*
		Measured by VAS or NRS Lower is better Based on data of 257 participants in 3 studies	Mean difference: **0.10 lower** (95% CI 0.75 lower - 0.55 higher)			
	Mid-term (6 months)	Measured by FHSQ or FFI Lower is better Based on data of 210 participants in 2 studies	Standardized mean difference: **0.04 lower** (95% CI 0.31 lower - 0.23 higher)		**Low** Due to serious imprecision, due to serious indirectness[1]	Custom-made insoles may result in little to no difference in mid-term pain when compared with sham or placebo in patients with plantar fasciopathy. *(Oliveira 2015, Rasenberg 2021)*
		Measured by VAS or NRS Lower is better Based on data of 210 participants in 2 studies	Mean difference: **0.14 lower** (95% CI 0.84 lower - 0.57 higher)			
	Long-term (12 months)	Measured by FHSQ Higher is better	Adjusted estimate of effect: **0.1 lower** (95% CI 7.8 lower - 7.7 higher)		**Low** Due to serious imprecision, due to serious indirectness[1]	Custom-made insoles may result in little to no difference in long-term pain when compared with

		Based on data of 89 participants in 1 study			sham or placebo in patients with plantar fasciopathy. *(Landorf 2006)*
Function (critical)	Short-term (3 months)	Measured by FHSQ or FFI Lower is better Based on data of 298 participants in 3 studies	Standardized mean difference: **0.12 lower** (95% CI 0.37 lower - 0.12 higher)	**Low** Due to serious imprecision, due to serious indirectness[1]	Custom-made insoles may result in little to no difference in short-term function when compared with sham or placebo in patients with plantar fasciopathy. *(Landorf 2006, Oliveira 2015, Rasenberg 2021)*
	Mid-term (6 months)	Measured by FHSQ or FFI Lower is better Based on data of 210 participants in 2 studies	Standardized mean difference: **0.10 lower** (95% CI 0.42 lower - 0.22 higher)	**Low** Due to serious imprecision, due to serious indirectness[1]	Custom-made insoles may result in little to no difference in mid-term function when compared with sham or placebo in patients with plantar fasciopathy. *(Oliveira 2015, Rasenberg 2021)*
	Long-term (12 months)	Measured by FHSQ Higher is better Based on data of 89 participants in 1 study	Adjusted estimate of effect: **4.3 higher** (95% CI 3.0 lower - 11.6 higher)	**Low** Due to serious imprecision, due to serious indirectness[2]	Custom-made insoles may result in little to no difference in long-term function when compared with sham or placebo in patients with plantar fasciopathy. *(Landorf 2006)*
Return to sport (important)		Based on data of 0 participants in 0 studies	-	**No GRADE**	No evidence was found regarding the effect of custom-made insoles on return to sport when compared with placebo or sham in patients with plantar fasciopathy.
Patient satisfaction (important)		Based on data of 139 participants in 1 study	Discomfort was reported by 32.9% in the intervention group and 11.6% in the control group. RD of 0.21 (95% CI 0.08 to 0.35)	**Very low** Due to very serious indirectness and serious imprecision[3]	The evidence is very uncertain about the effect of custom-made insoles on patient satisfaction when compared with sham or placebo in patients with plantar fasciopathy. *(Rasenberg 2021)*

Quality of life (important)	Based on data of 187 participants in 2 studies	There was little to no difference in the physical and mental health component at 3 and 6 months of follow-up	**Low** Due to serious imprecision, due to serious indirectness[1]	Custom-made insoles may result in little to no difference in quality of life when compared with sham or placebo in patients with plantar fasciopathy. *(Rasenberg 2021)*

[1] Imprecision: very serious. Due to low number of participants (-1 level), due to population without deviated foot position (-1 level).

[2] Imprecision: very serious. Due to overlap of the upper limit of the 95% confidence interval with the minimal clinically important difference (-1 level), due to population without deviated foot position (-1 level).

[3] Indirectness: serious. Due to an indirect measurement for the outcome, resulting from measuring discomfort instead of patient reported satisfaction (-1 level), due to population without deviated foot position (-1 level).

Imprecision: very serious. Due to low number of participants (-1 level), due to population without deviated foot position (-1 level).

Kennisvragen

Tijdens de ontwikkeling van deze module is systematisch naar onderzoeken gezocht die de zoekvraag kunnen beantwoorden. Door gebruik te maken van een systematische literatuuranalyse met beoordeling van de bewijskracht is duidelijk geworden dat er binnen deze module nog kennisvragen bestaan.

Aangezien er weinig goede studies zijn naar de effecten van op maat gemaakte zolen, meent de werkgroep dat (vervolg)onderzoek wenselijk is om in de toekomst een duidelijker antwoord te kunnen geven op vragen uit de praktijk.

Kennisvraag:

1. Wat is de effectiviteit van op maat gemaakte zolen bij patiënten met fasciopathie plantaris?
2. Verschilt de effectiviteit van op maat gemaakte zolen bij patiënten met fasciopathie plantaris, afhankelijk van de gebruikte vervaardigingstechniek, materiaalkeuze en individuele voetstand en gangpatroon?

Toelichting:

Deze kennisvraag is relevant omdat fasciopathie plantaris veel voorkomt en op maat gemaakte zolen vaak worden ingezet voor pijnverlichting. Er is echter weinig bekend over de effectiviteit van verschillende vervaardigingstechnieken.

Literatuur

Cotchett M, Rathleff MS, Dilnot M, Landorf KB, Morrissey D, Barton C. Lived experience and attitudes of people with plantar heel pain: a qualitative exploration. J Foot Ankle Res. 2020 Mar 6;13(1):12. doi: 10.1186/s13047-020-0377-3. PMID: 32143679; PMCID: PMC7059663.

Mørk M, Soberg HL, Hoksrud AF, Heide M, Groven KS. The struggle to stay physically active-A qualitative study exploring experiences of individuals with persistent plantar fasciopathy. J Foot Ankle Res. 2023 Apr 15;16(1):20. doi: 10.1186/s13047-023-00620-4. PMID: 37061709; PMCID: PMC10105408.

Rasenberg N, Bierma-Zeinstra SMA, Fuit L, Rathleff MS, Dieker A, van Veldhoven P, Bindels PJE, van Middelkoop M. 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):272-278. doi: 10.1136/bjsports-2019-101409. Epub 2020 Sep 2. PMID: 32878869; PMCID: PMC7907578.

Rasenberg N, Riel H, Rathleff MS, Bierma-Zeinstra SMA, van Middelkoop M. Efficacy of foot orthoses for the treatment of plantar heel pain: a systematic review and meta-analysis. Br J Sports Med. 2018 Aug;52(16):1040-1046. doi: 10.1136/bjsports-2017-097892. Epub 2018 Mar 19. PMID: 29555795.

Implementatietabel

Aanbeveling – 1 Overweeg bij patiënten bij wie een afwijkende voetstand en/of gangpatroon wordt vermoed, op maat gemaakte zolen.	Op basis van de beschikbare evidentie en ervaring uit de praktijk kon er onvoldoende richting aan de besluitvorming worden gegeven. Om die reden is er geen beschrijving van belemmeringen en kansen voor implementatie van de aanbeveling toegevoegd. Disseminatie van de kennis in deze module verloopt via de standaard route. De module wordt gepubliceerd op de Richtlijnendatabase.

Risk of Bias tables

Risk of bias table for systematic reviews

Study reference	Appropriate and clearly focused question?[1]	Comprehensive and systematic literature search?[2]	Description of included and excluded studies?[3]	Description of relevant characteristics of included studies?[4]	Assessment of scientific quality of included studies?[5]	Enough similarities between studies to make combining them reasonable?[6]	Potential risk of publication bias taken into account?[7]	Potential conflicts of interest reported?[8]
Rasenberg, 2018	Yes	Yes	Yes	Yes	Yes	Yes	No	No

5

Risk of bias table for intervention studies

Study reference	Was the allocation sequence adequately generated?	Was the allocation adequately concealed?	Blinding:	Was loss to follow-up (missing outcome data) infrequent?	Are reports of the study free of selective outcome reporting?	Was the study apparently free of other problems that could put it at a risk of bias?	Overall risk of bias
Rasenberg, 2021	Definitely yes Reason: Authors used computer-generated randomization.	Definitely yes Reason: Randomization created by independent person and hidden from the researchers.	Definitely yes Reason: Blinding of participants and general practitioners. Podiatrist were blinded the first consultation.	Definitely no Reason: 1 was lost to follow-up in the intervention arm.	Definitely yes Reason: The study was performed according to the published protocol.	Probably yes Reason: Funded by ZonMW and the NVvP, but the funders had no role in any part of the study.	Low risk of bias Reason: Correct randomization and blinding.

Table of excluded studies

Reference	Reason for exclusion
Babatunde OO, Legha A, Littlewood C, Chesterton LS, Thomas MJ, Menz HB, van der Windt D, Roddy E. Comparative effectiveness of treatment options for plantar heel pain: a systematic review with network meta-analysis. Br J Sports Med. 2019 Feb;53(3):182-194. doi: 10.1136/bjsports-2017-098998. Epub 2018 Jun 28. PMID: 29954828.	Did not include relevant RCT of Wrobel2015, reason unknown
Bishop C, Thewlis D, Hillier S. Custom foot orthoses improve first-step pain in individuals with unilateral plantar fasciopathy: a pragmatic randomised controlled trial. BMC Musculoskelet Disord. 2018 Jul 18;19(1):222. doi: 10.1186/s12891-018-2131-6. PMID: 30021556; PMCID: PMC6052580.	Wrong intervention: custom foot orthosis + new shoes or sham insole + new shoes versus sham insole in participants' own shoes.
Chesterton LS, Thomas MJ, Hendry G, Chen Y, Goddin D, Halliday N, Lawton SA, Lewis M, Mallen CD, Menz HB, Foster NE, Roddy E. Self-management advice, exercise and foot orthoses for plantar heel pain: the TREADON pilot and feasibility randomised trial. Pilot Feasibility Stud. 2021 Apr 1;7(1):92. doi: 10.1186/s40814-021-00808-0. PMID: 33795024; PMCID: PMC8015033.	Wrong intervention: only prefabricated foot orthoses, no custom made
Lourenço BM, Campos MGM, Maia L, Castro B, Trede RG, Oliveira VC. Efficacy of pharmacological and non-pharmacological therapies on pain intensity and disability for plantar fasciitis: a systematic review and meta-analysis. Br J Sports Med. 2023 Dec;57(23):1516-1521. doi: 10.1136/bjsports-2022-106403. Epub 2023 Aug 24. PMID: 37620126.	Did not include relevant RCT of Wrobel2015, reason unknown
Morrissey D, Cotchett M, Said J'Bari A, Prior T, Griffiths IB, Rathleff MS, Gulle H, Vicenzino B, Barton CJ. Management of plantar heel pain: a best practice guide informed by a systematic review, expert clinical reasoning and patient values. Br J Sports Med. 2021 Oct;55(19):1106-1118. doi: 10.1136/bjsports-2019-101970. Epub 2021 Mar 30. PMID: 33785535; PMCID: PMC8458083.	Meets PICO, but does not provide reasons for exclusion of studies.
Rasenberg N, Dijkgraaf LJM, Bindels PJ, Bierma-Zeinstra SM, van Middelkoop M. 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. J Foot Ankle Res. 2022 Feb 10;15(1):14. doi: 10.1186/s13047-022-00516-9. PMID: 35144668; PMCID: PMC8830116.	Secondary analysis of already included RCT.
Rasenberg N, van Middelkoop M, Bierma-Zeinstra SMA, El Alili M, Bindels P, Bosmans J. Cost-effectiveness of custom-made insoles versus usual care in patients with plantar heel pain in primary care: cost-effectiveness analysis of a randomised controlled trial. BMJ Open. 2021 Nov 3;11(11):e051866. doi: 10.1136/bmjopen-2021-051866. PMID: 34732484; PMCID: PMC8572391.	Secondary analysis of already included RCT.
Salvioli S, Guidi M, Marcotulli G. The effectiveness of conservative, non-pharmacological treatment, of plantar heel pain: A systematic review with meta-analysis. Foot (Edinb). 2017 Dec;33:57-67. doi: 10.1016/j.foot.2017.05.004. Epub 2017 Jun 15. PMID: 29126045.	Only pain as outcome, less recent than other well performed reviews.
Seligman DAR, Dawson D, Streiner DL, Seligman DJ, Davis A. Treating Heel Pain in Adults: A Randomized Controlled Trial of Hard vs Modified Soft Custom Orthotics and Heel Pads. Arch Phys Med Rehabil. 2021 Mar;102(3):363-370. doi: 10.1016/j.apmr.2020.10.124. Epub 2020 Nov 18. PMID: 33217374.	Wrong comparison: hard versus soft custom orthoses, no sham/placebo control group.
Shim DW, Sung SY, Chung WY, Kang KY, Park SJ, Lee JW, Chae DS. Superior pedal function recovery of newly designed three spike insole over total contact insole in refractory plantar fasciitis: A randomized, double-blinded, non-inferiority study. PLoS One. 2021 Jul 23;16(7):e0255064. doi: 10.1371/journal.pone.0255064. PMID: 34297721; PMCID: PMC8301654.	Wrong comparison: 3D printer Mandme PLABS insole versus total conatct insole, no sham/placebo control group.
Taseh A, Mathur V, Weaver B, Hashmi M, Vrolyk MA, Skolnik J, Ashkani-Esfahani S, Waryasz G. Role of insole material in treatment of plantar fasciitis: A randomized clinical trial. Foot Ankle Surg. 2024 Aug;30(6):524-528. doi: 10.1016/j.fas.2024.04.006. Epub 2024 Apr 17. PMID: 38677939.	Wrong comparison: trial comparing only prefabricated insoles, no custom made insoles, no sham/placebo, no full-text available.

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):322-328. doi: 10.1136/bjsports-2016-097355. Epub 2017 Sep 21. PMID: 28935689.	Meets PICO, but does not describe the study population.
Xu R, Wang Z, Ma T, Ren Z, Jin H. Effect of 3D Printing Individualized Ankle-Foot Orthosis on Plantar Biomechanics and Pain in Patients with Plantar Fasciitis: A Randomized Controlled Trial. Med Sci Monit. 2019 Feb 21;25:1392-1400. doi: 10.12659/MSM.915045. PMID: 30789873; PMCID: PMC6394143.	Wrong comparison: customized 3D printed ankle-foot orthoses versus traditional ankle-foot orthoses.

Zoekverantwoording

Zoekstrategie Embase.com 23 mei 2024

No.	Query	Results
#1	'plantar fasciitis'/exp OR 'plantar fasciopathy'/exp OR 'heel spur'/exp OR 'policeman heel'/exp OR (((calcane* OR heel* OR subcalcane*) NEAR/3 (spur* OR exostos* OR pain* OR policeman* OR jogger*)):ti,ab,kw) OR ((plant* NEAR/3 (fasciitis OR fasciopath* OR fascios* OR inflam*)):ti,ab,kw) OR (((baxter* OR plant* OR calcane* OR heel) NEAR/3 neuropath*):ti,ab,kw) OR calcaneodyn*:ti,ab,kw OR 'calcane* periostitis':ti,ab,kw	6447
#2	'insole'/exp OR 'orthosis'/exp OR (((shoe* OR heel* OR foot) NEAR/7 (insert OR inserts OR pad* OR cup* OR 'arch support*')):ti,ab,kw) OR 'insole*':ti,ab,kw OR 'orth?s?s':ti,ab,kw OR 'orthopeadic support*':ti,ab,kw OR 'orthotic*':ti,ab,kw	55237
#3	#1 AND #2	775
#4	#3 AND [2000-2024]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	541
#5	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	1030954
#6	'clinical trial'/exp OR 'randomization'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR 'placebo'/exp OR 'prospective study'/exp OR rct:ab,ti OR random*:ab,ti OR 'single blind':ab,ti OR 'randomised controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti	4038071
#7	'major clinical study'/de OR 'clinical study'/de OR 'case control study'/de OR 'family study'/de OR 'longitudinal study'/de OR 'retrospective study'/de OR 'prospective study'/de OR 'comparative study'/de OR 'cohort analysis'/de OR ((cohort NEAR/1 (study OR studies)):ab,ti) OR (('case control' NEAR/1 (study OR studies)):ab,ti) OR (('follow up' NEAR/1 (study OR studies)):ab,ti) OR (observational NEAR/1 (study OR studies)) OR ((epidemiologic NEAR/1 (study OR studies)):ab,ti) OR (('cross sectional' NEAR/1 (study OR studies)):ab,ti)	8241761
#8	'case control study'/de OR 'comparative study'/exp OR 'control group'/de OR 'controlled study'/de OR 'controlled clinical trial'/de OR 'crossover procedure'/de OR 'double blind procedure'/de OR 'phase 2 clinical trial'/de OR 'phase 3 clinical trial'/de OR 'phase 4 clinical trial'/de OR 'pretest posttest design'/de OR 'pretest posttest control group design'/de OR 'quasi experimental study'/de OR 'single blind procedure'/de OR 'triple blind procedure'/de OR (((control OR controlled) NEAR/6 trial):ti,ab,kw) OR (((control OR controlled) NEAR/6 (study OR studies)):ti,ab,kw) OR (((control OR controlled) NEAR/1 active):ti,ab,kw) OR 'open label*':ti,ab,kw OR (((double OR two OR three OR multi OR trial) NEAR/1 (arm OR arms)):ti,ab,kw) OR ((allocat* NEAR/10 (arm OR arms)):ti,ab,kw) OR placebo*:ti,ab,kw OR 'sham-control*':ti,ab,kw OR (((single OR double OR triple OR assessor) NEAR/1 (blind* OR masked)):ti,ab,kw) OR nonrandom*:ti,ab,kw OR 'non-random*':ti,ab,kw OR 'quasi-experiment*':ti,ab,kw OR crossover:ti,ab,kw OR 'cross	15109487

	over':ti,ab,kw OR 'parallel group*':ti,ab,kw OR 'factorial trial':ti,ab,kw OR ((phase NEAR/5 (study OR trial)):ti,ab,kw) OR ((case* NEAR/6 (matched OR control*)):ti,ab,kw) OR ((match* NEAR/6 (pair OR pairs OR cohort* OR control* OR group* OR healthy OR age OR sex OR gender OR patient* OR subject* OR participant*)):ti,ab,kw) OR ((propensity NEAR/6 (scor* OR match*)):ti,ab,kw) OR versus:ti OR vs:ti OR compar*:ti OR ((compar* NEAR/1 study):ti,ab,kw) OR (('major clinical study'/de OR 'clinical study'/de OR 'cohort analysis'/de OR 'observational study'/de OR 'cross-sectional study'/de OR 'multicenter study'/de OR 'correlational study'/de OR 'follow up'/de OR cohort*:ti,ab,kw OR 'follow up':ti,ab,kw OR followup:ti,ab,kw OR longitudinal*:ti,ab,kw OR prospective*:ti,ab,kw OR retrospective*:ti,ab,kw OR observational*:ti,ab,kw OR 'cross sectional*':ti,ab,kw OR cross?ectional*:ti,ab,kw OR multicent*:ti,ab,kw OR 'multi-cent*':ti,ab,kw OR consecutive*:ti,ab,kw) AND (group:ti,ab,kw OR groups:ti,ab,kw OR subgroup*:ti,ab,kw OR versus:ti,ab,kw OR vs:ti,ab,kw OR compar*:ti,ab,kw OR 'odds ratio*':ab OR 'relative odds':ab OR 'risk ratio*':ab OR 'relative risk*':ab OR 'rate ratio':ab OR aor:ab OR arr:ab OR rrr:ab OR (('or' OR 'rr') NEAR/6 ci):ab)))	
#9	#4 AND #5 – **SR's**	67
#10	#4 AND #6 NOT #9 – **RCT's**	160
#11	#4 AND (#7 OR #8) NOT (#9 OR #10) – **Observationele studies**	104
#12	#9 OR #10 OR #11	331

Zoekstrategie Ovid/Medline 23 mei 2024

#	Searches	Results
1	exp Fasciitis, Plantar/ or exp Heel Spur/ or ((calcane* or heel* or subcalcane*) adj3 (spur* or exostos* or pain* or policeman* or jogger*)).ti,ab,kf. or (plant* adj3 (fasciitis or fasciopath* or fascios* or inflam*)).ti,ab,kf. or ((baxter* or plant* or calcane* or heel) adj3 neuropath*).ti,ab,kf. or calcaneodyn*.ti,ab,kf. or calcane* periostitis.ti,ab,kf.	4464
2	exp Orthotic Devices/ or ((shoe* or heel* or foot) adj7 (insert or inserts or pad* or cup* or arch support*)).ti,ab,kf. or insole*.ti,ab,kf. or orth?s?s.ti,ab,kf. or orthopeadic support*.ti,ab,kf. or orthotic*.ti,ab,kf.	26481
3	1 and 2	502
4	limit 3 to yr="2000 -Current"	406
5	4 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	398
6	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	747755
7	exp clinical trial/ or randomized controlled trial/ or exp clinical trials as topic/ or randomized controlled trials as topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial or multicenter study or clinical trial).pt. or random*.ti,ab. or (clinic* adj trial*).tw. or ((singl* or doubl* or treb* or tripl*) adj (blind$3 or mask$3)).tw. or Placebos/ or placebo*.tw.	2728770
8	Epidemiologic studies/ or case control studies/ or exp cohort studies/ or Controlled Before-After Studies/ or Case control.tw. or cohort.tw. or Cohort analy$.tw. or (Follow up adj (study or studies)).tw. or (observational adj (study or studies)).tw. or Longitudinal.tw. or Retrospective*.tw. or prospective*.tw. or consecutive*.tw. or Cross sectional.tw. or Cross-sectional studies/ or historically controlled study/ or interrupted time series analysis/ [Onder exp cohort studies vallen ook longitudinale, prospectieve en retrospectieve studies]	4731601
9	Case-control Studies/ or clinical trial, phase ii/ or clinical trial, phase iii/ or clinical trial, phase iv/ or comparative study/ or control groups/ or controlled before-after studies/ or controlled clinical trial/ or double-blind method/ or historically controlled study/ or matched-pair analysis/ or single-blind method/ or (((control or controlled) adj6 (study or studies or trial)) or	5695443

	(compar* adj (study or studies)) or ((control or controlled) adj1 active) or "open label*" or ((double or two or three or multi or trial) adj (arm or arms)) or (allocat* adj10 (arm or arms)) or placebo* or "sham-control*" or ((single or double or triple or assessor) adj1 (blind* or masked)) or nonrandom* or "non-random*" or "quasi-experiment*" or "parallel group*" or "factorial trial" or "pretest posttest" or (phase adj5 (study or trial)) or (case* adj6 (matched or control*)) or (match* adj6 (pair or pairs or cohort* or control* or group* or healthy or age or sex or gender or patient* or subject* or participant*)) or (propensity adj6 (scor* or match*))).ti,ab,kf. or (confounding adj6 adjust*).ti,ab. or (versus or vs or compar*).ti. or ((exp cohort studies/ or epidemiologic studies/ or multicenter study/ or observational study/ or seroepidemiologic studies/ or (cohort* or 'follow up' or followup or longitudinal* or prospective* or retrospective* or observational* or multicent* or 'multi-cent*' or consecutive*).ti,ab,kf.) and ((group or groups or subgroup* or versus or vs or compar*).ti,ab,kf. or ('odds ratio*' or 'relative odds' or 'risk ratio*' or 'relative risk*' or aor or arr or rrr).ab. or (("OR" or "RR") adj6 CI).ab.))	
10	5 and 6 **– SR's**	49
11	(5 and 7) not 10 **– RCT's**	130
12	(5 and (8 or 9)) not (10 or 11) **– Observationele studies**	70
13	10 or 11 or 12	249

Module 6 Shockwave therapie

Search and select

A systematic review of the literature was performed to answer the following question(s):

What is the effectiveness of shockwavetherapy in comparison to placebo (with add on exercise therapy) in patients with plantar fasciopathy?

Table 1. PICO

Patients	Patients with plantar fasciopathy
Intervention	Radial extracorporeal shockwave therapy, focused extracorporeal shockwave therapy
Control	Placebo (with exercise therapy add-on)
Outcomes	Pain (critical), function (critical), side effects (important), return to sport (important), quality of life (important)
Other selection criteria	Study design: systematic reviews, meta-analyses and randomized controlled trials

Relevant outcome measures

The guideline panel considered pain, function and side effects as a **crucial** outcome measure for decision making; and return to sport and quality of life as an **important** outcome measure for decision making.

A priori, the guideline panel did not define the outcome measures listed above but used the definitions used in the studies.

The guideline panel defined 10% as a minimal clinically important difference for both continuous as well as dichotomous outcome measures. This includes a 10% difference on the outcome measurement on a continuous scale or an increase/decrease of relative risk (RRR) of 10% or more.

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms from 2000 until 28th of March 2024. The detailed search strategy is listed under the tab 'Literature search strategy'. The systematic literature search resulted in 278 hits.

Studies were selected based on the following criteria:

- Randomized controlled trials (RCTs), systematic reviews and/or meta-analyses;
- Studies according to the PICO;
- Studies including a minimum of 20 patients (10 patients per study arm);
- Full text English language publication.

Initially, 92 studies were selected based on title and abstract screening. After reading the full text, 77 studies were excluded (see the exclusion table under the tab 'Evidence tabellen'), and 15 studies were included.

Summary of literature

Description of studies

A total of 15 studies were included in the analysis of the literature. Important study characteristics and results are summarized in table 2. The assessment of the risk of bias is summarized in the risk of bias tables (under the tab ‘Evidence tabellen’).

Table 2. Characteristics of included studies

Study	Participants	Comparison	Follow-up	Outcome measures	Comments	Risk of bias (per outcome measure)*
Buchbinder 2002, Australia	N at baseline ESWT: 80 Placebo: 81 Age (mean ± SD) ESWT 52.2 ± 12.81 Placebo: 54.2 ± 12.05 Sex (% female) ESWT: 57.5 Placebo: 58.0 Baseline overall pain (mean VAS ± SD) ESWT: 71.5 ± 21.7 Placebo: 68.6 ±23.3 Baseline function (mean Maryland Foot Score ± SD) ESWT: 54.6 ± 16.0 Placebo: 53.4 ± 17.0 Inclusion: Patients had plantar heel pain for at least 6 weeks and clinical diagnosis, including thickened plantar fascia on ultrasound.	f-ESWT: 3 sessions of 2000/2500 shock waves per treatment for 3 weeks. Total cumulative dose 1000 mJ/mm2. Ultrasound gel used. sham ESWT: 3 sessions of 100 shock waves per treatment, for 3 weeks. Total dose 6.0 mJ/mm2.	6 weeks, 12 weeks	Pain (100 VAS) Function (Maryland Foot Score) Quality of life (SF-36 domains) Side effects	As-treated analysis (5 drop-outs in total). Conflicts of interest not reported.	LOW
Haake, 2003 Germany	N at baseline ESWT: 135 placebo: 136 Age (mean ± SD) ESWT 53.1 ± 10.8	f-ESWT: 4000 impulses of a positive energy flux density (0.08 mJ/mm2) under local anaesthesia with 2 ml mepivacaine 1%. Therapy was applied every two	6 weeks, 12 weeks	Pain (10-point VAS) Function (dichotomized Roles and Maudsley score) Side effects	Authors declared no conflicts of interest.	LOW

	Placebo: 52.9 ± 10.8 <u>Sex (% female)</u> ESWT: 73 Placebo: 78 <u>Baseline pain at rest (mean VAS ± SD)</u> ESWT: 3.9 ± 2.5 Placebo: 3.7 ± 2.3 <u>Inclusion</u>: Patients had plantar medial heel pain for at least 6 months and clinical diagnosis, and radiologically proven calcaneal spur	weeks plus or minus two days (3 × 4000 impulses). Sham-ESWT: Patients received the same regimen of therapy under local anaesthesia. A foil filled with air was fixed with ultrasound gel in front of the coupling cushion to reflect the shock waves				
Speed, 2003 United Kingdom	<u>N at baseline</u> ESWT:46 Placebo: 42 <u>Age (mean ± SD)</u> ESWT: 51.7± NR Placebo:52.5± NR <u>Sex (% female)</u> ESWT: 56% Placebo: 59.5% <u>Baseline VAS (mean ± SD)</u> ESWT: 73.6 (20.1) Placebo: 70.0 (20.1) <u>Inclusion:</u> Adult subjects with a clinical diagnosis of plantar fasciitis and at least 3 months of plantar heel pain	f-ESWT: 3 applications of Electromagnetic 1500 pulses at 0.12 mJ/mm^2 over 8 weeks. Placebo: 3 applications of Sham ESWT with deflated treatment minimal energy pulses (0.04 mJ/mm^2) over 8 wks.	4 weeks (12 weeks from baseline)	Pain (100 point VAS)	No conflicts of interest reported.	some concerns

Rompe, 2003 Germany	N at baseline ESWT: 22 Placebo: 23 Age (mean ± SD) ESWT: 43±NR Placebo: 40±NR Sex (% female) not reported (no significant difference between groups) Baseline VAS first walking pain (mean ± SD) ESWT: 6.9 ± 1.3 Placebo: 7.0 ± 1.3 Inclusion: Patients were long-distance runners (**recreational athletes**) with at least 12 months of symptoms	Low energy f-ESWT: 3 applications of 2 100 impulses of 0.16mJ/mm2, 4Hz radius 1.5-2cm over 3 wks Placebo: 3 applications of Sham ESWT over 3 wks with sound reflecting pad, no coupling gel.	6 months, 1 year	Pain (10 point VAS)	Conflicts of interest not reported.	Some concerns
Theodore, 2004 United States	N at baseline ESWT: 76 Placebo: 74 Age (mean ± SD) ESWT: 50±NR Placebo: 53±NR Sex (% female) ESWT: 81.6% Placebo: 63.5%* Baseline VAS first walking pain (mean ± SD)	f-ESWT: 1 session with 3800 shocks (3500 at 0.36 mJ/mm2) for a total of 1300 mJ/mm2 (generated using the Epos Ultradevice. Medial calcaneal nerve block using 5 mL of 1% xylocaine 15–20 minutes prior to the procedure). Placebo: sham ESWT. With thin air cushion on the therapy head.	6 weeks, 12 weeks	Pain (10-point VAS), Function (dichotomized Roles and Maudsley), QoL (SF-12)	Study was industry sponsored.	some concerns

	ESWT: 7.7 ± 1.4 Placebo: 7.7 ± 1.5 <u>Inclusion:</u> Patients had plantar medial heel pain for at least 6 months and clinical diagnosis, and participated in stretching program 6 months prior start of trial.					
Kudo, 2006 Canada	<u>N at baseline</u> ESWT: 58 Placebo: 56 <u>Age (mean ± SD)</u> ESWT: 51.1 ± 10.6 Placebo: 48.8 ± 9.8 <u>Sex (% female)</u> ESWT: 69.0% Placebo: 59.0% <u>Baseline VAS first walking pain (mean ± SD)</u> ESWT: 7.5 ± 1.5 Placebo: 7.9 ± 1.5 <u>Inclusion:</u> Patients had plantar medial heel pain for at least 6 months and clinical diagnosis, and participated in stretching program 6 months prior (similar to Theodore, 2004)	f-ESWT: 1 session of 3800 shockwaves, total energy delivery of 1,300 mJ/mm^2 (ED+) or 2,330 mJ/mm^2 (ED). Placebo: sham ESWT with thin foam cushion and ultrasound gel.	6 weeks, 12 weeks	Pain (10-point VAS), Function (dichotomized Roles and Maudsley), QoL (SF-12), Side effects	Study was industry sponsored.	Some concerns
Malay, 2006 United States	<u>N at baseline</u> ESWT: 115 Placebo: 57	f-ESWT: 3800 shockwave impulses, 150/minute for 25 minutes. Dose not reported, but	4 weeks, 12 weeks	Pain (10-point VAS) Side effects	Study was industry sponsored.	Some concerns

	Age (mean ± SD) ESWT: 50.8 ± 10.1 Placebo: 52.1 ± 11.1 Sex (% female) ESWT: 68.7% Placebo: 63.2% Inclusion: Included patients with chronic proximal plantar fasciitis.	variable (from level 1 up to 7 of the Orthospec device) Placebo ESWT: Same procedure as ESWT group, but with foam-insulated membrane				
Chow, 2007 Hong-Kong	n at baseline ESWT: 19 Placebo: 19 Age (mean ± SD) ESWT fixed dose: 51.9 ± 11.7 Placebo: 50.6 ± 9.8 Sex (% female) ESWT: 63.2% Placebo: 52.6% Inclusion: Included patients with plantar heel pain for at least 3 months	r-ESWT: rESWT in 3 sessions (1 per wk) of 1000 shock wave impulses, 3 Hz. Dose 0.05 mJ/ mm2, gradually increasing to highest possible tolerable pain level. Placebo ESWT: 3 sessions (1 per wk) of 30 shock wave impulses, 3 Hz. Dose 0.03 mJ/ mm2.	3 weeks	Pain (VAS) function (FFI)	Conflicts of interest not reported	HIGH
Gerdesmeyer, 2008 United States, Europe	n at baseline ESWT: 125 Placebo: 118 Age (mean ± SD) ESWT: 52.4 ± 12.0 Placebo: 52.0± 10.5	r-ESWT: 3 applications of radial ESWT with 2000 impulses at 0.16 mJ/mm2 over 6 weeks Control: Placebo: Sham ESWT. 3 sessions over 6 weeks	12 weeks	Pain (10-point VAS) function (dichotomized roles and Maudsley) QoL (SF-36) Side effects	The study was sponsored by the manufacturer	LOW

	Sex (% female) ESWT: 69.6% Placebo: 67.9% Baseline VAS first walking pain (mean ± SD) ESWT: 7.5 ± 1.5 Placebo: 7.5 ± 1.6 Inclusion: Patients with clinical diagnosis and at least 6 months of chronic plantar heel pain that proved resistant to conservative treatments.					
Ibrahim 2010, ibrahim 2017 United States	n at baseline ESWT: 25 Placebo: 25 Age (mean ± SD) ESWT: 56.6 ± 13.5 Placebo: 49.10± 12.8 Sex (% female) ESWT: 72% Placebo: 56% Baseline VAS first walking pain (mean ± SD) ESWT: 8.5 ± 1.7 Placebo: 8.9 ± 1.0 Inclusion: Patients with clinical diagnosis and at least 6 months of chronic plantar heel pain that	r-ESWT: 2 sessions 2,000 impulses (Air pressure of device at 3.5 bar) Dose =0.16 mJ/mm^2; 15 mm applicator at frequency of 8 Hz. Placebo: 2 sessions of sham ESWT performed with clasp on heel to prevent transmission of impulses from applicator to skin	4 weeks, 12 weeks, 1 year	Pain (10 point VAS), Function (Modified Roles and Maudsley) Side effects	One of the authors served as consultant for manufacturer, authors declared no other conflicts of interest.	LOW

	proved resistant to conservative treatments.					
Saxena, 2012	n at baseline ESWT: 11 Placebo: 14 Age (mean ± SD) ESWT: 47.9 ± 12.6 Placebo: 47.6 ± 9.9 Sex (% female) ESWT: 36% Placebo: 42% Baseline VAS first walking pain (mean ± SD) ESWT: 8.7 ± 1.4 Placebo: 8.0 ± 1.1 Inclusion: Patients were **athletes**. Patients with clinical diagnosis and at least 6 months of chronic plantar heel pain that proved resistant to conservative treatments	f-ESWT: 3 sessions, once per week with 2000 impulses and dose of 0.24 mJ/mm^2 at frequency of 4 Hz. Placebo: 3 sessions (once per week) of sham ESWT performed with blocking head to prevent transmission of impulses from applicator to skin	1 year	Pain (10-point VAS) Function (roles and Maudsley)	Study also included surgical study arm, which is not included in this analysis.	HIGH
Gollwitzer, 2015 United States	n at baseline ESWT: 125 Placebo: 121 Age (mean ± SD) ESWT: 50.0 ± 11.2 Placebo: 47.4 ± 10.6 Sex (% female) ESWT: 68% Placebo: 72.7%	f-ESWT: 3 applications of ESWT 2000 waves to the point of maximal tenderness at 0.25 mJ/mm2 over 3 weeks. placebo: Sham ESWT with airfilled standoff preventing transmission. 3 sessions over 3 weeks	12 weeks	Pain (10-point VAS) Function (Roles and Maudsley) Side effects	Funded by manufacturer, but they had no active role.	LOW

	Baseline VAS first walking pain (mean ± SD) ESWT: 7.9 ± 1.6 Placebo: 8.0 ± 1.6 Inclusion: Patients with clinical diagnosis and at least 6 months of chronic plantar heel pain that proved resistant to conservative treatments					
Hawamdeh, 2016 Jordan	n at baseline ESWT: 12 Placebo: 12 Age (mean ± SD) Not reported Sex (% female) ESWT: 66% Placebo: 86% Baseline VAS first walking pain (mean ± SD) ESWT: 6.2 ± 2.3 Placebo: 6.6± 2.3 Inclusion: Adults with diagnosis of plantar fasciitis	f-ESWT: 3 sessions (over 3 wks) of 2000 shockwaves Dose: 0.25mj/mm2. ESWT was followed by 10-min ice application and 3 times 30 second plantar stretching exercises Placebo: sham-ESWT identical to ESWT group with clasp on heel to prevent transmission. 3 sessions for 3 weeks	3 weeks	Pain (10-point VAS) Function (Roles and Maudsley)	Conflicts of interest not reported	HIGH
Şah, 2023 Turkey	n at baseline f-ESWT group: 30 r-ESWT group: 33 placebo: 29 Age (mean ± SD)	f-ESWT: 5 minutes of focused ESWT with 500 pulses at 5Hz for 1.40 minutes and 1800 pulses at 10 Hz for 3 minutes. Dosage was 0.02–0.60 mJ/mm2.	4 weeks, 12 weeks	Pain and function (both via FFI)	Compared focused, radial and sham ESWT.	LOW

	f-ESWT group: 46 ± 11.3 r-ESWT group: 48.7 ± 10.6 placebo: 52.2 ± 10.5 <u>Sex (% female)</u> f-ESWT group: 50% r-ESWT group: 51% placebo: 55% <u>Baseline FFI pain (mean ± SD)</u> f-ESWT group: 60 .0± 7.5 r-ESWT group: 62.8 ± 11.7 placebo: 59.2 ± 12.3 <u>Inclusion:</u> Patients with clinical diagnosis of plantar fasciitis as well as calcaneal spur present	r-ESWT: radial ESWT for 5 minutes with 500 pulses at 5Hz for 1.40 10 Hz with 1800 pulses for 3 minutes. All with a dosage of 0.204 mJ/mm2 - sham ESWT (0 Joule), with same frequency and pressure values as radial ESWT group All ESWT groups applied in three sessions, with 2-4 day intervals, for 1 week total			Authors declared no conflicts of interest.	

*For further details, see risk of bias table in the appendix

Results

1. Pain (crucial)

Pain was reported by all studies. 14 studies assessed pain with the visual analogue scale of either 10 or 100 points (VAS; scale of 0 to 10 or 100 with 0 representing no pain and 10 or 100 the worst pain imaginable). Haake (2003) and Chow (2007) assessed pain on palpation instead of overall pain. Theodore (2004) assessed pain at first walking in the morning. Sah (2023) reported on pain using the pain subcategory of the Foot function index (FFI) which consists of 9 items (resulting in a score of 0-90) assessing pain in different situations.

The results on pain were pooled for three follow-up periods: short term pain, assessed between 3-6 weeks after last treatment; mid-term pain, assessed at 12 weeks after last treatment; and long-term pain, assessed at one year after treatment.
As different scales were used for assessment, the results were pooled using the standardized mean difference (SMD).

Nine studies assessed short-term pain (figure 1). When pooling the results of 1009 patients, this resulted in an SMD of -0.70 (95% CI -1.18 to -0.22) in favor of ESWT. To assess the clinical relevance on the found effect, the SMD was transformed back to a 10-point VAS, resulting in a mean difference (MD) of -1.93 (95% CI -3.19 to -0.60). This is a clinically relevant difference.

Pain at 12 weeks (mid-term) was assessed in ten studies with in total 1559 patients, off which the pooled results lead to an SMD of -0.56 (95% CI -0.89 to -0.24). After transforming this back to the VAS this results in an MD of -2.13 (95% CI -3.38 to -0.95) in favour of ESWT. This is also a clinically relevant difference.

Four studies (n=357) assessed long-term pain at one year after last intervention. This resulted in an SMD of -1.26 (95% CI -2.32 to -0.20), which transformed to the VAS equaled an MD of -5,61 (95% CI -10,00 to -0.89) in favour of ESWT. This is also a clinically relevant difference.

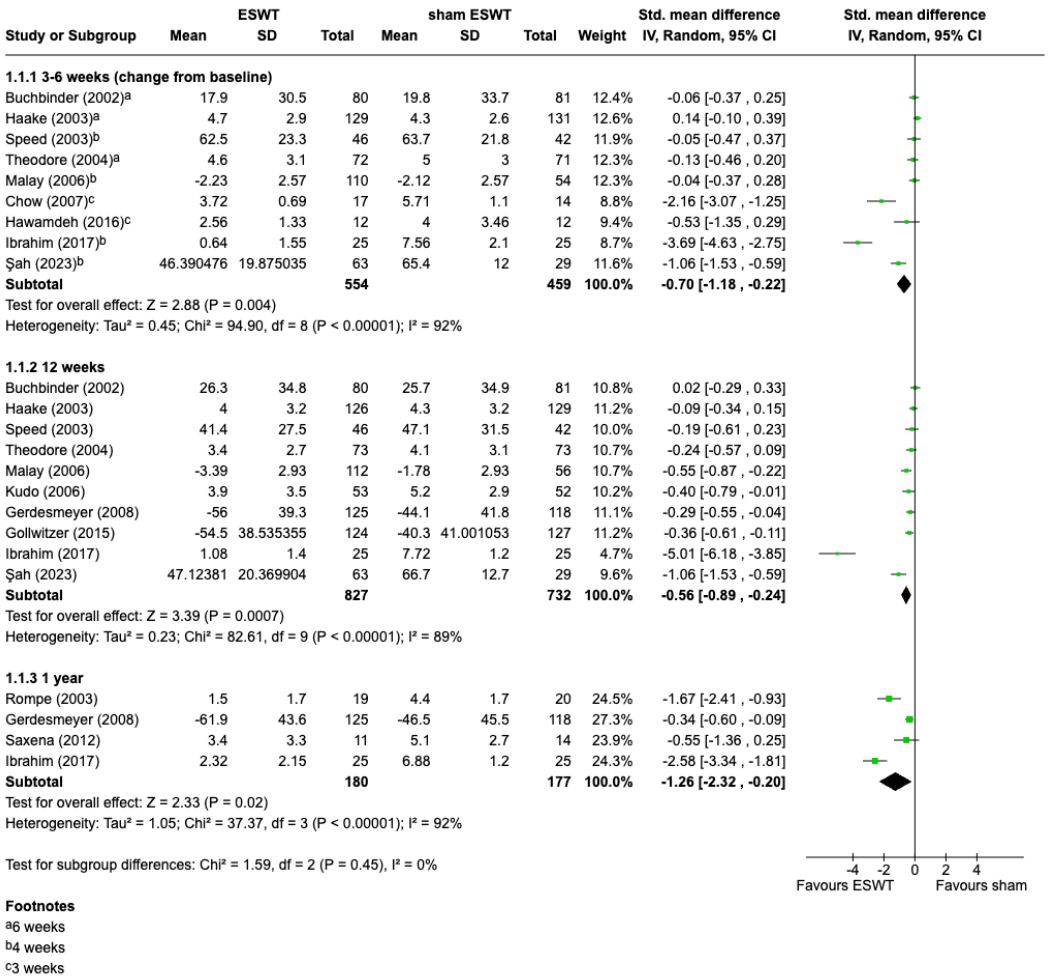


Figure 1. Meta-analysis of the effect of ESWT on pain (continuous scales)

2. Function (crucial)

Eleven of the included studies reported on function. Haake (2003), Theodore (2004), Kudo (2006), Gerdesmeyer, (2008), Saxena (2012), Gollwitzer (2015), Hawamdeh (2016) and Ibrahim (2010, 2017) used the Roles and Maudsley (R&M) score to assess function (score of 1 to 4, ranging from full movement and no pain to severe limitation of movement with pain).

Chow (2007) and Sah (2023) reported on function using the disability subcategory of the Foot function index (FFI) which consists of nine items (rated on a 10-point VAS, resulting in a score between 0 and 90) assessing disability in different daily tasks.
Buchbinder (2002) assessed function using the Maryland Foot Score, a disability index that derives a score from 0 to 100 points, measuring pain and function of the foot.

For short term function (3-6) weeks, the continuous score of the R&M (Hawamdeh 2016 & Ibrahim 2010/2017) was pooled together with the FFI disability subcategory and the Maryland Foot score, resulting in an SMD of -1.58 (95% CI -2.86 to -0.30). Transforming this back the R&M this results in an MD of -0.95 (95% CI -1.60 to -0.18) in favour of ESWT. This is a clinically relevant difference.
For mid-term function, which was reported by four studies (n = 547), the SMD of -0.77 (95% CI -1.43 to -0.11) was transformed to an MD of -0.75 (95% -1.39 to -0.11) in favour of ESWT on the R&M score. This was also a clinically relevant difference.
Long-term function was assessed by Saxena (2012) and Ibrahim (2010/2017) and was pooled to an SMD of -0.73 (95% CI -1.20 to -0.26). This was transformed back to an R&M MD of

-5.61 (95% CI -10.00 to -0.89). This was also a clinically relevant difference.

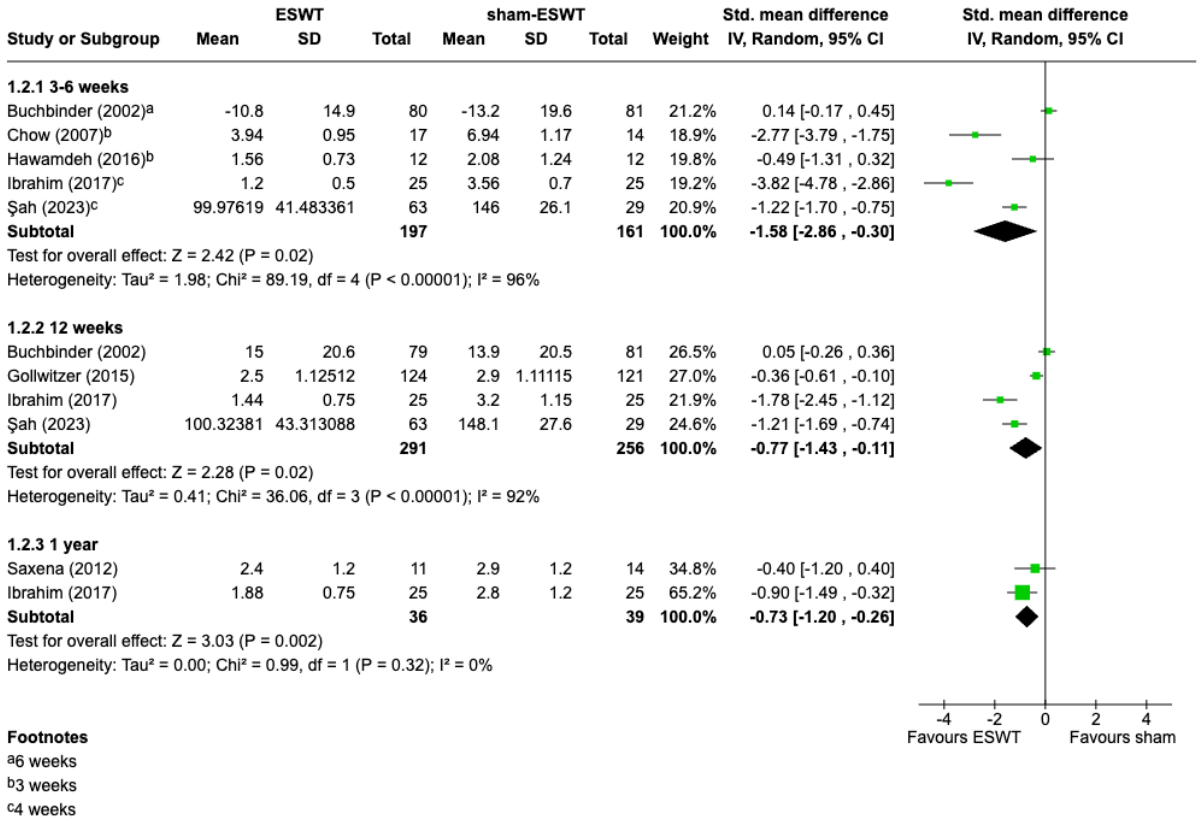


Figure 2. Meta-analysis of function on continuous scale. Divided in subgroups for short-term, mid-term and long-term effects.

Four studies (n= 750 patients) assessed the R&M score as a dichotomous outcome, in which patients with the scores 1 and 2 (Excellent, good) were scored as successful events, and the scores 3 and 4 (fair, poor) as unsuccessful. Results for mid-term (12 weeks) function are displayed in figure 3. The meta-analysis resulted in an RR of 1.34 (95% CI 1.15 to 1.57).

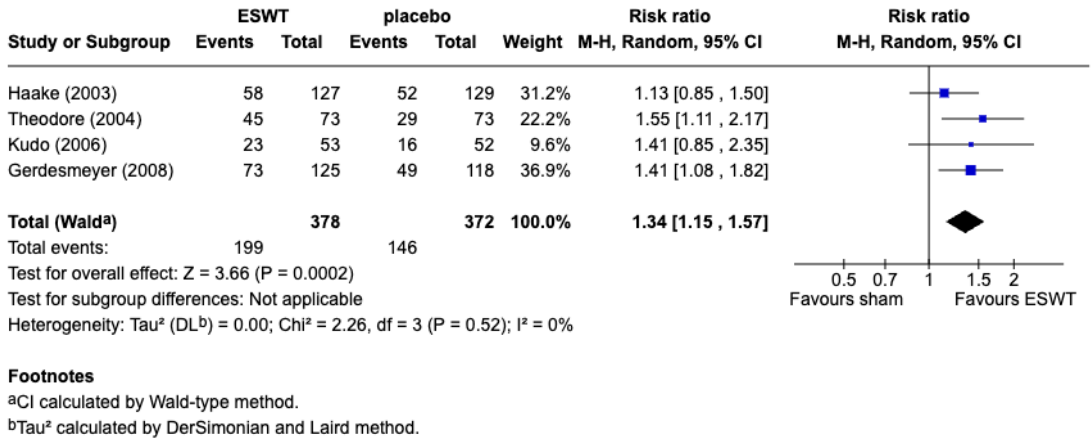


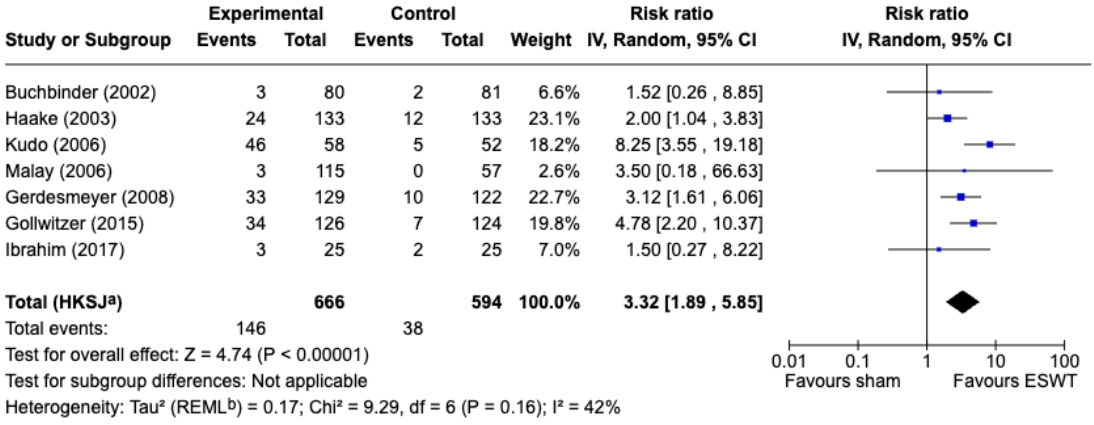
Figure 3. Meta analysis of function (12 weeks, dichotomized, shows RR for excellent to good score on the Roles and Maudsley score).

3. Side effects (crucial)

Seven studies (n = 1260) assessed side effects as a pre-specified outcome measure. Common reported side effects were redness, swelling, heat, numbness and pain or discomfort shortly

after intervention. The incidence of these and similar side effects are pooled in figure 4, which resulted in an RR of 3.32 (95% CI 1.89 to 5.85) in favour of ESWT, meaning there was a higher risk in the ESWT group. The risk difference between groups was 0.18 (95% CI -0.04 to 0.40) and was also in favour of ESWT. This was a clinically relevant effect.

None of the studies reported any serious adverse events.



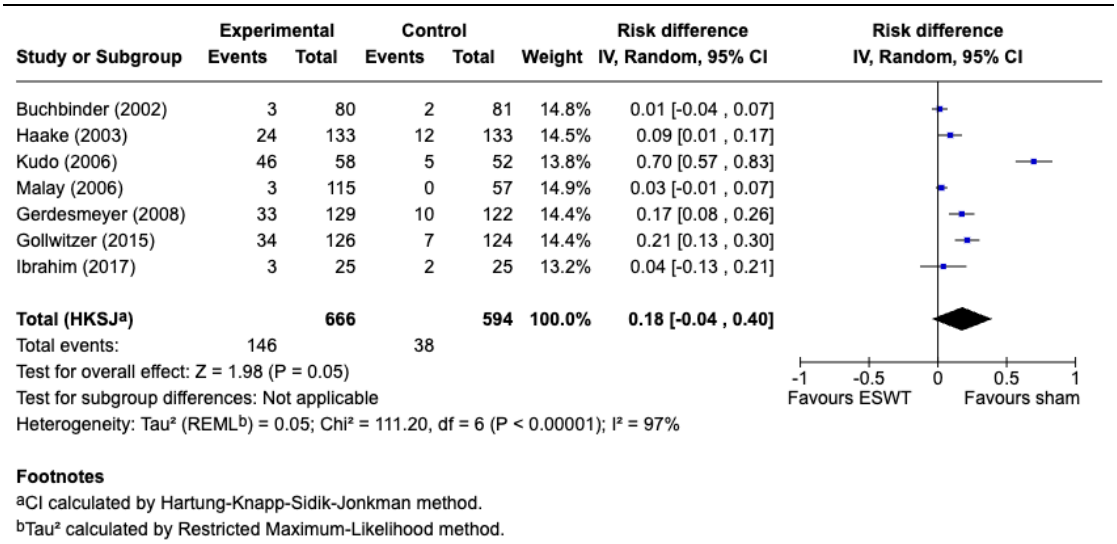
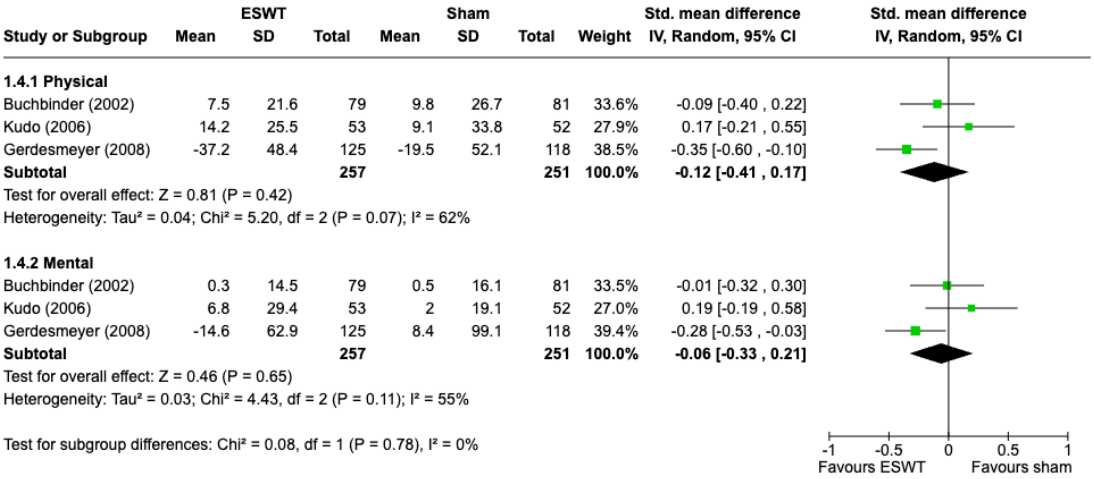


Figure 4. adverse events during or immediately post-intervention

4. Quality of life (important)

Four of the included studies assessed quality of life. Buchbinder (2002) and Gerdesmeyer (2008) used the physical and mental subscales of Short Form-36 Health Survey (SF-36) and Theodore (2004) and Kudo (2006) used the subscales of Short Form-12 Health Survey (SF-12), which is a shortened form of the SF-36 with fewer items. The subscales of both instruments range from 0 to 100, yet due to construct and unit differences an SMD was needed to pool the results. Theodore (2004) did not report the results (mean and SD) of the SF-12 questionnaire but stated solely that no statistically significant changes were found. The other three studies (n= 508) were pooled in a meta-analysis (figure 5), resulting in an SMD of -0.12 (95% CI -0.41 to 0.17) for the physical subscale and -0.06 (95% CI -0.33 to 0.21) for the mental subscale. When transforming these back to the sf-36 this resulted in an MD of

-2.91 (95% CI -9.96 to 4.13) and -0.92 (95% CI -5.05 to 3.21) respectively. Both of these differences were not clinically relevant.



5. Return to sport (important)

No studies reported on return to sport.

Summary of Findings

Outcome Timeframe	**Study results and measurements**	**Absolute effect estimates** sham-ESWT ESWT	**Certainty of the evidence** (Quality of evidence)	**Summary**
Short-term pain 3-6 weeks	Measured by: VAS Scale: 0 - 10 Lower better Based on data from 1013 participants in 9 studies Follow up 3-6 weken	Difference: **MD 1.93 lower** (CI 95% 3.19 lower - 0.61 lower)	**Low** Due to serious risk of bias, Due to serious imprecision[2]	Extracorporale shockwave therapy may reduce short-term pain when compared with placebo in patients with plantar fasciopathy.
Mid-term pain 12 weeks	Measured by: VAS Scale: 0 - 10 Lower better Based on data from 1559 participants in 10 studies Follow up 12 weeks	Difference: **MD 2.13 lower** (CI 95% 3.38 lower - 0.95 lower)	**Moderate** Due to serious imprecision[3]	Extracorporale shockwave therapy probably reduces pain at 12 weeks when compared with placebo in patients with plantar fasciopathy
Long-term pain 1 year	Measured by: Scale: - High better Based on data from 357 participants in 4 studies Follow up 1 year	Difference: **MD 5.61 lower** (CI 95% 10.00 lower - 0.89 lower)	**Low** Due to serious risk of bias, Due to serious imprecision[4]	Extracorporale shockwave therapy may reduce long-term pain when compared with placebo in patients with plantar fasciopathy.
Short-term function	Measured by: Roles & Maudsley score Scale: 1 - 4 Lower better Based on data from 358 participants in 5 studies Follow up 3-6 weeks	Difference: **MD 0.95 lower** (CI 95% 1.60 lower - 0.18 lower)	**Low GRADE** Due to serious risk of bias, Due to serious imprecision[5]	Extracorporale shockwave therapy may improve short-term function when compared with placebo in patients with plantar fasciopathy.
Mid-term function	Measured by: Roles & Maudsley score Scale: 1 - 4 Lower better Based on data from 567 participants in 4 studies Follow up 12 weeks	Difference: **MD 0.75 lower** (CI 95% 1.39 lower - 0.11 lower)	**Moderate GRADE** Due to serious imprecision[6]	Extracorporale shockwave therapy probably slightly improves function at 12 weeks when compared with placebo in patients with plantar fasciopathy

Long-term function	Measured by: Roles & Maudsley score Scale: 1 - 4 Lower better Based on data from 80 participants in 2 studies Follow up 1 year	Difference: **MD 5.61 lower** (CI 95% 10.0 lower - 0.89 lower)		**Low GRADE** Due to serious risk of bias, Due to serious imprecision[7]	Extracorporale shockwave therapy may improve long-term function when compared with placebo in patients with plantar fasciopathy.
Side effects	Relative risk: 3.32 (CI 95% 1.89 - 5.85) Based on data from 1260 participants in 7 studies Follow up during /post treatment	**1** per 1000	**3** per 1000	**Low GRADE** Due to very serious risk of bias, Due to serious inconsistency[1]	Extracorporale shockwave therapy may lead to more short-term adverse events (pain, discomfort, swelling, redness) when compared with placebo in patients with plantar fasciopathy.
		Difference: **2 more per 1000** (CI 95% 1 more - 5 more)			
Quality of life-physical	Measured by: SF-36 (physical domain) Scale: 0 - 100 High better Based on data from 508 participants in 3 studies Follow up 12 weeks	Difference: **MD 2.91 lower** (CI 95% 9.96 lower - 4.13 higher)		**Moderate GRADE** Due to serious inconsistency[8]	Extracorporale shockwave therapy probably has little or no difference on physical quality of life when compared with placebo in patients with plantar fasciopathy
Quality of life-Mental	Measured by: SF-36 (mental domain) Scale: 0 - 100 High better Based on data from 508 participants in 3 studies Follow up 12 weeks	Difference: **MD 0.92 lower** (CI 95% 5.05 lower - 3.21 higher)		**Moderate GRADE** Due to serious inconsistency[9]	Extracorporale shockwave therapy probably has little or no difference on mental quality of life when compared with placebo in patients with plantar fasciopathy
Return to sport				**No GRADE**	No evidence was found regarding the effect of extracorporale shockwave therapy on return to sport when compared with placebo in patients with plantar fasciopathy.

1. **Risk of Bias: very serious.** Selective outcome reporting, Trials stopping earlier than scheduled, resulting in potential for overestimating benefits, Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Incomplete data and/or large loss to follow up, due to [reason];
2. **Risk of Bias: serious.** Inadequate concealment of allocation during randomization process, resulting in potential for selection bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias, Incomplete data and/or large loss to follow up, Missing intention-to-treat analysis; **Imprecision: serious.** Wide confidence intervals;
3. **Imprecision: serious.** Wide confidence intervals;
4. **Risk of Bias: serious.** Inadequate concealment of allocation during randomization process, resulting in potential for selection bias, Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias, Incomplete data and/or large loss to follow up, Missing intention-to-treat analysis; **Imprecision: serious.** Wide confidence intervals;

5. **Risk of Bias: serious.** Inadequate concealment of allocation during randomization process, resulting in potential for selection bias, Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias, Incomplete data and/or large loss to follow up, Missing intention-to-treat analysis; **Imprecision: serious.** Wide confidence intervals;
6. **Imprecision: serious.** Wide confidence intervals;
7. **Risk of Bias: serious.** Inadequate concealment of allocation during randomization process, resulting in potential for selection bias, Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias, Incomplete data and/or large loss to follow up, Missing intention-to-treat analysis; **Imprecision: serious.** Wide confidence intervals, Low number of patients;
8. **Inconsistency: serious.** The direction of the effect is not consistent between the included studies; Point estimates vary widely;
9. **Inconsistency: serious.** Point estimates vary widely; The direction of the effect is not consistent between the included studies;

Kennisvragen

Patients	Patients with plantar fasciopathy
Intervention	Radial extracorporeal shockwave therapy, *dose x*
Control 1	Radial extracorporeal shockwave therapy, *dose y*
Control 2	Placebo/sham
Outcomes	Return to work, Pain function, side effects, return to sport , quality of life (important)
Other selection criteria	Study design: systematic reviews, meta-analyses and randomized controlled trials

Omtrent de gebruikte protocollen van toepassing van ESWT is er nogal veel variatie. In de studies van voldoende kwaliteit blijkt zowel gefocusseerde als radiale ESWT toegepast te worden. Ook varieert de dosis en het aantal behandelingen. Voor een nauwkeurigere vaststelling van de werkzame dosis zouden grotere studies van voldoende kwaliteit benodigd zijn.

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Haake M, Buch M, Schoellner C, Goebel F, Vogel M, Mueller I, Hausdorf J, Zamzow K, Schade-Brittinger C, Mueller HH. Extracorporeal shock wave therapy for plantar fasciitis: randomised controlled multicentre trial. BMJ. 2003 Jul 12;327(7406):75. doi: 10.1136/bmj.327.7406.75. PMID: 12855524; PMCID: PMC164919.

Hawamdeh, Ziad & Alghwiri, Alia & Nassar, Aseel. (2016). The Short-Term Effect of Extracorporeal Shock Wave in Treating Plantar Fasciitis: RCT. Jordan Medical Journal. 50. 1-11. 10.12816/0025979.

Heide M, Røe C, Mørk M, Myhre K, Brunborg C, Brox JI, Hoksrud AF. Is radial extracorporeal shock wave therapy (rESWT), sham-rESWT or a standardised exercise programme in combination with advice plus customised foot orthoses more effective than advice plus customised foot orthoses alone in the treatment of plantar fasci. Br J Sports Med. 2024 Jul 31;58(16):910-918.

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Malay DS, Pressman MM, Assili A, Kline JT, York S, Buren B, Heyman ER, Borowsky P, LeMay C. Extracorporeal shockwave therapy versus placebo for the treatment of chronic proximal plantar fasciitis: results of a randomized, placebo-controlled, double-blinded, multicenter intervention trial. J Foot Ankle Surg. 2006 Jul-Aug;45(4):196-210. doi: 10.1053/j.jfas.2006.04.007. PMID: 16818146.

Roerdink RL, Dietvorst M, van der Zwaard B, van der Worp H, Zwerver J. Complications of extracorporeal shockwave therapy in plantar fasciitis: Systematic review. Int J Surg. 2017 Oct;46:133-145. doi: 10.1016/j.ijsu.2017.08.587. Epub 2017 Sep 7. PMID: 28890412.

Rompe JD, Decking J, Schoellner C, Nafe B. Shock wave application for chronic plantar fasciitis in running athletes. A prospective, randomized, placebo-controlled trial. Am J Sports Med. 2003 Mar-Apr;31(2):268-75. doi: 10.1177/03635465030310021901. PMID: 12642264.

Şah V, Kaplan Ş, Özkan S, Adanaş C, Toprak M. Comparison between radial and focused types of extracorporeal shock-wave therapy in plantar calcaneal spur: A randomized sham-controlled trial. Phys Sportsmed. 2023 Feb;51(1):82-87. doi: 10.1080/00913847.2022.2091413. Epub 2022 Jun 21. PMID: 35713119.

Saxena A, Fournier M, Gerdesmeyer L, Gollwitzer H. Comparison between extracorporeal shockwave therapy, placebo ESWT and endoscopic plantar fasciotomy for the treatment of chronic plantar heel pain in the athlete. Muscles Ligaments Tendons J. 2013 Jan 21;2(4):312-6. PMID: 23738317; PMCID: PMC3666533.

Speed CA, Nichols D, Wies J, Humphreys H, Richards C, Burnet S, Hazleman BL. Extracorporeal shock wave therapy for plantar fasciitis. A double blind randomised controlled trial. J Orthop Res. 2003 Sep;21(5):937-40. doi: 10.1016/S0736-0266(03)00048-2. PMID: 12919884.

Theodore GH, Buch M, Amendola A, Bachmann C, Fleming LL, Zingas C. Extracorporeal shock wave therapy for the treatment of plantar fasciitis. Foot Ankle Int. 2004 May;25(5):290-7. doi: 10.1177/107110070402500503. PMID: 15134608.

Implementatietabel

Aanbeveling – 1 Overweeg shockwave als aanvullende behandeling voor patiënten met fasciopathie plantaris, mits: • De patiënt adequaat is behandeld via educatie en oefentherapie gedurende minimaal 12 weken (linkjes naar richtlijnmodules); • De patiënt niet eerder is behandeld met shockwave therapie binnen deze ziekte-episode. Zowel radiaal als gefocusseerde shockwave kunnen middels 3 sessies worden toegepast.	Op basis van de beschikbare evidentie en ervaring uit de praktijk kon er onvoldoende richting aan de besluitvorming worden gegeven. Om die reden is er geen beschrijving van belemmeringen en kansen voor implementatie van de aanbeveling toegevoegd. Disseminatie van de kennis in deze module verloopt via de standaard route. De module wordt gepubliceerd op de Richtlijnendatabase.

Risk of Bias table

Study reference	Was the allocation sequence adequately generated?	Was the allocation adequately concealed?	Blinding: Was knowledge of the allocated interventions adequately prevented?	Was loss to follow-up (missing outcome data) infrequent?	Are reports of the study free of selective outcome reporting?	Was the study apparently free of other problems that could put it at a risk of bias?	Overall risk of bias If applicable/necessary, per outcome measure
Buchbinder, 2002	Definitely yes Patients were randomized and stratified by treatment center (3 treatment sites) in blocks of 4 to receive either active treatment or placebo regimens according to a computer-generated random numbers list created by the study biostatistician	definitely yes, treatments were given by a single extracorporeal shock wave (ESW) therapist who was informed of treatment allocation (by central telephone) just prior to commencement of treatment according to the participant's identification number.	Probably yes Patients and the single outcome assessor were blinded; healthcare provider and data analyst were not	Probably no, 4/85 (<5%) withdrew from placebo group, and 1/81 withdrew from ESWT group so LTFU was low, however as-treated analysis was done	Definitely yes, All outcomes reported	Definitely yes; Reason: No other problems noted	**LOW**

		Care was taken to ensure that study participants did not meet, and individual study participants were asked to wait in separate waiting areas.					
Haake, 2003	Definitely yes Random permuted blocks of sizes six and four were used to provide each centre with a separate computer generated list of random treatment assignments	definitely yes, The study doctor was told by telephone what treatment had been allocated to his or her patient when the patient turned up for the first intervention	Probably yes Patients and outcome assessors were blinded, study doctor and caregiver performing intervention were not	Probably no, 8/137 (5%) withdrew from placebo group, and 8/135 withdrew from ESWT group ,so LTFU was low, however how protocol violations (receiving other treatment) were handled. Also as-treated analysis was done	Definitely yes, All outcomes reported	Definitely yes; Reason: No other problems noted	**LOW**
Speed, 2003	Probably yes, Subjects were randomised using randomisation tables	Not reported	Probably yes Patients and outcome assessors were blinded	Probably yes, 4/46 ESWT group and 8/42 placebo group withdrew. Intention to treat analysis was done.	Not reported	Definitely yes; Reason: No other problems noted	Some concerns?
Rompe, 2003	Not reported	Probably yes, Randomization by use of identical sealed envelopes	Probably yes Patients and outcome assessors were blinded, physican performing intervention was not	Definitely no, High loss to follow up due to self-reported ineffective intervention in both groups. No intention to treat protocol, power not reached	Not reported	Probably no; Baseline characteristics not reported	Some concerns
Theodore, 2004	Not reported	Not reported	Probably yes Patients and outcome assessors were blinded,	Probably yes, Low loss to follow up but no intention to treat analysis	Not reported	Definitely no; Baseline not equal between groups (gender)	Some concerns

Kudo, 2006	Definitely yes, randomization scheme was generated by Biostat International, Inc., Tampa, Florida.	Definitely yes, Sealed, opaque, tamper-proof envelopes containing individual randomization assignments	Probably no, Even though patients and outcome assessors were blinded, comparing of blinding showed a significant difference between groups (related to experienced pain)	Probably yes, Low loss to follow up but no intention to treat analysis	Not reported	Definitely yes; Reason: No other problems noted	Some concerns
Malay, 2006	Definitely yes, Randomization was determined by computer-generated random numbers separately for each study center.		Probably yes Patients and outcome assessors were blinded, physician performing intervention was not	Probably yes, Loss to follow up +/- 10% in both groups, but intention to treat analysis with LOCF	Definitely yes, All outcomes reported	Probably no, - Study was sponsored by manufacturer - Use of the participant diary to record walking activity could have been biased by inaccuracies	Some concerns
Chow, 2007	Not reported	Not reported	Probably no, Patients were blinded, all others not reported	Definitely no, LTFU was higher in control group (26%), with as treated analysis	Not reported	Definitely yes; Reason: No other problems noted	HIGH
Gerdesmeyer 2008	Definitely yes, allocation in permuted blocks of 4 to 8, stratified by treatment center with the use of a computer-generated random list	Definitely yes, Concealment of randomization was guaranteed by nontransparent envelopes.	Probably yes, Both patients and assessing physicians were blinded to randomization as well as to the evaluating physician. Others not reported	definitely yes, Loss to follow up low in both groups, and intention to treat analysis with LOCF	Definitely yes, All outcomes reported	Probably no, The study was sponsored by the manufacturer	LOW
Ibrahim, 2010/2017	Definitely yes, Randomization was performed by a computerized	Definitely yes, An administrative assistant distributed interventions via	Probably yes, Both patients and study investigators were blinded to randomization or	Definitely yes, No loss to follow up	Definitely yes, All outcomes reported	Definitely yes; Reason: No other problems noted	LOW

	random number generator created by an independent biostatistician	opaque, sealed envelopes	patient records. Others not reported				
Saxena, 2012	Definitely yes, Randomization was done by a computerized program	Definitely yes, Numbering was placed in sealed envelopes. A non-blinded investigator recorded the subjects' category.	Probably no, Patients blinded, others not reported	Not reported	Not reported	Probably no, Potential selection bias due to surgery option	HIGH
Gollwitzer 2015	Definitely yes, Randomization via permuted blocks of four to eight, stratified by treatment center, with the use of a computer-generated random list	Definitely yes, Concealed allocation with non-transparent envelopes	Probably yes, participants and evaluating physicians were blinded, treating physicians were not	Probably yes, Loss to follow up +/- 10% in both groups, but intention to treat analysis with LOCF	Definitely yes, All outcomes reported	Probably yes, The study was sponsored by the manufacturer, but they were not involved actively	LOW
Hawamdeh, 2016	Not reported	Not reported	Probably no, Patients blinded, others not reported	Definitely no, Higher loss-to follow up in placebo group, as treated analysis	Not reported	Definitely yes; Reason: No other problems noted	HIGH
Sah, 2023	Probably yes, Random allocation software randomized patients in three groups by a block randomization method. Size of blocks unknown	Not reported	Probably yes, participants and assessors were blinded, others not reported	Probably yes, Loss to follow-up was low and equal among groups, but as treated analysis	Definitely yes, All outcomes reported	Definitely yes; Reason: No other problems noted	LOW

Table of excluded studies

Reference	Reason for exclusion
Abt T, Hopfenmüller W, Mellerowicz H. Stosswellentherapie bei therapieresistenter Plantarfasziitis mit Fersensporn: eine prospektiv randomisiert plazebokontrollierte Doppelblindstudie [Shock wave therapy for recalcitrant plantar fasciitis with heel spur: a prospective randomized placebo-controlled double-blind study]. Z Orthop Ihre Grenzgeb. 2002 Sep-Oct;140(5):548-54. German. doi: 10.1055/s-2002-34001. PMID: 12226782.	German language
Akınoğlu B, Köse N. A comparison of the acute effects of radial extracorporeal shockwave therapy, ultrasound therapy, and exercise therapy in plantar fasciitis. J Exerc Rehabil. 2018 Apr 26;14(2):306-312. doi: 10.12965/jer.1836048.024. PMID: 29740568; PMCID: PMC5931170.	Wrong control, no placebo
Akinoglu B, Köse N, Kirdi N, Yakut Y. Comparison of the Acute Effect of Radial Shock Wave Therapy and Ultrasound Therapy in the Treatment of Plantar Fasciitis: A Randomized Controlled Study. Pain Med. 2017 Dec 1;18(12):2443-2452. doi: 10.1093/pm/pnx113. PMID: 28575496.	Double study
Alvarez RG, Ogden JA, Jaakkola J, Cross GL. Symptom duration of plantar fasciitis and the effectiveness of Orthotripsy. Foot Ankle Int. 2003 Dec;24(12):916-21. doi: 10.1177/107110070302401208. PMID: 14733347.	study limitations, unblinded FDA study
Aqil A, Siddiqui MR, Solan M, Redfern DJ, Gulati V, Cobb JP. Extracorporeal shock wave therapy is effective in treating chronic plantar fasciitis: a meta-analysis of RCTs. Clin Orthop Relat Res. 2013 Nov;471(11):3645-52. doi: 10.1007/s11999-013-3132-2. Epub 2013 Jun 28. PMID: 23813184; PMCID: PMC3792262.	Too few studies included
Babatunde OO, Legha A, Littlewood C, Chesterton LS, Thomas MJ, Menz HB, van der Windt D, Roddy E. Comparative effectiveness of treatment options for plantar heel pain: a systematic review with network meta-analysis. Br J Sports Med. 2019 Feb;53(3):182-194. doi: 10.1136/bjsports-2017-098998. Epub 2018 Jun 28. PMID: 29954828.	Reporting of search strategy insufficient
Böddeker R, Schäfer H, Haake M. Extracorporeal shockwave therapy (ESWT) in the treatment of plantar fasciitis--a biometrical review. Clin Rheumatol. 2001;20(5):324-30. doi: 10.1007/pl00011207. PMID: 11642513.	Only includes risk of bias analysis
Boob MA Jr, Phansopkar P, Somaiya KJ. Physiotherapeutic Interventions for Individuals Suffering From Plantar Fasciitis: A Systematic Review. Cureus. 2023 Jul 31;15(7):e42740. doi: 10.7759/cureus.42740. PMID: 37654968; PMCID: PMC10467524.	Wrong intervention
Buch M, Knorr U, Fleming L, Theodore G, Amendola A, Bachmann C, Zingas C, Siebert WE. Extrakorporale Stosswellentherapie beim symptomatischen Fersensporn. Eine Ubersicht [Extracorporeal shockwave therapy in symptomatic heel spurs. An overview]. Orthopade. 2002 Jul;31(7):637-44. German. doi: 10.1007/s00132-002-0323-z. PMID: 12219661.	German language
Caglar Okur, Sibel & Aydın, Abdulkadir. (2019). Comparison of extracorporeal shock wave therapy with custom foot orthotics in plantar fasciitis treatment: A prospective randomized one-year follow-up study. Journal of musculoskeletal & neuronal interactions. 19. 178-186.	Wrong comparison
Chang KV, Chen SY, Chen WS, Tu YK, Chien KL. Comparative effectiveness of focused shock wave therapy of different intensity levels and radial shock wave therapy for treating plantar fasciitis: a systematic review and network meta-analysis. Arch Phys Med Rehabil. 2012 Jul;93(7):1259-68. doi: 10.1016/j.apmr.2012.02.023. Epub 2012 Mar 12. PMID: 22421623.	Search strategy insufficient
Charles R, Fang L, Zhu R, Wang J. The effectiveness of shockwave therapy on patellar tendinopathy, Achilles tendinopathy, and	Reporting of search strategy insufficient

plantar fasciitis: a systematic review and meta-analysis. Front Immunol. 2023 Aug 16;14:1193835. doi: 10.3389/fimmu.2023.1193835. PMID: 37662911; PMCID: PMC10468604.	
Chen CM, Lee M, Lin CH, Chang CH, Lin CH. Comparative efficacy of corticosteroid injection and non-invasive treatments for plantar fasciitis: a systematic review and meta-analysis. Sci Rep. 2018 Mar 5;8(1):4033. doi: 10.1038/s41598-018-22402-w. PMID: 29507320; PMCID: PMC5838257.	Wrong comparison
Chew KT, Leong D, Lin CY, Lim KK, Tan B. Comparison of autologous conditioned plasma injection, extracorporeal shockwave therapy, and conventional treatment for plantar fasciitis: a randomized trial. PM R. 2013 Dec;5(12):1035-43. doi: 10.1016/j.pmrj.2013.08.590. Epub 2013 Aug 22. PMID: 23973504.	No placebo as control, solely conventional treatment, thus wrong control
Cinar E, Saxena S, Akkurt HE, Uygur F. Extracorporeal shockwave therapy in the management of plantar fasciitis: A randomized controlled trial. Foot (Edinb). 2020 Sep;44:101679. doi: 10.1016/j.foot.2020.101679. Epub 2020 Jul 13. PMID: 32674009.	Wrong comparison
Cinar E, Saxena S, Uygur F. Combination Therapy Versus Exercise and Orthotic Support in the Management of Pain in Plantar Fasciitis: A Randomized Controlled Trial. Foot Ankle Int. 2018 Apr;39(4):406-414. doi: 10.1177/1071100717747590. Epub 2018 Jan 12. PMID: 29327602.	Same study population as Cinar 2020
Cosentino R, Falsetti P, Manca S, De Stefano R, Frati E, Frediani B, Baldi F, Selvi E, Marcolongo R. Efficacy of extracorporeal shock wave treatment in calcaneal enthesophytosis. Ann Rheum Dis. 2001 Nov;60(11):1064-7. doi: 10.1136/ard.60.11.1064. PMID: 11602481; PMCID: PMC1753417.	study limitations: no limiting of-or correction for other concurrent interventions
Crawford F, Thomson C. Interventions for treating plantar heel pain. Cochrane Database Syst Rev. 2003;(3):CD000416. doi: 10.1002/14651858.CD000416. Update in: Cochrane Database Syst Rev. 2010 Jan 20;(1):CD000416. doi: 10.1002/14651858.CD000416.pub2. PMID: 12917892.	More interventions, no meta-analysis
Díaz López AM, Guzmán Carrasco P. Efectividad de distintas terapias físicas en el tratamiento conservador de la fascitis plantar: revisión sistemática [Effectiveness of different physical therapy in conservative treatment of plantar fasciitis: systematic review]. Rev Esp Salud Publica. 2014 Jan-Feb;88(1):157-78. Spanish. doi: 10.4321/S1135-57272014000100010. PMID: 24728397.	Spanish language
Dizon JN, Gonzalez-Suarez C, Zamora MT, Gambito ED. Effectiveness of extracorporeal shock wave therapy in chronic plantar fasciitis: a meta-analysis. Am J Phys Med Rehabil. 2013 Jul;92(7):606-20. doi: 10.1097/PHM.0b013e31828cd42b. PMID: 23552334.	Reporting of search strategy insufficient
Gollwitzer H, Diehl P, von Korff A, Rahlfs VW, Gerdesmeyer L. Extracorporeal shock wave therapy for chronic painful heel syndrome: a prospective, double blind, randomized trial assessing the efficacy of a new electromagnetic shock wave device. J Foot Ankle Surg. 2007 Sep-Oct;46(5):348-57. doi: 10.1053/j.jfas.2007.05.011. PMID: 17761319.	Due to lack of reporting of results
Grecco MV, Brech GC, Greve JM. One-year treatment follow-up of plantar fasciitis: radial shockwaves vs. conventional physiotherapy. Clinics (Sao Paulo). 2013;68(8):1089-95. doi: 10.6061/clinics/2013(08)05. PMID: 24037003; PMCID: PMC3752632.	Wrong comparison
Greve JM, Grecco MV, Santos-Silva PR. Comparison of radial shockwaves and conventional physiotherapy for treating plantar fasciitis. Clinics (Sao Paulo). 2009;64(2):97-103. doi: 10.1590/s1807-59322009000200006. PMID: 19219314; PMCID: PMC2666476.	Wrong comparison

Guimarães JS, Arcanjo FL, Leporace G, Metsavaht LF, Conceição CS, Moreno MVMG, Vieira TEM, Moraes CC, Gomes Neto M. Effects of therapeutic interventions on pain due to plantar fasciitis: A systematic review and meta-analysis. Clin Rehabil. 2023 Jun;37(6):727-746. doi: 10.1177/02692155221143865. Epub 2022 Dec 26. PMID: 36571559.	Reporting of search strategy insufficient
Badil Güloğlu S, Yalçın Ü. Comparison of effects of low-level laser therapy and extracorporeal shock wave therapy in calcaneal spur treatment: A prospective, randomized, clinical study. Turk J Phys Med Rehabil. 2021 May 25;67(2):218-224. doi: 10.5606/tftrd.2021.5260. PMID: 34396073; PMCID: PMC8343161.	Wrong comparison
Hammer DS, Rupp S, Kreutz A, Pape D, Kohn D, Seil R. Extracorporeal shockwave therapy (ESWT) in patients with chronic proximal plantar fasciitis. Foot Ankle Int. 2002 Apr;23(4):309-13. doi: 10.1177/107110070202300403. PMID: 11991475.	Wrong comparison
Hammer DS, Adam F, Kreutz A, Kohn D, Seil R. Extracorporeal shock wave therapy (ESWT) in patients with chronic proximal plantar fasciitis: a 2-year follow-up. Foot Ankle Int. 2003 Nov;24(11):823-8. doi: 10.1177/107110070302401103. PMID: 14655885.	Wrong comparison
Ho C. Extracorporeal shock wave treatment for chronic plantar fasciitis (heel pain). Issues Emerg Health Technol. 2007 Jan;(96 (part 1)):1-4. PMID: 17302019.	Wrong study design
Hsiao MY, Hung CY, Chang KV, Chien KL, Tu YK, Wang TG. Comparative effectiveness of autologous blood-derived products, shock-wave therapy and corticosteroids for treatment of plantar fasciitis: a network meta-analysis. Rheumatology (Oxford). 2015 Sep;54(9):1735-43. doi: 10.1093/rheumatology/kev010. Epub 2015 Apr 6. PMID: 25848072.	Wrong intervention
Küçükakkaş, Okan & Öz, Beyzanur & Koçyiğit, H.. (2017). Efficacy of different doses of radial extracorporeal shock wave therapy in patients with painful calcaneal spur. Turkiye Fiziksel Tip ve Rehabilitasyon Dergisi. 63. 31-41. 10.5606/tftrd.2017.23590.	Turkish language
Landorf KB. Plantar heel pain and plantar fasciitis. BMJ Clin Evid. 2015 Nov 25;2015:1111. PMID: 26609884; PMCID: PMC4661045.	No risk of bias analysis
Landorf KB, Menz HB. Plantar heel pain and fasciitis. BMJ Clin Evid. 2008 Feb 5;2008:1111. PMID: 19450330; PMCID: PMC2907928.	Old version of Landorf 2015
Pisirici P, Cil ET, Coskunsu DK, Saylı U, Subasi F. Extracorporeal Shockwave Therapy Versus Graston Instrument-Assisted Soft-Tissue Mobilization in Chronic Plantar Heel Pain: A Randomized Controlled Trial. J Am Podiatr Med Assoc. 2022 Nov-Dec;112(6):21-036. doi: 10.7547/21-036. PMID: 36125974.	Wrong control, no placebo
Vahdatpour B, Sajadieh S, Bateni V, Karami M, Sajjadieh H. Extracorporeal shock wave therapy in patients with plantar fasciitis. A randomized, placebo-controlled trial with ultrasonographic and subjective outcome assessments. J Res Med Sci. 2012 Sep;17(9):834-8. PMID: 23826009; PMCID: PMC3697207.	Conflicting results reported within article
Zhiyun L, Tao J, Zengwu S. Meta-analysis of high-energy extracorporeal shock wave therapy in recalcitrant plantar fasciitis. Swiss Med Wkly. 2013 Jul 7;143:w13825. doi: 10.4414/smw.2013.13825. PMID: 23832373.	No search strategy reported

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Fasciopathie Plantaris - UV6 Shockwavetherapie

Uitgangsvraag/modules: Wat is de plaats van shockwavetherapie bij de behandeling bij patiënten met fasciopathie plantaris?	
Database(s): Embase.com, Ovid/Medline	Datum: 28-3-2024
Periode: vanaf 2000	Talen: geen restrictie
Literatuurspecialist: Esther van der Bijl	Rayyan review: https://rayyan.ai/reviews/979942
BMI-zoekblokken: voor verschillende opdrachten wordt (deels) gebruik gemaakt van de zoekblokken van BMI-Online https://blocks.bmi-online.nl/ Bij gebruikmaking van een volledig zoekblok zal naar de betreffende link op de website worden verwezen.	
Toelichting: Voor deze vraag is gezocht op de elementen fasciopathie plantaris EN shockwavetherapie. → De volgende sleutelartikelen worden gevonden met deze search: • Roerdink RL, Dietvorst M, van der Zwaard B, van der Worp H, Zwerver J. Complications of extracorporeal shockwave therapy in plantar fasciitis: Systematic review. Int J Surg. 2017 Oct;46:133-145. doi: 10.1016/j.ijsu.2017.08.587. Epub 2017 Sep 7. PMID: 28890412. • Jessup RL, Oates MJ, Johnston RV, Buchbinder R. Shockwave therapy for plantar heel pain (plantar fasciitis). Cochrane Database Syst Rev. 2019 Nov 25;2019(11):CD013490. doi: 10.1002/14651858.CD013490. PMCID: PMC6875429.	
Te gebruiken voor richtlijntekst: In de databases Embase.com en Ovid/Medline is op 28 maart 2024 systematisch gezocht naar systematische reviews en RCTs over de plaats van shockwavetherapie bij de behandeling bij patiënten met fasciopathie plantaris. De literatuurzoekactie leverde 278 unieke treffers op.	

Zoekopbrengst 28-3-2024

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	89	74	104
RCT	164	123	174
~~Observationeel~~			
Totaal	253	197	**278***

****in Rayyan***

5 ***Zoekstrategie Embase.com 28-3-2024***

No.	Query	Results
#1	'plantar fasciitis'/exp OR 'plantar fasciopathy'/exp OR 'heel spur'/exp OR 'policeman heel'/exp OR (((calcane* OR heel* OR subcalcane*) NEAR/3 (spur* OR exostos* OR pain* OR policeman* OR jogger*)):ti,ab,kw) OR ((plant* NEAR/3 (fasciitis OR fasciopath* OR fascios* OR inflam*)):ti,ab,kw) OR (((baxter* OR plant* OR calcane* OR heel) NEAR/3 neuropath*):ti,ab,kw) OR calcaneodyn*:ti,ab,kw OR 'calcane* periostitis':ti,ab,kw	6372
#2	'shock wave'/exp OR 'shock wave therapy'/exp OR 'ultrasound therapy'/exp OR 'radiation'/exp OR ((('non ioniz*' OR 'nonioniz*') NEAR/3 radiat*):ti,ab,kw) OR (((extracorporeal OR radial) NEAR/3 shock*):ti,ab,kw) OR 'shock wave*':ti,ab,kw OR 'shockwave*':ti,ab,kw OR eswt:ti,ab,kw OR hesw:ti,ab,kw OR ecst:ti,ab,kw OR ecsw:ti,ab,kw	857465
#3	#1 AND #2	790
#4	#3 AND [2000-2024]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	543
#5	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR	1014761

	umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	
#6	'randomized controlled trial'/exp OR random*:ti,ab OR (((pragmatic OR practical) NEAR/1 'clinical trial*'):ti,ab) OR ((('non inferiority' OR noninferiority OR superiority OR equivalence) NEAR/3 trial*):ti,ab) OR rct:ti,ab,kw	2178974
#7	#4 AND #5 **– SR's**	89
#8	#4 AND #6 NOT #7 **– SR's**	164
#9	#7 OR #8	253

Zoekstrategie Ovid/Medline 28-3-2024

#	Searches	Results
1	exp Fasciitis, Plantar/ or exp Heel Spur/ or ((calcane* or heel* or subcalcane*) adj3 (spur* or exostos* or pain* or policeman* or jogger*)).ti,ab,kf. or (plant* adj3 (fasciitis or fasciopath* or fascios* or inflam*)).ti,ab,kf. or ((baxter* or plant* or calcane* or heel) adj3 neuropath*).ti,ab,kf. or calcaneodyn*.ti,ab,kf. or calcane* periostitis.ti,ab,kf.	4416
2	exp Extracorporeal Shockwave Therapy/ or exp Radiation, Nonionizing/ or exp Ultrasonic Therapy/ or ((non ioniz* or nonioniz*) adj3 radiat*).ti,ab,kf. or ((extracorporeal or radial) adj3 shock*).ti,ab,kf. or shock wave*.ti,ab,kf. or shockwave*.ti,ab,kf. or eswt.ti,ab,kf. or hesw.ti,ab,kf. or ecst.ti,ab,kf. or ecsw.ti,ab,kf.	338029
3	1 and 2	440
4	limit 3 to yr="2000 -Current"	419
5	4 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	377
6	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	735289
7	exp randomized controlled trial/ or randomized controlled trials as topic/ or random*.ti,ab. or rct?.ti,ab. or ((pragmatic or practical) adj "clinical trial*").ti,ab,kf. or ((non-inferiority or noninferiority or superiority or equivalence) adj3 trial*).ti,ab,kf.	1700385
8	5 and 6 **– SR's**	74
9	(5 and 7) not 8 **– RCT's**	123
10	8 or 9	197

Module 7 Corticosteroïden

Search and select

A systematic review of the literature was performed to answer the following question:
What is de efficacy of corticosteroid-injections in patients with plantar fasciopathy compared to placebo?

P: patients	= Patients with plantar fasciopathy
I: intervention	= Corticosteroid-injection
C: control	= Placebo or placebo as add-on to physical therapy
O: outcome measure	= Function, pain, adverse events, return to sport and quality of life

Relevant outcome measures

The guideline development group considered function, pain and adverse events as a **crucial** outcome measure for decision making; and return to sport and quality of life as an **important** outcome measure for decision making.

A priori, the working group did not define the outcome measures listed above but used the definitions used in the studies. Important adverse events are infection, rupture, atrophy and pain.

The working group defined a 10% difference for both continuous outcome measures and dichotomous outcome measures informing on relative risk (RR ≤ 0.91 and ≥ 1.1).

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until March 28th, 2024. The detailed search strategy is available upon request. The systematic literature search resulted in 238 hits.
Studies were selected based on the following criteria:

- Randomized controlled trials (RCTs), systematic review and/or meta-analysis;
- studies on patients with plantar fasciopathy;
- described corticosteroid injection as intervention;
- described placebo or placebo as add-on to physical therapy as control;
- described at least one of the critical outcome measures as described in the PICO;
- minimum of 10 patients per arm.

In case of a systematic review:

- minimum of two databases searched;
- detailed search strategy with search date;
- in- and exclusion criteria;
- exclusion table;
- evidence table for included studies;
- risk of bias assessment per study.

33 studies were initially selected based on title and abstract screening. After reading the full text, 29 studies were excluded (see the table with reasons for exclusion under the tab Methods), and 4 studies were included.

Results

Four studies were included in the analysis of the literature. The assessment of the risk of bias is summarized in the risk of bias tables.

Summary of literature

Description of studies

David (2017) performed a systematic review on the effectiveness of corticosteroid injection in adult patients with plantar heel pain due to plantar fasciitis. They included RCTs with patients >16 years of age with plantar fasciitis. The comparison intervention was not specified before analysis, but they do perform a separate analysis on studies that use no intervention or a placebo intervention as a comparison. Primary outcomes reported were heel pain, function and serious adverse events. They also reported on return to activity or work and health-related quality of life. However, these outcome measures were not reported by the studies included in this review. They reported on these outcome measures in short (<1month), medium (1-6 months) and long term (>6 month) follow up.

For this module we excluded studies from David (2017) that did not use a placebo as control, and studies published before 2000 from our analysis. This resulted in 3 RCTs that could be considered for this review (Abdihakin 2012, Ball 2013 and McMillan 2012).
Additionally, we extended the analysis of David (2017) with the 3 RCTs from our search that were published after the search date of David (2017) and that adhered to our PICO. Characteristics of these studies are summarized in Table 1.

All 3 additional RCTs contained 3 arms of which two were corticosteroid injection and a saline injection (placebo). The third arm consisted of autologous whole blood injection (Digra, 2023), Plasma injection (Elizondo-Rodriguez, 2021) or palpation guided steroid injection (Mahindra, 2016) using a peppering technique. respectively. Peppering technique is after insertion the needle is withdrawn and redirected and reinserted multiple times. We only took the arms with corticosteroid injection and with placebo in consideration for this review.

Studies were conducted in Australia (McMillan,2012), the United Kingdom (Ball,2013), Kenya (Abdihakim, 2012), India (Digra, 2023, Mahindra, 2016) and Mexico (Elizondo-Rodriguez, 2012). Follow-up period ranged from 2 months to 24 weeks. Mean age ranged from 34 (Mahindra, 2016) to 54 years (McMillan,2012). All studies reported on pain and four out of six reported on function (Elizondo-Rodriquez, 2012, Mahindra, 2016, Abdihakin 2012 and McMillan 2012). Adverse events were not reported in detail by any study. No studies reported on return to sport or quality of life.

Table 1. Characteristics of the included studies.

Study (year) **Study type**	**Intervention (n)**	**Characteristics**	**Control (n)**	**Characteristics**	**Outcomes of interest reported**	**FU**	**ROB**	**Considerations**
Abdihakin (2012) RCT *from David(2017)*	Palpation-guided steroid injection and conservative management (47)	Age: 41.0±9.6 %male: 49 VAS (0-10): 8.6±1.3	Saline injection and conservative management (41)	Age: 45.1±8.2 %male: 46 VAS (0-10): 8.74±1.5	Pain (VAS) Function; foot-function index	2 months	High risk of reporting bias – no adverse events reported	
Ball (2013) RCT *from David(2017)*	Ultrasound guided steroid injection (22)	Age: 49.0±12.9 % male: 45 VAS (0-100): 62.0±19.2	Ultrasound guided placebo injection (22)	Age: 50.1±10.6 %male: 52 VAS (0-100): 56.0(27.9)	Pain (VAS) Adverse events	12 weeks	High risk of incomplete outcome data reporting, high risk of selective reporting bias.	Frequent loss to follow up/ dropouts
McMillan (2012) RCT *from David(2017)*	Intrafascial steroid injection - (41)	Age: 51.7±11.9 % male: 46 FHS – pain: 36.8±19.9 FHS- function 53.4±25.5	Intrafascial injection – saline (41)	Age: 53.6±9.0 % male: 58 FHS – pain: 35.9±20.4 FHS- function 60.2±25.3	Pain (foot health status questionnaire), function(foot health status questionnaire, Adverse events, first step pain	12 weeks	Low risk of bias	12 pt. In each arm had a bilateral injection which was treated as one injection.
Digra (2023) RCT (group B and C)	Palpation guided injection with methylprednisolone acetate at 0 and 2 weeks (20)	Mean age: 45.0 (SD not reported)	Palpation guided Injection with saline at 0 and 2 weeks (20)	Mean age: 42.2 (SD not reported)	Pain (VAS)	12 weeks	High	Very little description of group demographics. No adverse events, no clear blinding procedure
Mahindra (2016) RCT (group B and C)	Steroid injection (methylprednisolone) peppering technique (30) physical therapy (stretching)	Age: 33.9±8.6 % male: 48 VAS: 7.7	Saline injection (30) physical therapy (stretching)	Age: 35.5±9.5 % male: 44 VAS: 7.6	Pain (VAS) Foot and Ankle Society Function: (AOFAS)	3 months	Some concerns (adverse events)	No information on adverse events

Elizondo-Rodriguez (2021)	Steroid injection (25)	Age: 46.4±11.0 %male: 24 VAS (0-10): 7.7±1.9 MFS: 83.9±13.4	Anesthetic injection (23)	Age: 49.3±10.6 %male: 24 VAS (0-10): 7.9±1.2 MFS: 84.6±12.1	Pain (VAS) Function (MFS) Side effects	24 weeks	Low risk	
Abbreviations: AOFAS: Ankle and Hindfoot score, MFS: Maryland Foot Score, SD: standard deviation, VAS: visual analogue scale for pain								

Results

1. **Function (crucial)**

Elizondo-Rodriguez (2021) reported on function with the Maryland Foot Scale (MFS) with a maximum of 100 points based on pain and function criteria. The higher the score the better the function. A score above 90 represents an excellent outcome. They report a mean MFS (SD) at 4 weeks post intervention of 94.3 (1.30) in the intervention group compared to 90.3 in the placebo group resulting in a difference (95%CI) of 4.0 (2.60 to 5.40) points in favor of the steroid group. However, at 24 weeks post intervention they report an MFS(SD) of 96.1 (1.78) in the group receiving steroid injection compared to 99.4 in the placebo group resulting in a difference (95%CI) of -3.3 (-4.35 to -2.25) points in favor of the placebo group. Both differences are not clinically relevant.

Abdihakin (2012) reported on function with the foot function index (FFI) (0-100). The lower the score the better the function. They report a FFI (SD) at 2 months post-intervention of 42.3 (17.2) in the group receiving the steroid injection compared to 40.5(13.3) in the placebo group resulting in a mean difference (95%CI) of 1.8(-4.83 to 8.39) in favor of the placebo group. This difference is not clinically relevant.

McMillan (2012) reported the foot function subscale of the Foot Health Status Questionnaire (0-100) in which a higher score represents better function. They report a difference (95%CI) at 12 weeks post-intervention of 4.1(-3.8 to 11.9) points in favor of the steroid group. This difference is not clinically relevant.

Although Mahindra (2016) reports on function with the AOFAS score, they do not provide scores for the placebo group, therefore we could not take them into account for this analysis.

2. **Pain (crucial)**

All studies reported on pain. They all defined pain with the VAS scale (0-10 or 0-100; higher score represents more pain), except for McMillan (2012) who reported the foot pain subscale of the Foot Health Status Questionnaire (0-100) in which a higher score represents less pain. To pool results the VAS 0-10 was multiplied by 10 and the FHSQ score was multiplied by -1. Pooled results show that both in the short term <1 month and in the medium term 1 <6 months, participants experience less pain in the steroid group (Figure 1). Mean difference was -13.61 [-32.66 to 5.44] and -17.40 [-37.29 to 2.50] respectively in favor of the steroid group. This difference is clinically relevant (>10%). No data are available for a follow-up after 6 months.

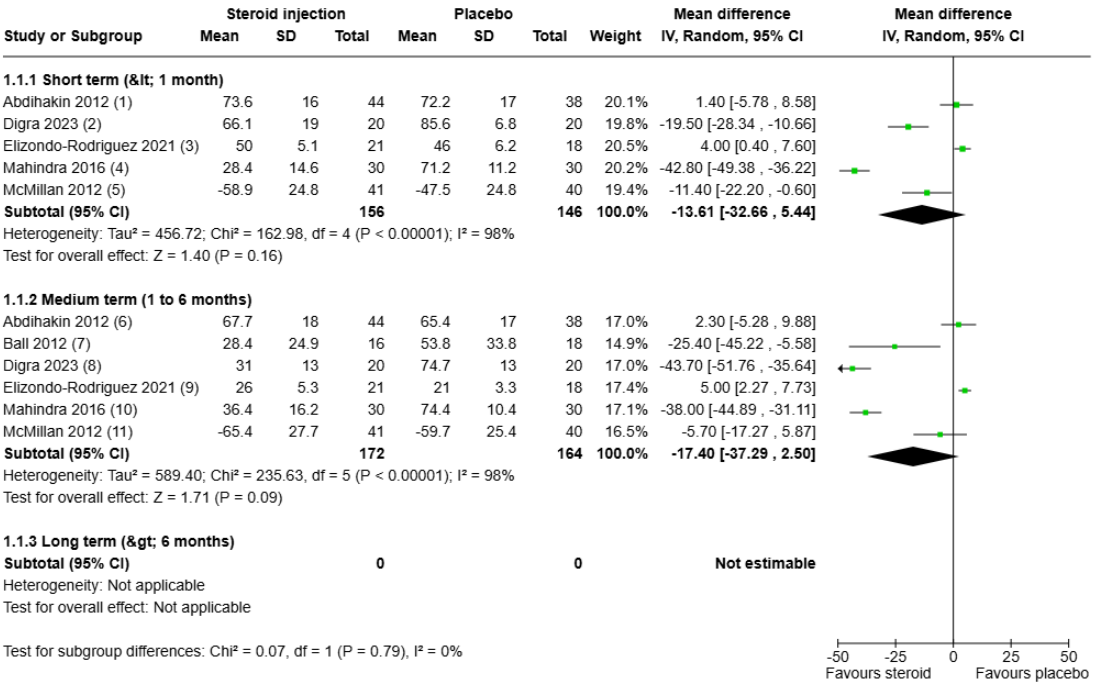

Figure 7; pooled results of the pain scores

3. Adverse events (important)

None of the studies report on any (serious) adverse events. Elizondo (2021), Ball (2013) and McMillan (2012) explicitly state this. The other studies do not report on adverse events.

Ball (2013) also reported on repeat ultrasound injection. After the intervention participants were offered a repeat injection if treatment failed. One patient (5%) in the corticosteroid group needed a repeat injection at 12 weeks compared to 11 (52%) patients in the placebo group. An important note is that six patients in the steroid group were lost to follow-up at 12 weeks, with two of them withdrawing due to heel pain. This might have led to a more favorable result for the intervention than what actually occurred.

4. Return to sport (important)

No studies reported on the effect of steroid injections on return to sport in patients with plantar fasciopathy.

5. Quality of Life (important)

No studies reported on the effect of steroid injections on quality of life in patients with plantar fasciopathy.

Level of evidence of the literature

1. **Function**

The level of evidence regarding the outcome measure function started as high because it was based on RCT's and was downgraded by 2 levels to low because of conflicting results (inconsistency -1) and a low number of included studies and participants (imprecision -1).

2. **Pain**

The level of evidence regarding the outcome measure pain started as high because it was based on RCT's and was downgraded by 2 levels to low because of study limitations (risk of bias due to missing baseline characteristics -1) and the confidence interval crossing the border of clinical relevance (imprecision -1).

3. **Adverse events**

The level of evidence regarding the outcome measure adverse events started as high because it was based on RCT's and was downgraded by 3 levels to very low because of study limitations (high risk of reporting bias -2), and a low number of included studies and participants (imprecision -1).

4. **Return to sport**

No studies reported on the effect of steroid injections on return to sport in patients with plantar fasciopathy.

5. **Quality of Life**

No studies reported on the effect of steroid injections on quality of life in patients with plantar fasciopathy.

Conclusions

1. **Function**

Low GRADE	Corticosteroid injections may result in little to no difference in function when compared with placebo in patients with plantar fasciopathy. *Source: David (2017) (Abdihakin, 2012; McMillan, 2012) , Elizondo-Rodriguez (2021)*

2. **Pain**

Low GRADE	Corticosteroid injections may result in a reduction of pain when compared with placebo in patients with plantar fasciopathy. *Source: David (2017), Elizondo-Rodriguez (2021), Digra (2023), Mahindra (2016)*

3. **Adverse events**

Very low GRADE	The evidence is very uncertain about the effect of corticosteroid injections on adverse events compared to placebo in patients with plantar fasciopathy. *Source: David (2017), Elizondo-Rodriguez (2021)*

4. **Return to Sport**

No GRADE	No evidence was found regarding the effect of corticosteroid injections return to sport compared to placebo in patients with plantar fasciopathy

	Source: -

5. Quality of life

No GRADE	No evidence was found regarding the effect of corticosteroid injections on quality of life compared to placebo in patients with plantar fasciopathy *Source: -*

Kennisvragen

Tijdens de ontwikkeling van deze module is systematisch naar onderzoeken gezocht die de zoekvraag kunnen beantwoorden. Door gebruik te maken van een systematische literatuuranalyse met beoordeling van de bewijskracht is duidelijk geworden dat er binnen deze module nog kennisvragen bestaan. De werkgroep meent dat (vervolg)onderzoek wenselijk is om in de toekomst een duidelijker antwoord te kunnen geven op vragen uit de praktijk.

What is de efficacy of corticosteroid-injections in patients with plantar fasciopathy compared to placebo?

Wat is de effectiviteit van corticosteroïd-injecties bij patiënten met fasciopathie plantaris?

P: patients	= Patients with plantar fasciopathy
I: intervention 1	= Corticosteroid-injection (dose 10)
I: intervention 2	= Corticosteroid-injection (dose 40)
C: control	= Placebo or placebo as add-on to physical therapy
O: outcome measure	= Function, pain, adverse events, return to sport and quality of life

Wat is de effectiviteit van echo-geleide corticosteroïd-injecties bij patiënten met fasciopathie plantaris?

P: patients	= Patients with plantar fasciopathy
I: intervention	= Corticosteroid-injection (ultrasound guided)
C: control	= Corticosteroid-injection without ultrasound
O: outcome measure	= Function, pain, adverse events, return to sport and quality of life

Literatuur

David, J. A., Sankarapandian, V., Christopher, P. R. H., Chatterjee, A., & Macaden, A. S. (2017). Injected corticosteroids for treating plantar heel pain in adults. Cochrane Database of Systematic Reviews, 2017(6). https://doi.org/10.1002/14651858.CD009348.pub2

Digra N, Beri A, Sharma S, Verma R. Autologous Whole-Blood Versus Corticosteroid Local Injection in Treatment of Plantar Fasciitis: A Randomized Single Blind Placebo-Controlled Study. Cureus. 2023 Sep 20;15(9):e45588. doi: 10.7759/cureus.45588. PMID: 37868394; PMCID: PMC10587858.

Elizondo-Rodríguez, J., Simental-Mendía, M., Peña-Martínez, V., Vilchez-Cavazos, F., Tamez-Mata, Y., & Acosta-Olivo, C. (2021). Comparison of Botulinum Toxin A, Corticosteroid, and Anesthetic Injection for Plantar Fasciitis. Foot and Ankle International, 42(3), 305–313. https://doi.org/10.1177/1071100720961093

Johannsen, F. E., Herzog, R. B., Malmgaard-Clausen, N. M., Hoegberget-Kalisz, M., Magnusson, S. P., & Kjaer, M. (2019). Corticosteroid injection is the best treatment in plantar fasciitis if combined with controlled training. Knee Surgery, Sports Traumatology, Arthroscopy, 27(1), 5–12. https://doi.org/10.1007/s00167-018-5234-6

Lee, H. S., Choi, Y. R., Kim, S. W., Lee, J. Y., Seo, J. H., & Jeong, J. J. (2014). Risk factors affecting chronic rupture of the plantar fascia. Foot and Ankle International, 35(3), 258–263. https://doi.org/10.1177/1071100713514564

Mahindra, P., Yamin, M., Selhi, H. S., Singla, S., & Soni, A. (2016). Chronic plantar fasciitis: Effect of platelet- rich plasma, corticosteroid, and placebo. Orthopedics, 39(2), e285–e289. https://doi.org/10.3928/01477447-20160222-01

McMillan, A. M., Landorf, K. B., Gilheany, M. F., Bird, A. R., Morrow, A. D., & Menz, H. B. (2012). Ultrasound guided corticosteroid injection for plantar fasciitis: Randomised controlled trial. BMJ (Online), 344(7859), 1–12. https://doi.org/10.1136/bmj.e3260

Morrissey, D., Cotchett, M., Said J'bari, A., Prior, T., Griffiths, I. B., Rathleff, M. S., Gulle, H., Vicenzino, B., & Barton, C. J. (2021). Management of plantar heel pain: A best practice guide informed by a systematic review, expert clinical reasoning and patient values. British Journal of Sports Medicine, 55(19), 1106–1118. https://doi.org/10.1136/bjsports-2019-101970

Mosca, M., Fuiano, M., Massimi, S., Censoni, D., Catanese, G., Grassi, A., Caravelli, S., & Zaffagnini, S. (2022). Ruptures of the Plantar Fascia: A Systematic Review of the Literature. Foot and Ankle Specialist, 15(3), 272–282. https://doi.org/10.1177/1938640020974889

Sconfienza, L. M., Adriaensen, M., Albano, D., Alcala-Galiano, A., Allen, G., Aparisi Gómez, M. P., Aringhieri, G., Bazzocchi, A., Beggs, I., Chianca, V., Corazza, A., Dalili, D., De Dea, M., del Cura, J. L., Di Pietto, F., Drakonaki, E., Facal de Castro, F., Filippiadis, D., Gitto, S., … Obradov, M. (2021). Clinical indications for image-guided interventional procedures in the musculoskeletal system: a Delphi-based consensus paper from the European Society of Musculoskeletal Radiology (ESSR)—part VI, foot and ankle. European Radiology. https://doi.org/10.1007/s00330-021-08125-z

Whittaker, G. A., Munteanu, S. E., Menz, H. B., Bonanno, D. R., Gerrard, J. M., & Landorf, K. B. (2019). Corticosteroid injection for plantar heel pain: A systematic review and meta-analysis. BMC Musculoskeletal Disorders, 20(1). https://doi.org/10.1186/s12891-019-2749-z

Implementatietabel

Aanbeveling – 1: Wees terughoudend met lokale corticosteroïd injecties, deze zijn te overwegen indien eerdere conservatieve behandelingen en pijnstilling niet de gewenste uitkomst hebben. Bespreek samen met de patiënt de volgende mogelijke effecten van een lokale corticosteroïd injectie: • Mogelijk vermindert pijn op de korte termijn, het effect op functie is onbekend. • Op de lange termijn is het effect onduidelijk voor zowel pijn als functie. • De risico's op ernstige complicaties lijken laag, maar hebben wel een negatieve impact indien deze ontstaan: ruptuur van de fascia plantaris, infectie en huid- en vet atrofie.	Op basis van de beschikbare evidentie en ervaring uit de praktijk kon er onvoldoende richting aan de besluitvorming worden gegeven. Om die reden is er geen beschrijving van belemmeringen en kansen voor implementatie van de aanbeveling toegevoegd. Disseminatie van de kennis in deze module verloopt via de standaard route. De module wordt gepubliceerd op de Richtlijnendatabase.

Risk of bias table for intervention studies (randomized controlled trials; based on Cochrane risk of bias tool and suggestions by the CLARITY Group at McMaster University)

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?**	**Was the allocation adequately concealed?**	**Blinding: Was knowledge of the allocated interventions adequately prevented? |Were all involved blinded?**	**Was loss to follow-up (missing outcome data) infrequent?**	**Are reports of the study free of selective outcome reporting?**	**Was the study apparently free of other problems that could put it at a risk of bias?**	**Overall risk of bias If applicable/necessary, per outcome measure** **LOW/Some concerns/ HIGH**
Digra, 2023	Probably no Reason: "patients were divided into three groups by	No information Reason: no description of allocation	No information Reason: no description of blinding	No information Reason: no mention of loss to follow up	Probably no Reason: All outcomes in the methods are	Probably no: Reason: no baseline characteristics reported for main	HIGH (all outcome measures) Reason: Unclear blinding procedure,

	simple randomization" No further clarification				reported. However these are minimal and no baseline characteristics are reported.	outcome measures. No adverse events reported.	missing baseline characteristics, missing demographics.
Mahindra, 2016	Definitely yes Reason: Central randomization with computer programming	No information Reason: no description of allocation	Probably yes Reason: Patients were blinded, outcome assessor was blinded. (blinding of analysts not reported)	No information Reason: no mention of loss to follow up	Probably yes Reason: No protocol available. Alle measures in introduction are reported.	Probably no: Reason: No information on adverse events reported.	Some concerns Reason: No information on adverse events. Missing information om some points regarding risk of bias
Elizondo-Rodriguez, 2021	Definitely yes Reason: Central randomization with computer programming	No information Reason: no description of allocation	Probably yes Reason: patients were blinded. Data collectors/outcome assessors were blinded. (blinding of analysts not reported)	Probably yes Missing data was infrequent and multiple imputation was used to hand missing data. Sensitivity analysis was performed with ITT analysis.	Probably yes Reason: No protocol available. Alle measures in introduction are reported.	Probably yes Reason: no other problems noted	Low ;

Table of excluded studies

Reference	Reason for exclusion
Al-Boloushi Z, López-Royo MP, Arian M, Gómez-Trullén EM, Herrero P. Minimally invasive non-surgical management of plantar fasciitis: A systematic review. J Bodyw Mov Ther. 2019 Jan;23(1):122-137. doi: 10.1016/j.jbmt.2018.05.002. Epub 2018 Jun 1. PMID: 30691739.	Systematic review of insufficient quality
Ang TW. The effectiveness of corticosteroid injection in the treatment of plantar fasciitis. Singapore Med J. 2015 Aug;56(8):423-32. doi: 10.11622/smedj.2015118. PMID: 26311907; PMCID: PMC4545130.	Systematic review including only 2 relevant RCTs that are already in literature search.
Arnold MJ, Gruber J. Injected Corticosteroids for Plantar Heel Pain. Am Fam Physician. 2018 Feb 1;97(3):169-170. PMID: 29431981.	Wrong article type: clinical summary
Assad S, Ahmad A, Kiani I, Ghani U, Wadhera V, Tom TN. Novel and Conservative Approaches Towards Effective Management of Plantar Fasciitis. Cureus. 2016 Dec 5;8(12):e913. doi: 10.7759/cureus.913. PMID: 28083457; PMCID: PMC5215813.	Systematic review of insufficient quality
Babatunde OO, Legha A, Littlewood C, Chesterton LS, Thomas MJ, Menz HB, van der Windt D, Roddy E. Comparative effectiveness of treatment options for plantar heel pain: a systematic review with network meta-analysis. Br J Sports Med. 2019 Feb;53(3):182-194. doi: 10.1136/bjsports-2017-098998. Epub 2018 Jun 28. PMID: 29954828.	SYstematic review with fewer relevant outcome measures compared to David(2017)
Ball EM, McKeeman HM, Patterson C, Burns J, Yau WH, Moore OA, Benson C, Foo J, Wright GD, Taggart AJ. Steroid injection for inferior heel pain: a randomised controlled trial. Ann Rheum Dis. 2013 Jun;72(6):996-1002. doi: 10.1136/annrheumdis-2012-201508. Epub 2012 Jun 27. PMID: 22739993.	In David(2017)
Celik D, Kuş G, Sırma SÖ. Joint Mobilization and Stretching Exercise vs Steroid Injection in the Treatment of Plantar Fasciitis: A Randomized Controlled Study. Foot Ankle Int. 2016 Feb;37(2):150-6. doi: 10.1177/1071100715607619. Epub 2015 Sep 23. PMID: 26400901.	Wrong comparison: no placebo but stretching exercise.
Chen CM, Lee M, Lin CH, Chang CH, Lin CH. Comparative efficacy of corticosteroid injection and non-invasive treatments for plantar fasciitis: a systematic review and meta-analysis. Sci Rep. 2018 Mar 5;8(1):4033. doi: 10.1038/s41598-018-22402-w. PMID: 29507320; PMCID: PMC5838257.	Does not include comparison to placebo
Crawford F, Atkins D, Edwards J. Interventions for treating plantar heel pain. The Foot. 2001 Dec; 11(4);228-250. doi; /10.1054/foot.2002.0689.	Wrong article type: citation
Crawford F. Plantar heel pain (including plantar fasciitis). Clin Evid. 2002 Dec;(8):1238-49. Update in: Clin Evid. 2003 Dec;(10):1431-43. PMID: 12603938.	Review with articles untill 1997
Crawford F, Thomson C. Interventions for treating plantar heel pain. Cochrane Database Syst Rev. 2003;(3):CD000416. doi: 10.1002/14651858.CD000416.	Cochrane review untill 2002, no pooled data, focusses on different types of treatment
Dev K, Meena AS, Meena M, Joshi M.A Randomized Control Study of Comparison of Standard Care versusUltrasonography Guided Single Dose of MethylprednisoloneAcetate Injection for Planar Fasciopathy. European Journal of Molecular and Clinical Medicine. 2022; 9(3).	Wrong comparison: not placebo but physical therapy
Gao R, Sun J, Zhang L, Chen S, Dong W, Yu H, Han B, Tan M, Li X. Comparative Effectiveness of Minimally Invasive Nonsurgical Treatments for Plantar Fasciitis: A Network Meta-analysis of 30 Randomized Controlled Trials. Pain Physician. 2021 Nov;24(7):E955-E971. PMID: 34704707.	tematic review of insufficient quality
Hsiao MY, Hung CY, Chang KV, Chien KL, Tu YK, Wang TG. Comparative effectiveness of autologous blood-derived products, shock-wave therapy and corticosteroids for treatment of plantar fasciitis: a network meta-analysis. Rheumatology (Oxford). 2015	Does not include comparison to placebo

Sep;54(9):1735-43. doi: 10.1093/rheumatology/kev010. Epub 2015 Apr 6. PMID: 25848072.	
Karimzadeh A, Raeissadat SA, Erfani Fam S, Sedighipour L, Babaei-Ghazani A. Autologous whole blood versus corticosteroid local injection in treatment of plantar fasciitis: A randomized, controlled multicenter clinical trial. Clin Rheumatol. 2017 Mar;36(3):661-669. doi: 10.1007/s10067-016-3484-6. Epub 2016 Dec 12. PMID: 27957618.	Does not include comparison to placebo
Kuldeep, S. and Gaur, R. and Jindal, R. Comparison of The Efficacy of Different Treatment Modalities in Use for Plantar Fasciitis: A Randomized Controlled Trial International Journal of Pharmaceutical and Clinical Research	Full-text not available
Kumar, V. A. and Khalid, K. M. and Vajrangi, A. and Sherikar, N. and Srinivas, R. and Rakshith, C. H. Y. and Kurupati, R. B. and Rajanna, P.A Comparative Study Between Platelet-Rich Plasma And Corticosteroid Injection For Plantar Fasciitis. 2024	Full-text not available
Li H, Lv H, Lin T. Comparison of efficacy of eight treatments for plantar fasciitis: A network meta-analysis. J Cell Physiol. 2018 Jan;234(1):860-870. doi: 10.1002/jcp.26907. Epub 2018 Aug 4. PMID: 30078188.	systematic review of insufficient quality
Li Z, Yu A, Qi B, Zhao Y, Wang W, Li P, Ding J. Corticosteroid versus placebo injection for plantar fasciitis: A meta-analysis of randomized controlled trials. Exp Ther Med. 2015 Jun;9(6):2263-2268. doi: 10.3892/etm.2015.2384. Epub 2015 Mar 24. PMID: 26136971; PMCID: PMC4473350.	All relevant studies in cluded in David(2017)
McMillan AM, Landorf KB, Gilheany MF, Bird AR, Morrow AD, Menz HB. Ultrasound guided corticosteroid injection for plantar fasciitis: randomised controlled trial. BMJ. 2012 May 22;344:e3260. doi: 10.1136/bmj.e3260. PMID: 22619193.	In David (2017)
Orhan Ö, Ağır H, Sarıkaya B, Dolap MA, Altay MA. Pain relief and functional improvement provided by extracorporeal shock wave therapy in plantar fasciitis is better than corticosteroid injection and kinesio taping: A randomized trial. Turkish Journal of Physical Medicine and Rehabilitation. 2023	Does not include comparison to placebo
Peña-Martínez VM, Acosta-Olivo C, Simental-Mendía LE, Sánchez-García A, Jamialahmadi T, Sahebkar A, Vilchez-Cavazos F, Simental-Mendía M. Effect of corticosteroids over plantar fascia thickness in plantar fasciitis: a systematic review and meta-analysis. Phys Sportsmed. 2023 Jun 13:1-12. doi: 10.1080/00913847.2023.2223673. Epub ahead of print. PMID: 37293970.	Primary aim is to study plantar fascia thickness, secondary pain. Not only placebo as control
Riel H, Vicenzino B, Olesen JL, Bach Jensen M, Ehlers LH, Rathleff MS. 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. Br J Sports Med. 2023 Sep;57(18):1180-1186. doi: 10.1136/bjsports-2023-106948. Epub 2023 Jul 6. PMID: 37414460; PMCID: PMC10579183.	Does not include comparison to placebo
Ryan M, Hartwell J, Fraser S, Newsham-West R, Taunton J. Comparison of a physiotherapy program versus dexamethasone injections for plantar fasciopathy in prolonged standing workers: a randomized clinical trial. Clin J Sport Med. 2014 May;24(3):211-7. doi: 10.1097/JSM.0000000000000021. PMID: 24172656.	Does not include comparison to placebo
Seth I, Bulloch G, Seth N, Lower K, Rodwell A, Rastogi A, Gibson D, Bedi H. The role of corticosteroid injections in treating plantar fasciitis: A systematic review and meta-analysis. Foot (Edinb). 2023 Mar;54:101970. doi: 10.1016/j.foot.2023.101970. Epub 2023 Feb 3. PMID: 36774828.	No comparison to placebo but to other treatments
Shetty SH, Dhond A, Arora M, Deore S. Platelet-Rich Plasma Has Better Long-Term Results Than Corticosteroids or Placebo for Chronic Plantar Fasciitis: Randomized Control Trial. J Foot Ankle Surg. 2019 Jan;58(1):42-46. doi: 10.1053/j.jfas.2018.07.006. Epub 2018 Nov 15. PMID: 30448183.	Incomplete reports on outcome data

Tsikopoulos K, Vasiliadis HS, Mavridis D. Injection therapies for plantar fasciopathy ('plantar fasciitis'): a systematic review and network meta-analysis of 22 randomised controlled trials. Br J Sports Med. 2016 Nov;50(22):1367-1375. doi: 10.1136/bjsports-2015-095437. Epub 2016 May 3. PMID: 27143138.	Less recent than David (2017), similar objective
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;13(1):60. doi: 10.1186/s13047-020-00428-6. PMID: 32993721; PMCID: PMC7526364.	Wrong study type: predictor study
Whittaker GA, Munteanu SE, Menz HB, Bonanno DR, Gerrard JM, Landorf KB. Corticosteroid injection for plantar heel pain: a systematic review and meta-analysis. BMC Musculoskelet Disord. 2019 Aug 17;20(1):378. doi: 10.1186/s12891-019-2749-z. PMID: 31421688; PMCID: PMC6698340.	Fewer relevant outcome measures reported compared to David (2017)

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Fasciopathie Plantaris – UV7 Corticosteroïden	
Uitgangsvraag/modules: Wat is de plaats van corticosteroïd-injecties bij de behandeling bij patiënten met fasciopathie plantaris?	
Database(s): Embase.com, Ovid/Medline	Datum: 28-3-2024
Periode: vanaf 2000	Talen: geen restrictie
Literatuurspecialist: Esther van der Bijl	Rayyan review: https://rayyan.ai/reviews/980292
BMI-zoekblokken: voor verschillende opdrachten wordt (deels) gebruik gemaakt van de zoekblokken van BMI-Online https://blocks.bmi-online.nl/ Bij gebruikmaking van een volledig zoekblok zal naar de betreffende link op de website worden verwezen.	

Toelichting:
Voor deze vraag is gezocht op de elementen corticosteroïden EN fasciopathie plantaris.

→ De sleutelartikelen worden gevonden met deze search.

- Babatunde OO, Legha A, Littlewood C, Chesterton LS, Thomas MJ, Menz HB, van der Windt D, Roddy E. Comparative effectiveness of treatment options for plantar heel pain: a systematic review with network meta-analysis. Br J Sport4 s Med. 2019 Feb;53(3):182-194. doi: 10.1136/bjsports-2017-098998. Epub 2018 Jun 28. PMID: 29954828.
- Riel H, Vicenzino B, Olesen JL, Bach Jensen M, Ehlers LH, Rathleff MS. 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. Br J Sports Med. 2023 Sep;57(18):1180-1186. doi: 10.1136/bjsports-2023-106948. Epub 2023 Jul 6. PMID: 37414460; PMCID: PMC10579183
- Peña-Martínez VM, Acosta-Olivo C, Simental-Mendía LE, Sánchez-García A, Jamialahmadi T, Sahebkar A, Vilchez-Cavazos F, Simental-Mendía M. Effect of corticosteroids over plantar fascia thickness in plantar fasciitis: a systematic review and meta-analysis. Phys Sportsmed. 2023 Jun 13:1-12. doi: 10.1080/00913847.2023.2223673. Online ahead of print.PMID: 37293970 Review.
- Ahadi T, Nik SS, Forogh B, Madani SP, Raissi GR. Comparison of the Effect of Ultrasound-Guided Injection of Botulinum Toxin Type A and Corticosteroid in the Treatment of Chronic Plantar Fasciitis: A Randomized Controlled Trial. Am J Phys Med Rehabil. 2022 Aug 1;101(8):733-737. doi: 10.1097/PHM.0000000000001900. Epub 2021 Oct 8.
- Tabrizi A, Dindarian S, Mohammadi S.J The Effect of Corticosteroid Local Injection Versus Platelet-Rich Plasma for the Treatment of Plantar Fasciitis in Obese Patients: A Single-Blind, Randomized Clinical Trial. Foot Ankle Surg. 2020 Jan-Feb;59(1):64-68. doi: 10.1053/j.jfas.2019.07.004.
- David JA, Sankarapandian V, Christopher PR, Chatterjee A, Macaden AS. Injected corticosteroids for treating plantar heel pain in adults. Cochrane Database Syst Rev. 2017 Jun 11;6(6):CD009348. doi: 10.1002/14651858.CD009348.pub2
- Tsikopoulos K, Vasiliadis HS, Mavridis D. Injection therapies for plantar fasciopathy ('plantar fasciitis'): a systematic review and network meta-analysis of 22 randomised controlled trials. Br J Sports Med. 2016 Nov;50(22):1367-1375. doi: 10.1136/bjsports-2015-095437. Epub 2016 May 3.

Te gebruiken voor richtlijntekst:
In de databases Embase.com en Ovid/Medline is op 28 maart 2024 systematisch gezocht naar systematische reviews en RCTs over de plaats van corticosteroïd-injecties bij de behandeling bij patiënten met fasciopathie plantaris. De literatuurzoekactie leverde 238 unieke treffers op.

Zoekopbrengst 28-3-2024

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	91	61	100
RCT	129	81	138
Observationeel			
Totaal	220	142	**238***

****in Rayyan***

Zoekstrategie Embase.com 28-3-2024

No.	Query	Results
#1	'plantar fasciitis'/exp OR 'plantar fasciopathy'/exp OR 'heel spur'/exp OR 'policeman heel'/exp OR (((calcane* OR heel* OR subcalcane*) NEAR/3 (spur* OR exostos* OR pain* OR policeman* OR jogger*)):ti,ab,kw) OR ((plant* NEAR/3 (fasciitis OR fasciopath* OR fascios* OR inflam*)):ti,ab,kw) OR (((baxter* OR plant* OR calcane* OR heel) NEAR/3 neuropath*):ti,ab,kw) OR calcaneodyn*:ti,ab,kw OR 'calcane* periostitis':ti,ab,kw	6372
#2	'corticosteroid'/exp OR 'corticosteroid therapy'/exp OR corticosteroid*:ti,ab,kw OR glucocortico*:ti,ab,kw OR 'adrenal cortex hormone*':ti,ab,kw OR 'adrenal steroid*':ti,ab,kw OR corticoid*:ti,ab,kw OR corticotherap*:ti,ab,kw	1281681
#3	#1 AND #2	824
#4	#3 AND [2000-2024]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	575
#5	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	1014761
#6	'randomized controlled trial'/exp OR random*:ti,ab OR (((pragmatic OR practical) NEAR/1 'clinical trial*'):ti,ab) OR ((('non inferiority' OR noninferiority OR superiority OR equivalence) NEAR/3 trial*):ti,ab) OR rct:ti,ab,kw	2178974
#7	#4 AND #5 **– SR's**	91
#8	#4 AND #6 NOT #7 **– RCT's**	129
#9	#7 OR #8	220

5

Zoekstrategie Ovid/Medline 28-3-2024

#	**Searches**	**Results**
1	exp Fasciitis, Plantar/ or exp Heel Spur/ or ((calcane* or heel* or subcalcane*) adj3 (spur* or exostos* or pain* or policeman* or jogger*)).ti,ab,kf. or (plant* adj3 (fasciitis or fasciopath* or fascios* or inflam*)).ti,ab,kf. or ((baxter* or plant* or calcane* or heel) adj3 neuropath*).ti,ab,kf. or calcaneodyn*.ti,ab,kf. or calcane* periostitis.ti,ab,kf.	4416
2	exp Adrenal Cortex Hormones/ or corticosteroid*.ti,ab,kf. or glucocortico*.ti,ab,kf. or 'adrenal cortex hormone*'.ti,ab,kf. or 'adrenal steroid*'.ti,ab,kf. or corticoid*.ti,ab,kf. or corticotherap*.ti,ab,kf.	530831
3	1 and 2	324
4	limit 3 to yr="2000 -Current"	279
5	4 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	259

6	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	735289
7	exp randomized controlled trial/ or randomized controlled trials as topic/ or random*.ti,ab. or rct?.ti,ab. or ((pragmatic or practical) adj "clinical trial*").ti,ab,kf. or ((non-inferiority or noninferiority or superiority or equivalence) adj3 trial*).ti,ab,kf.	1700385
8	5 and 6 **– SR's**	61
9	(5 and 7) not 8 **– RCT's**	81
10	8 or 9	142

Module 8 Autologe bloedproducten

Module 8a Plaatjes rijk plasma (PRP)

Search and select

A systematic review of the literature was performed to answer the following question(s):
What is the effectiveness of Platelet Rich Plasma (PRP) or Autologous Whole Blood (AWB) injections compared to placebo in patients with Plantar Fasciitis (PF)?

The overall search encompassed two questions and two PICO's (both PRP and AWB). Below, the selection process of one of these is described in detail.

Table 1. PICO 1

Patients	Patients with Plantar Fasciopathy
Intervention	Platelet Rich Plasma (PRP) injections
Control	Placebo (or as add-on on exercise therapy)
Outcomes	Pain (crucial), function (crucial), adverse events (crucial), quality of life (important), return to sport (important)
Other selection criteria	Study design: systematic reviews, meta -analyses and randomized controlled trials

Relevant outcome measures

The guideline panel considered pain, function and adverse events as **crucial** outcome measures for decision making; and quality of life or return to sport as **important** outcome measures for decision making.

A priori, the guideline panel did not define the outcome measures listed above but used the definitions used in the studies. The guideline panel was explicitly interested in a follow-up period of at least 3 months.

The guideline panel defined 10% as a minimal clinically important difference for both continuous as well as dichotomous outcome measures. This includes a 10% difference on the outcome measurement on a continuous scale or an increase/decrease of relative risk (RRR) of 10% or more.

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until 28 March 2024. The detailed search strategy is listed under the tab 'Literature search strategy'. The systematic literature search resulted in 155 hits. Studies were selected based on the following criteria:

- Randomized controlled trials (RCTs), systematic reviews and/or meta-analyses;
- Studies according to the PICO;
- Studies including a minimum of 20 patients (10 patients per study arm);
- Full text English language publication

Initially, 19 studies were selected based on title and abstract screening. After reading the full text, 14 studies were excluded (see the exclusion table under the tab 'Evidence tabellen'), and 5 studies were included for PRP and AWB. Below, 2 studies evaluating PRP are described.

Summary of literature

Description of studies

A total of 2 RCTs were included in the analysis of the literature. Mahindra (2016) and Kumar (2024) both used a 3-arm comparison including a PRP injection, a corticosteroid (CS) injection and a placebo injection group.

Important study characteristics and results are summarized in table 1. The assessment of the risk of bias is summarized in the risk of bias tables (under the tab 'Evidence tabellen').

Mahindra (2016) performed a RCT comparing PRP, CS and placebo (saline) injections in chronic plantar fasciitis (PF). A total of 75 patients (25 per arm) with chronic PF diagnosed on history and physical examination, who had no response to at least 3 months of conservative treatment (physical therapy/ NSAIDs/ orthotics) were included. Each patient received one injection. Relevant outcome measures included pain (VAS score) and function (American Orthopaedic Foot and Ankle Score (AOFAS); measuring function as activity limitations, maximum walking distance, walking surfaces, gait abnormality, sagittal motion, hindfoot motion, ankle-hindfoot stability and foot alignment and pain). Outcomes were measured at baseline, 3 weeks and after 3 months. In this literature analysis only the follow up at 3 months was included.

Kumar (2024) performed a RCT comparing PRP, CS and placebo (saline) injections in plantar fasciitis (PF). A total of 120 patients (40 per arm) with clinical symptoms consistent with PF, without previous therapy including local steroid injections were included. Each patient received one injection. Relevant outcome measures included pain (VAS score) and function (Foot and Ankle Outcome Score (FAOS); measuring function as foot/ankle symptoms and difficulties, joint stiffness, difficulties with physical functioning in daily living, sports and recreational activities, quality of life and pain). Outcomes were measured at baseline, after 3 months (12 weeks) and 6 months.

Table 2. Characteristics of included studies

RCT (author year)	Intervention	Participants (number, age, sex, duration of symptoms)	Control	Participants (number, age, other important characteristics)	Follow-up	Outcome measures	Risk of bias (per outcome measure)*	Remarks
Mahindra (2016)	Injection 2.5- 3 ml PRP Administration: point of maximum tenderness in the heel using the peppering method.	N at baseline: 25 Age (mean ± sd): 30.7y ± 7.4 Sex: 32% male Duration of symptoms: not reported	Injection 1 ml saline Administration: point of maximum tenderness in the heel using the peppering method.	N at baseline: 25 Age (mean ± sd): 35.5 y ± 9.5 Sex: 44% male Duration of symptoms: not reported	Baseline, 3 weeks, 3 months	Pain (VAS); scale 0-10 Function (AOFAS); scale 0-100	Some concerns (all outcome measures)	Additional arm CS not included
Kumar (2024)	Injection 1 ml PRP & 0,1 ml calcium chloride Administration: close to plantar fascia insertion using the peppering method	N at baseline: 40 Age (mean ± sd): 43.6 y ± 8.0 Sex: 38.3% male (total population) Duration of symptoms (mean ± sd): 6.8 months ± 2.9	Injection 1 ml saline Administration: close to plantar fascia insertion using the peppering method	N at baseline: 40 Age (mean ± sd): 43.8 y ± 9.0 Sex: 38.3% male (total population) Duration of symptoms (mean ± sd): 7.1 months ± 2.9	Baseline, 3 months, 6 months	Pain (VAS); scale 0-10 Function (FAOS); scale 0-100	Some concerns (all outcome measures)	Additional arm CS not included
*For further details, see risk of bias table in the appendix								

Results

Results are described per outcome measure. All results are summarized and presented in the Summary of Findings table, including the level of evidence, using GRADE (table 3).

1. Pain (crucial)

Pain was assessed at short term (3 months) and long term (6 months). All five studies reported pain using the VAS (Visual Analogue Score) on a 0-10 or 0-100 scale or NRS (Numeric Rating scale) on a 0-10 scale. Higher scores indicated more pain. To pool the results, the VAS measured on a 0-100 scale was divided by 10.

Short-term pain (measured at 3 months follow-up) for PRP was assessed in two studies. Mahindra (2016) and Kumar (2024) compared PRP versus placebo (saline) and included 65 patients in each arm. The pooled mean difference group was -3.12 (95% CI: -6.62 to 0.38) favoring the PRP group. This was a clinically relevant difference (>10% on a 0-10 scale).

Kumar (2024) also assessed *long-term pain* (measured at 6 months follow-up) they found a clinically relevant mean difference of -4.84 (95% CI: -5.42 to -4.26) favoring the PRP group (>10% on a 0-10 scale).
Results are summarized in a forest plot (Figure 1)

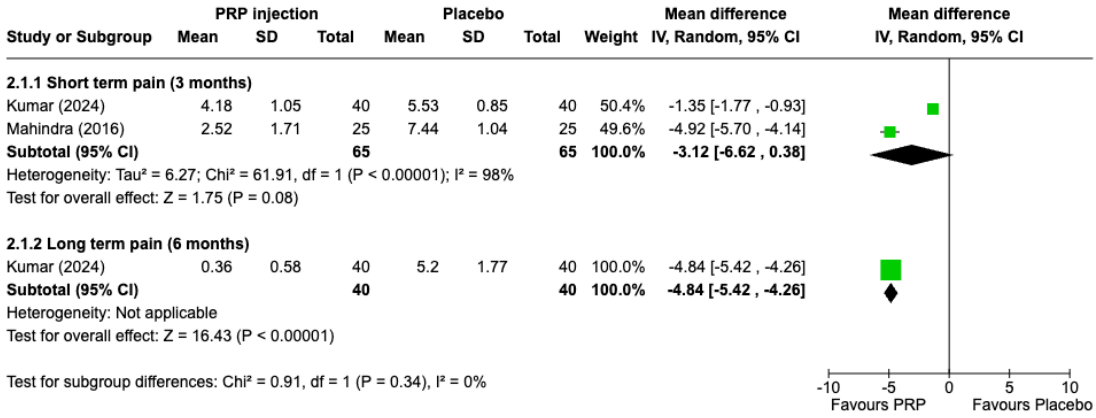

Figure 1: forest plot showing pooled results for short- and long- term pain for PRP

2. Function (crucial)

Function was assessed at short term (3 months) and long term (6 months). Two studies Mahindra (2016) and Kumar (2024) reported on function using different scales (AOFAS and FAOS; all on a 0-100 scale). For both the AOFAS and FAOS a higher score represented better function. We used the standardized mean difference to facilitate pooling

Short-term function (measured at 3 months follow-up) for PRP was assessed in two studies. Mahindra (2016) and Kumar (2024) compared PRP versus placebo (saline) and included 65 patients in each arm, measuring function using the AOFAS and FAOS respectively.
Due to differences in outcome measurement scales we presented the standardized mean difference.
The standardized mean difference group was 2.57 (95% CI: 0.32 to 4.82) indicating a large effect (> 0.8 (according to Cohen 1988)); favoring the PRP group.
Kumar (2024) also assessed *long-term pain* (measured at 6 months follow-up) to assess function (FAOS) and found a SMD of 3.10 (95% CI: 2.44 to 3.76) favoring the PRP group.
Results are summarized in a forest plot (Figure 2)

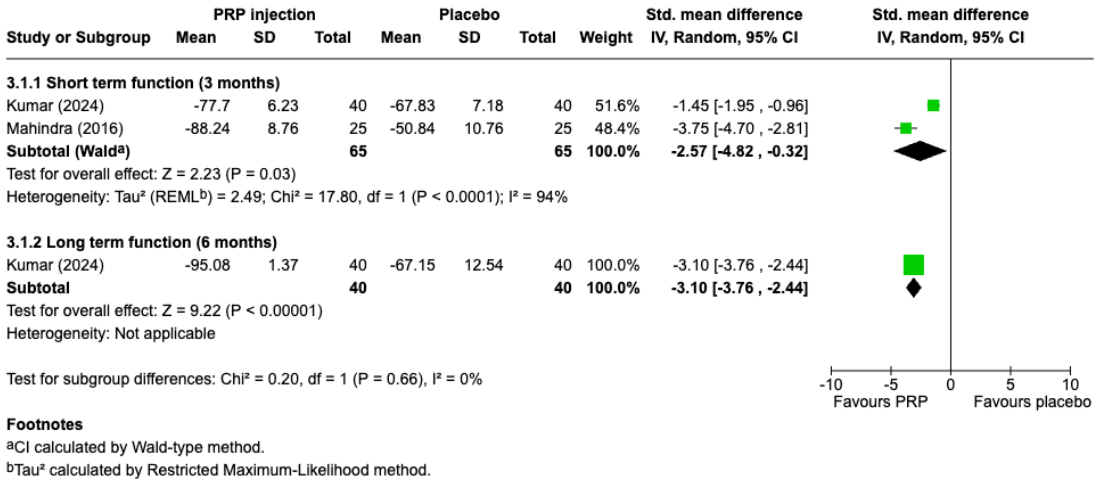

Figure 2: forest plot showing pooled results for short- and long- term pain for PRP

3. Adverse events (crucial)

No studies reported on the effect of PRP injections on adverse events.

4. Quality of life (important)

No studies reported on the effect of PRP injections on quality of life.

5. Return to sport (important)

No studies reported on the effect of PRP injections on return to sport.

Summary of Findings

Table 3 Summary of findings table including GRADE for PRP

Outcome	Term	Study results and measurements	Absolute effect estimates*		Certainty of evidence (GRADE)	Conclusions
			PRP injection	placebo		
Pain (crucial)	Short term (3 months)	Measured by VAS on a 0-10 scale. Based on 2 studies including data from 130 patients	Difference: **MD 3.12 lower** (95% CI: 6.62 lower to 0.38 higher) Favoring PRP		**Low** Due to serious risk of bias and serious imprecision[1]	PRP injections may reduce short term pain when compared with placebo in patients with plantar fasciopathy. Kumar (2024), Mahindra (2016),
	Long term (6 months)	Measured by VAS on a 0-10 scale. Based on 1 study including data from 80 patients	Difference: **MD 4.84 lower** (95% CI: 5.42 lower to 4.26 lower) Favoring PRP		**Low** Due to serious risk of bias and imprecision[2]	PRP injections may reduce long term pain when compared with placebo in patients with plantar fasciopathy. Kumar (2024)
Function (crucial)	Short term (3 months)	Function was measured by AOFAS or FAOS, on a 0-100 scale Based on 2 studies including data from 130 patients	Difference: **SMD 2.57 higher** (95% CI: 0.32 higher to 4.82 higher) Favoring PRP		**Low** Due to serious risk of bias and serious imprecision[1]	PRP injections may increase short term function when compared with placebo in patients with plantar fasciopathy. Mahindra (2016), Kumar (2024)
	Long term (6 months)	Function was measured by FAOS, on a 0-100 scale. Based on 1 study (80 patients)	Difference: **SMD 3.10 higher** (95% CI: 2.44 higher to 3.76 higher) Favoring PRP		**Low** Due to serious risk of bias and serious imprecision[2]	PRP injections may increase long term function when compared with placebo in patients with plantar fasciopathy. Kumar (2024)
Adverse events (crucial)		No studies	-		**No GRADE**	No evidence was found regarding the effect of PRP injections on adverse events when compared with placebo in patients with plantar fasciopathy.
Quality of life (important)		No studies	-		**No GRADE**	No evidence was found regarding the effect of PRP injections on quality of life when compared with placebo in patients with plantar fasciopathy.
Return to sport (important)		No studies	-		**No GRADE**	No evidence was found regarding the effect of PRP injections on return to sport when compared with placebo in patients with plantar fasciopathy.

Reasons for downgrading certainty of evidence (levels of downgrading -1 or -2)

1. Risk of Bias: Potential RoB mainly due to lack of detailed information on allocation, blinding and potential loss to follow up (-1 level)
   Imprecision: due to overlap of the 95% CI with the minimal clinically important difference, i.e. boundary of CI includes possibility of benefit or harm (-1 level)
2. Risk of Bias: Potential RoB mainly due to lack of detailed information on allocation, blinding and potential loss to follow up (-1 level)
   Imprecision: results included patients from only one study, limited sample size; not reaching the optimal information size (-1 level)
3. Risk of Bias: Potential RoB. mainly due to lack of detailed information on allocation and blinding (-1 level)
   Inconsistency: large heterogeneity with no overlap in confidence intervals (-1 level)
   Imprecision: due to overlap of the 95% CI with the minimal clinically important difference, i.e. boundary of CI includes possibility of benefit and harm (-2 levels)

Kennisvragen

Tijdens de ontwikkeling van deze module is systematisch naar onderzoeken gezocht die de zoekvraag kunnen beantwoorden. Door gebruik te maken van een systematische literatuuranalyse met beoordeling van de bewijskracht is duidelijk geworden dat er binnen deze module nog kennisvragen bestaan. De werkgroep meent dat (vervolg)onderzoek wenselijk is om in de toekomst een duidelijker antwoord te kunnen geven op vragen uit de praktijk.

What is the effectiveness of Platelet Rich Plasma (PRP) or Autologous Whole Blood (AWB) injections compared to placebo in patients with Plantar Fasciitis (PF)?

P = patiënten met fasciopathie plantaris met persisterende klachten na conservatieve behandeling > 6 maanden
I = PRP injectie
C = placebo injectie
O = mate van pijnklachten, functie, QoL, kosteneffectiviteit en adverse events

Literatuur

Cotchett M, Rathleff MS, Dilnot M, Landorf KB, Morrissey D, Barton C. Lived experience and attitudes of people with plantar heel pain: a qualitative exploration. J Foot Ankle Res. 2020 Mar 6;13(1):12. doi: 10.1186/s13047-020-0377-3. PMID: 32143679; PMCID: PMC7059663.

Digra N, Beri A, Sharma S, Verma R. Autologous Whole-Blood Versus Corticosteroid Local Injection in Treatment of Plantar Fasciitis: A Randomized Single Blind Placebo-Controlled Study. Cureus. 2023 Sep 20;15(9):e45588. doi: 10.7759/cureus.45588. PMID: 37868394; PMCID: PMC10587858.

Dohan Ehrenfest DM, Andia I, Zumstein MA, Zhang CQ, Pinto NR, Bielecki T. Classification of platelet concentrates (Platelet-Rich Plasma-PRP, Platelet-Rich Fibrin-PRF) for topical and infiltrative use in orthopedic and sports medicine: current consensus, clinical implications and perspectives. Muscles Ligaments Tendons J. 2014 May 8;4(1):3-9. PMID: 24932440; PMCID: PMC4049647.

Franchini M, Cruciani M, Mengoli C, Marano G, Pupella S, Veropalumbo E, Masiello F, Pati I, Vaglio S, Liumbruno GM. Efficacy of platelet-rich plasma as conservative treatment in orthopaedics: a systematic review and meta-analysis. Blood Transfus. 2018 Nov;16(6):502-513. doi: 10.2450/2018.0111-18. Epub 2018 Sep 3. PMID: 30201082; PMCID: PMC6214820.

Kalaci A, Cakici H, Hapa O, Yanat AN, Dogramaci Y, Sevinç TT. Treatment of plantar fasciitis using four different local injection modalities: a randomized prospective clinical trial. J Am Podiatr Med Assoc. 2009 Mar-Apr;99(2):108-13. doi: 10.7547/0980108. PMID: 19299346.

Kiter E, Celikbas E, Akkaya S, Demirkan F, Kiliç BA. Comparison of injection modalities in the treatment of plantar heel pain: a randomized controlled trial. J Am Podiatr Med Assoc. 2006 Jul-Aug;96(4):293-6. doi: 10.7547/0960293. PMID: 16868321.

Kumar VA, Khalid KM, Vajrangi A, Sherikar N, Srinivas R, Rakshith CHY, Kurupati RB, Rajanna P. A Comparative Study Between Platelet-Rich Plasma And Corticosteroid Injection For Plantar Fasciitis. Research journal of pharmaceutical, biological and chemical sciences. 2024. 15(1), 159-166.doi:10.33887

Mahindra P, Yamin M, Selhi HS, Singla S, Soni A. Chronic Plantar Fasciitis: Effect of Platelet-Rich Plasma, Corticosteroid, and Placebo. Orthopedics. 2016 Mar-Apr;39(2):e285-9. doi: 10.3928/01477447-20160222-01. Epub 2016 Feb 25. PMID: 26913766.

Mørk M, Soberg HL, Hoksrud AF, Heide M, Groven KS. The struggle to stay physically active-A qualitative study exploring experiences of individuals with persistent plantar fasciopathy.

J Foot Ankle Res. 2023 Apr 15;16(1):20. doi: 10.1186/s13047-023-00620-4. PMID: 37061709; PMCID: PMC10105408.

Morrissey D, Cotchett M, Said J'Bari A, Prior T, Griffiths IB, Rathleff MS, Gulle H, Vicenzino B, Barton CJ. Management of plantar heel pain: a best practice guide informed by a systematic review, expert clinical reasoning and patient values. Br J Sports Med. 2021 Oct;55(19):1106-1118. doi: 10.1136/bjsports-2019-101970. Epub 2021 Mar 30. PMID: 33785535; PMCID: PMC8458083.

Wheeler PC, Dudson C, Gregory KM, Singh H, Boyd KT. Autologous Blood Injection With Dry-Needling vs Dry-Needling Alone Treatment for Chronic Plantar Fasciitis: A Randomized Controlled Trial. Foot Ankle Int. 2022 May;43(5):646-657. doi: 10.1177/10711007211061365. Epub 2022 Jan 24. PMID: 35068224.

Implementatietabel

Aanbeveling – 1 Overweeg een PRP injectie alleen als potentiële behandeling voor fasciopathie plantaris bij uitblijven van resultaat na conservatieve behandeling na meer dan 6 maanden	Op basis van de beschikbare evidentie en ervaring uit de praktijk kon er onvoldoende richting aan de besluitvorming worden gegeven. Om die reden is er geen beschrijving van belemmeringen en kansen voor implementatie van de aanbeveling toegevoegd. Disseminatie van de kennis in deze module verloopt via de standaard route. De module wordt gepubliceerd op de Richtlijnendatabase.

Risk of bias table for intervention studies (randomized controlled trials; based on Cochrane risk of bias tool and suggestions by the CLARITY Group at McMaster University)

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?**	**Was the allocation adequately concealed?**	**Blinding: Was knowledge of the allocated interventions adequately prevented? |Were patients blinded? | Were healthcare providers blinded? | Were data collectors blinded? | Were outcome assessors blinded? | Were data analysts blinded?**	**Was loss to follow-up (missing outcome data) infrequent?**	**Are reports of the study free of selective outcome reporting?**	**Was the study apparently free of other problems that could put it at a risk of bias?**	**Overall risk of bias** **If applicable/necessary, per outcome measure** **LOW/Some concerns/ HIGH**
Mahindra (2016)	Definitely yes Reason: Central randomization with computer programming	Probably no Reason: no description of allocation	Probably yes Reason: double blinded: Patients were blinded, outcome assessor was blinded. (blinding of data collector/ analysts not reported)	Probably no Reason: Seems no loss to follow up (short period) but no description of any loss to follow up given	Probably yes Reason: all relevant outcomes reported, but no detailed description in methodology	Probably yes: Reason: seems no other risks of biases, but detailed information (methodology or adverse events) is lacking	Some concerns (all outcome measures) Reason: No information on adverse events. Missing information om some points regarding risk of bias
Kumar (2024)	Definitely yes Reason: randomization with computer generated sequence	Probably no Reason: no description of allocation	Probably no Reason: No information on blinding of patients' health care providers, data collectors, outcome assessor or data analysts.	Probably no Reason: Seems no loss to follow up (short period) but no description of any loss to follow up given	Probably yes Reason: all relevant outcomes reported, but no detailed description in methodology	Probably yes: Reason: seems no other risks of biases, but detailed information (methodology or adverse events) is lacking	Some concerns (all outcome measures) Reason: Unclear blinding procedure, and no detailed information on used methodology to assess the risk of bias on all items

5

Table of excluded studies

Reference	Reason for exclusion
Johnson-Lynn S, Cooney A, Ferguson D, Bunn D, Gray W, Coorsh J, Kakwani R, Townshend D. A Feasibility Study Comparing Platelet-Rich Plasma Injection With Saline for the Treatment of Plantar Fasciitis Using a Prospective, Randomized Trial Design. Foot Ankle Spec. 2019 Apr;12(2):153-158. doi: 10.1177/1938640018776065. Epub 2018 May 21. PMID: 29779399.	No data presented to provide effect estimates
Shetty SH, Dhond A, Arora M, Deore S. Platelet-Rich Plasma Has Better Long-Term Results Than Corticosteroids or Placebo for Chronic Plantar Fasciitis: Randomized Control Trial. J Foot Ankle Surg. 2019 Jan;58(1):42-46. doi: 10.1053/j.jfas.2018.07.006. Epub 2018 Nov 15. PMID: 30448183.	No data presented to provide effect estimates
de Vos RJ, van Veldhoven PL, Moen MH, Weir A, Tol JL, Maffulli N. Autologous growth factor injections in chronic tendinopathy: a systematic review. Br Med Bull. 2010;95:63-77. doi: 10.1093/bmb/ldq006. Epub 2010 Mar 2. PMID: 20197290.	Wrong population (FP and others) and wrong control group (no placebo with/without exercise therapy)
Karimzadeh A, Raeissadat SA, Erfani Fam S, Sedighipour L, Babaei-Ghazani A. Autologous whole blood versus corticosteroid local injection in treatment of plantar fasciitis: A randomized, controlled multicenter clinical trial. Clin Rheumatol. 2017 Mar;36(3):661-669. doi: 10.1007/s10067-016-3484-6. Epub 2016 Dec 12. PMID: 27957618.	Wrong control group (no placebo with/without exercise therapy)
Chew KT, Leong D, Lin CY, Lim KK, Tan B. Comparison of autologous conditioned plasma injection, extracorporeal shockwave therapy, and conventional treatment for plantar fasciitis: a randomized trial. PM R. 2013 Dec;5(12):1035-43. doi: 10.1016/j.pmrj.2013.08.590. Epub 2013 Aug 22. PMID: 23973504.	Wrong control group (no placebo with/without exercise therapy)
Gao R, Sun J, Zhang L, Chen S, Dong W, Yu H, Han B, Tan M, Li X. Comparative Effectiveness of Minimally Invasive Nonsurgical Treatments for Plantar Fasciitis: A Network Meta-analysis of 30 Randomized Controlled Trials. Pain Physician. 2021 Nov;24(7):E955-E971. PMID: 34704707.	Wrong comparison (no direct comparison PRP with placebo with/without exercise therapy)
Li H, Lv H, Lin T. Comparison of efficacy of eight treatments for plantar fasciitis: A network meta-analysis. J Cell Physiol. 2018 Jan;234(1):860-870. doi: 10.1002/jcp.26907. Epub 2018 Aug 4. PMID: 30078188.	Wrong control group (no placebo with/without exercise therapy, 1 RCT already included)
Guimarães JS, Arcanjo FL, Leporace G, Metsavaht LF, Conceição CS, Moreno MVMG, Vieira TEM, Moraes CC, Gomes Neto M. Effects of therapeutic interventions on pain due to plantar fasciitis: A systematic review and meta-analysis. Clin Rehabil. 2023 Jun;37(6):727-746. doi: 10.1177/02692155221143865. Epub 2022 Dec 26. PMID: 36571559.	Wrong comparison (no direct comparison PRP with placebo with/without exercise therapy)
Franchini M, Cruciani M, Mengoli C, Marano G, Pupella S, Veropalumbo E, Masiello F, Pati I, Vaglio S, Liumbruno GM. Efficacy of platelet-rich plasma as conservative treatment in orthopaedics: a systematic review and meta-analysis. Blood Transfus. 2018 Nov;16(6):502-513. doi: 10.2450/2018.0111-18. Epub 2018 Sep 3. PMID: 30201082; PMCID: PMC6214820.	Wrong population (FP and others) and wrong control group (no placebo with/without exercise therapy)
Assad S, Ahmad A, Kiani I, Ghani U, Wadhera V, Tom TN. Novel and Conservative Approaches Towards Effective Management of Plantar Fasciitis. Cureus. 2016 Dec 5;8(12):e913. doi: 10.7759/cureus.913. PMID: 28083457; PMCID: PMC5215813.	Wrong control group (no placebo with/without exercise therapy, 1 RCT already included)
Yu T, Xia J, Li B, Zhou H, Yang Y, Yu G. Outcomes of platelet-rich plasma for plantar fasciopathy: a best-evidence synthesis. J Orthop Surg Res. 2020 Sep 21;15(1):432. doi: 10.1186/s13018-020-01783-7. PMID: 32958046; PMCID: PMC7504858.	Wrong control group (no placebo with/without exercise therapy, 1 RCT already included)
Herber A, Covarrubias O, Daher M, Tung WS, Gianakos AL. Platelet rich plasma therapy versus other modalities for treatment of plantar fasciitis: A systematic review and meta-analysis. Foot Ankle Surg. 2024 Jun;30(4):285-293. doi: 10.1016/j.fas.2024.02.004. Epub 2024 Feb 15. PMID: 38395675.	Wrong control group (no placebo with/without exercise therapy, 1 RCT already included)

Masiello F, Pati I, Veropalumbo E, Pupella S, Cruciani M, De Angelis V. Ultrasound-guided injection of platelet-rich plasma for tendinopathies: a systematic review and meta-analysis. Blood Transfus. 2023 Mar;21(2):119-136. doi: 10.2450/2022.0087-22. Epub 2022 Oct 17. PMID: 36346880; PMCID: PMC10072988.	Wrong population (FP and others) and wrong control group (no placebo with/without exercise therapy)

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Fasciopathie Plantaris - UV8 Autologe factoren	
Uitgangsvraag/modules: Wat is de plaats van autologe bloedproducten bij de behandeling van patiënten met fasciopathie plantaris?	
Database(s): Embase.com, Ovid/Medline	Datum: 28-3-2024
Periode: vanaf 2000	Talen: geen restrictie
Literatuurspecialist: Esther van der Bijl	Rayyan review: https://rayyan.ai/reviews/980355
BMI-zoekblokken: voor verschillende opdrachten wordt (deels) gebruik gemaakt van de zoekblokken van BMI-Online https://blocks.bmi-online.nl/ Bij gebruikmaking van een volledig zoekblok zal naar de betreffende link op de website worden verwezen.	
Toelichting: Voor deze vraag is gezocht op de elementen fasciopathie plantaris EN autologe bloedproducten. → De sleutelartikelen worden gevonden met deze search. • Platelet-Rich Plasma Has Better Long-Term Results Than Corticosteroids or Placebo for Chronic Plantar Fasciitis: Randomized Control Trial. Shetty SH, Dhond A, Arora M, Deore S. J Foot Ankle Surg. 2019 Jan;58(1):42-46. • Autologous Blood Injection With Dry-Needling vs Dry-Needling Alone Treatment for Chronic Plantar Fasciitis: A Randomized Controlled Trial. Wheeler PC, Dudson C, Gregory KM, Singh H, Boyd KT. Foot Ankle Int. 2022 May;43(5):646-657.	
Te gebruiken voor richtlijntekst: In de databases Embase.com en Ovid/Medline is op 28 maart 2024 systematisch gezocht naar systematische reviews en RCTs over de plaats van autologe bloedproducten bij de behandeling van patiënten met fasciopathie plantaris. De literatuurzoekactie leverde 155 unieke treffers op.	

5 ***Zoekopbrengst 28-3-2024***

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	58	43	62
RCT	86	48	93
~~Observationeel~~			
Totaal	144	91	**155***

****in Rayyan***

Zoekstrategie Embase.com 28-3-2024

No.	Query	Results
#1	'plantar fasciitis'/exp OR 'plantar fasciopathy'/exp OR 'heel spur'/exp OR 'policeman heel'/exp OR (((calcane* OR heel* OR subcalcane*) NEAR/3 (spur* OR exostos* OR pain* OR policeman* OR jogger*)):ti,ab,kw) OR ((plant* NEAR/3 (fasciitis OR fasciopath* OR fascios* OR inflam*)):ti,ab,kw) OR (((baxter* OR plant* OR calcane* OR heel) NEAR/3 neuropath*):ti,ab,kw) OR calcaneodyn*:ti,ab,kw OR 'calcane* periostitis':ti,ab,kw	6372
#2	'thrombocyte rich plasma'/exp OR 'platelet-rich plasma cell'/exp OR 'blood autotransfusion'/exp OR (((blood OR plasma) NEAR/3 (autotransfusion* OR autologous	47371

	OR 'platelet rich*' OR 'thrombocyte rich*')):ti,ab,kw) OR ((prp NEAR/3 inject*):ti,ab,kw) OR 'autoh*emotransfusion':ti,ab,kw	
#3	#1 AND #2	292
#4	#3 AND [2000-2024]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	249
#5	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	1014761
#6	'clinical trial'/exp OR 'randomization'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR 'placebo'/exp OR 'prospective study'/exp OR rct:ab,ti OR random*:ab,ti OR 'single blind':ab,ti OR 'randomised controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti	4001894
#7	#4 AND #5 **– SR's**	58
#8	#4 AND #6 NOT #7 **– RCT's**	86
#9	#7 OR #8	144

Zoekstrategie Ovid/Medline 28-3-2024

#	Searches	Results
1	exp Fasciitis, Plantar/ or exp Heel Spur/ or ((calcane* or heel* or subcalcane*) adj3 (spur* or exostos* or pain* or policeman* or jogger*)).ti,ab,kf. or (plant* adj3 (fasciitis or fasciopath* or fascios* or inflam*)).ti,ab,kf. or ((baxter* or plant* or calcane* or heel) adj3 neuropath*).ti,ab,kf. or calcaneodyn*.ti,ab,kf. or calcane* periostitis.ti,ab,kf.	4416
2	exp Platelet-Rich Plasma/ or exp Blood Transfusion, Autologous/ or ((blood or plasma) adj3 (autotransfusion* or autologous or 'platelet rich*' or 'thrombocyte rich*')).ti,ab,kf. or (prp adj3 inject*).ti,ab,kf. or 'autoh*emotransfusion'.ti,ab,kf.	32277
3	1 and 2	155
4	limit 3 to yr="2000 -Current"	155
5	4 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	144
6	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	735289

7	exp clinical trial/ or randomized controlled trial/ or exp clinical trials as topic/ or randomized controlled trials as topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial or multicenter study or clinical trial).pt. or random*.ti,ab. or (clinic* adj trial*).tw. or ((singl* or doubl* or treb* or tripl*) adj (blind$3 or mask$3)).tw. or Placebos/ or placebo*.tw.	2706138
8	5 and 6 **– SR's**	43
9	(5 and 7) not 8 **– RCT's**	48
10	8 or 9	91

Module 8b Autoloog bloed injectie (ABI)

Search and select

A systematic review of the literature was performed to answer the following question:
What is the effectiveness of Platelet Rich Plasma (PRP) or Autologous Whole Blood (AWB) injections compared to placebo in patients with Plantar fasciopathy (PF)?

The overall search encompassed two questions and two PICO's (both PRP and AWB). Below, the selection process of autologous (whole) blood (AWB) injections is described in detail.

Table 1. PICO 2

Patients	Patients with Plantar fasciopathy
Intervention	Autologous (whole) blood (AWB) injections
Control	Placebo (or as add-on on exercise therapy)
Outcomes	Pain (crucial), function (crucial), adverse events (crucial), quality of life (important), return to sport (important)
Other selection criteria	Study design: systematic reviews, meta -analyses and randomized controlled trials

Relevant outcome measures

The guideline panel considered pain, function and adverse events as **crucial** outcome measures for decision making; and quality of life or return to sport as **important** outcome measures for decision making.

A priori, the guideline panel did not define the outcome measures listed above but used the definitions used in the studies. The guideline panel was explicitly interested in a follow-up period of at least 3 months.

The guideline panel defined 10% as a minimal clinically important difference for both continuous as well as dichotomous outcome measures. This includes a 10% difference on the outcome measurement on a continuous scale or an increase/decrease of relative risk (RRR) of 10% or more.

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until 28 March 2024. The detailed search strategy is listed under the tab 'Literature search strategy'. The systematic literature search resulted in 155 hits. Studies were selected based on the following criteria:

- Randomized controlled trials (RCTs), systematic reviews and/or meta-analyses;
- Studies according to the PICO;
- Studies including a minimum of 20 patients (10 patients per study arm);
- Full text English language publication

Initially, 19 studies were selected based on title and abstract screening. After reading the full text, 14 studies were excluded (see the exclusion table under the tab 'Evidence tabellen'), and 5 studies were included for PRP and AWB. Below, 3 studies evaluating AWB are described.

Summary of literature

Description of studies

A total of 3 RCTs were included in the analysis of the literature. Digra (2023), Wheeler (2022) and Kalaci (2009) compared AWB injections with placebo.

All these studies, except Wheeler (2022), used a 3-arm comparison including a AWB injection, a corticosteroid (CS) injection and a placebo injection group. We excluded the CS -group in the literature analysis, as this specifically focused on AWB injections. CS was dealt with in the module 'Corticosteroid-injections'. Important study characteristics and results are summarized in table 5. The assessment of the risk of bias is summarized in the risk of bias tables (under the tab 'Evidence tabellen').

Digra (2023) performed a RCT comparing Autologous Whole-Blood (AWB), CS and placebo (saline) injections in Plantar Fasciitis (PF). A total of 60 patients (20 per arm) with at least 2 weeks of heel pain and clinically diagnosed PF were included. Each patient received 2 injections: one at inclusion and one after 2 weeks. Relevant outcome measures included pain (VAS score). These were measured at 3 weeks, 6 weeks and 3 months (12 weeks). In this literature analysis only the follow up at 3 months were included.

Wheeler (2022) performed a RCT comparing autologous blood and placebo (ultrasound guided dry needling) in patients with chronic PF. A total of 90 patients (45 per arm), ≥18 years, with chronic (> 6 months) (ultrasound or MRI confirmed) PF, who failed to improve with a home exercise program of > 3 months were included. Patients were excluded in case of previous or current partially / full thickness tears of the PF seen on ultrasonography/ MRI, other known causes for pain, unable/ unwilling to do structured rehabilitation program alongside the injection, CS injection within 3 months, or patients on anticoagulation. Each patient received one injection: an ultrasound guided AB injection including dry needling or a dry needling injection alone, both groups received an additional structured home exercise program. Relevant outcome measures included pain (Numeric Rating Scale score) and function (revised Foot Functin Index (FFI-r); measuring function as pain and stiffness, difficulty in daily functioning, activity limitations, social issues on functioning due to foot problems). In addition, other Patient Reported Outcome Measures were used but these were not included in this literature analysis due to the lack of detailed data to assess between group differences. Outcomes were measured at baseline, 2 weeks, 6 weeks, 3 months and 6 months follow-up. In this literature analysis only the follow up at 3 and 6 months were included.

Kalaci (2009) performed a multicenter RCT comparing autologous blood, CS, CS with peppering and placebo (local anesthetic injection with peppering) injection in patients with PF. A total of 100 patients (25 per arm) with PF without previous injection or surgery for PF in the previous 6 months were included. Each patient received one injection. Relevant outcome measures included pain (VAS score) and function (categorized Roles and Maudsley scores). Only the results for pain were included in this literature analysis due to the lack of detailed data to assess between group differences. Outcomes were measured at baseline, after 3 weeks and 6 months follow up. In this literature analysis only the follow up at 6 months was included.

Table 2. Characteristics of included studies

RCT (author year)	Intervention	Participants (number, age, sex, duration of symptoms)	Control	Participants (number, age, other important characteristics)	Follow-up	Outcome measures	Risk of bias (per outcome measure)*	Remarks
Digra (2023)	Injection 2ml AWB (drawn from antecubital vein) & 2ml lignocaine Adminstration: location of greatest discomfort was palpated to determine the injection site using the walkover technique. At baseline and 2 weeks	N at baseline: 20 Age (mean ± sd): 41.5 y ± not reported Sex: 55% male (total population) Duration of symptoms: not reported	Injection 2 ml saline & 2ml lignocaine Adminstration: location of greatest discomfort was palpated to determine the injection site using the walkover technique. At baseline and 2 weeks	N at baseline: 20 Age (mean ± sd): 42.2 y, not reported Sex: 55% male (total population) Duration of symptoms: not reported	3 and 6 weeks, 3 months	Pain (VAS); scale 0-100	High (pain)	Additional arm CS not included
Wheeler (2022)	Injection 3-4 ml Autologous whole blood & 1- 2 ml lidocaine using US guided dry needling Administration: close to plantar fascia at site of thickening, insertion using the peppering method.	N at baseline: 45 Age (mean ± sd): 48.5 y ± 9.0 Sex: 42.2% male Duration of symptoms (mean ± sd): 45.7 months ± 32.5	Ultrasound guided dry needling. Administration: close to plantar fascia at site of thickening, insertion using the peppering method	N at baseline: 45 Age (mean ± sd): 50.4 y ± 8.9 Sex: 24.4% male Duration of symptoms (mean ± sd): 34.3 m ± 22.0	Baseline, 2 and 6 weeks, 3 and 6 months	Pain and stiffness (NRS); scale 0-10 Functional FFI-r ; scale 0-100 Other PROMs to assess function and Quality of life: (MOXFQ/FAAM/EQ5D/HADS/PSQI) not included for further analysis	Some concerns (all outcome measures)	-
Kalaci (2009)	Injection 2 ml autologous blood Administration: point of maximum	N at baseline: 25 Age (mean ± sd): 52.9 y ± 11.1	2 ml lidocaine+ peppering Administration: point of maximum	N at baseline: 25 Age (mean ± sd): 49.9y ± 10.8	Baseline, 3 weeks, 6 months	Pain (VAS); scale 0-10 Function (categorized R&M); not included for further analysis	High (all outcome measures)	Additional arms (CS, CS & peppering) not included

	tenderness in the heel using the peppering method.	Sex: 24% male Duration of symptoms (mean± sd): 8.1 months ± 12.8	tenderness in the heel using the peppering method.	Sex: 28% male Duration of symptoms (mean ± sd): 11.9 months ± 20.6				

*For further details, see risk of bias table in the appendix

Results

Results are described per outcome measure. All results are summarized and presented in the Summary of Findings table, including the level of evidence, using GRADE (table 6).

1. Pain (crucial)

Pain was assessed at short term (3 months) and long term (6 months). All five studies reported pain using the VAS (Visual Analogue Score) on a 0-10 or 0-100 scale or NRS (Numeric Rating scale) on a 0-10 scale. Higher scores indicated more pain. To pool the results, the VAS measured on a 0-100 scale was divided by 10.

Short-term pain (measured at 3 months follow-up) for AWB was assessed in two studies. Digra (2023) and Wheeler (2022) compared AWB versus placebo (saline or ultrasound guided dry needling, resp.) including 65 patients in each arm. The pooled mean difference was -2.48 (95% CI: -6.75 to 1.80) favoring the AWB group, which was clinically relevant (>10% on a 0-10 scale), but statistically not significant.

Long-term pain (measured at 6 months follow-up) for AWB was assessed in two studies. Wheeler (2022) and Kalaci (2009) compared AWB versus placebo (ultrasound guided dry needling or lidocaine and peppering, resp.) including 70 patients in each arm. The pooled mean difference was 0.39 (95% CI: -0.50 to 1.28) favoring the placebo group. Which was as well as not statistically significant as not clinically relevant (< 10% on a 0-10 scale).

Results are summarized in a forest plot (Figure 2).

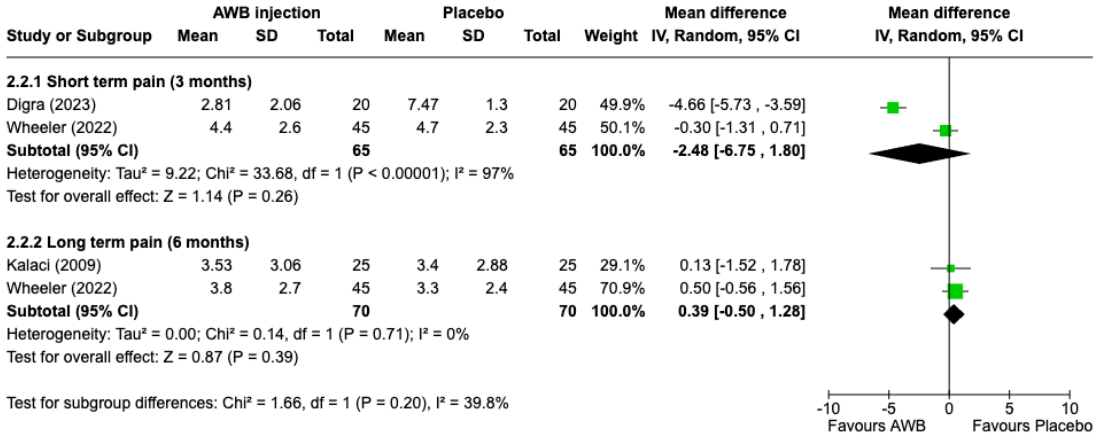

Figure 1: forest plot showing pooled results for short- and long- term pain for AWB

2. Function (crucial)

Only one study Wheeler (2022) compared AWB versus placebo (ultrasound guided dry needling) to measure short-term (3 months) and long-term function (6 months), including 45 patients in each arm. Function was measured using the FFI-r scale (on a 0-100 scale), with lower scores representing better function.

For s*hort-term function* (measured at 3 months follow-up) a mean difference of -1.50 (95% CI: -10.93 to 7.93) was found favouring the AWB group. For *long-term function* (measured at 6 months follow-up) a mean difference of 5.90 (95% CI: -3.75 to 15.55) was found favouring the placebo group. Both results were not statistically significant and clinically relevant (<10% on a 0-100 scale). Results are presented in a forest plot (Figure 4).

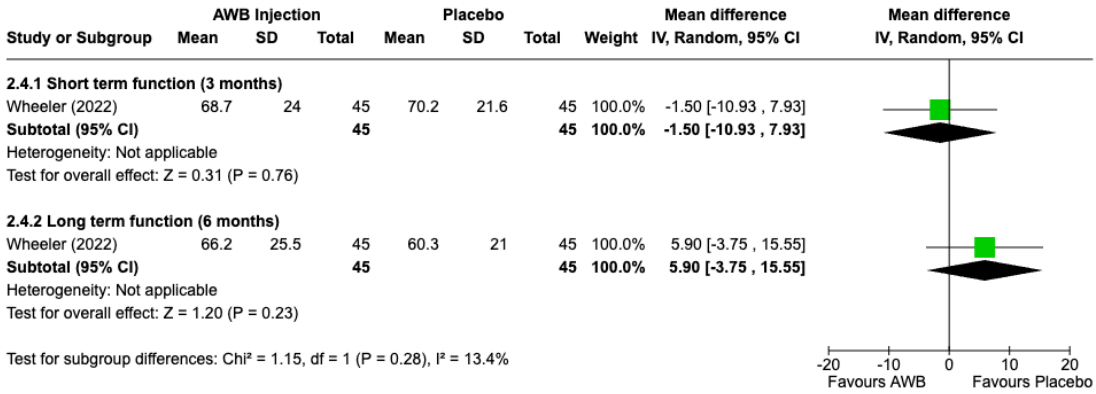

Figure 4: forest plot showing pooled results for short- and long-term function for AWB

3. Adverse events (crucial)

No studies reported on the effect of AWB injections on adverse events.

4. Quality of life (important)

Wheeler (2022) assessed several PROMS (MOXFQ, FAAM, EQ5D 5L, PSQI and HADS to assess general health and impact of symptoms on several areas of patient functioning including quality of life. However, no detailed information was provided to extract between group differences for Quality of Life.

5. Return to sport (important)

No studies reported on the effect of AWB injections on return to sport.

Table 3. Summary of findings table including GRADE for AWB

Outcome	Short or long term	Study results and measurements	Absolute effect estimates*		Certainty of evidence (GRADE)	Conclusions
			AWB injection	placebo		
Pain (crucial)	Short term (3 months)	Measured by VAS/NRS on a 0-10 scale. Based on 2 studies including data from 130 patients	Difference: **MD 2.48 lower** (95% CI: 6.75 lower to 1.80 higher) Favoring AWB		**Very Low** Due to serious risk of bias, serious inconsistency and serious imprecision[3]	The evidence is very uncertain about the short-term effect of AWB injection on pain when compared with placebo in patients with plantar fasciopathy. Digra (2023), Wheeler (2022)
	Long term (6 months)	Measured by VAS/NRS on a 0-10 scale. Based on 2 studies including data from 140 patients	Difference: **MD 0.39 higher** (95% CI: 0.50 lower to 1.28 higher) Favoring placebo		**Low** Due to serious risk of bias and serious imprecision[1]	AWB injections may result in little to no difference on long term pain compared with placebo in patients with plantar fasciopathy. Weeler (2022), Kalaci (2009)
Function (crucial)	Short term (3 months)	Function was measured by FFI-r, on a 0-100 scale with lower scores representing better function Based on 1 study including data from 90 patients	Difference: **MD 1.50 lower** (95% CI: -10.93 lower to 7.93 higher) Favoring AWB		**Low** Due to serious risk of bias and serious imprecision[1]	AWB injections may result in little to no difference on short term function compared with placebo in patients with plantar fasciopathy. Wheeler (2022)
	Long term (6 months)	Function was measured by FFI-r, on a 0-100 scale with lower scores representing better function; Based on 1 study including data from 90 patients.	Difference: **MD 5.90 higher** (95% CI: -3.75 lower to 15.55 higher) Favoring placebo		**Low** Due to serious risk of bias, due to seriousimprecision[1]	AWB injections may result in little to no difference on long term function compared with placebo in patients with plantar fasciopathy. Wheeler (2022)
Adverse events (crucial)		No studies	-		**No GRADE**	No evidence was found regarding the effect of AWB injections on adverse events when compared with placebo in patients with plantar fasciopathy.

Quality of life (important)		No studies	-	**No GRADE**	No evidence was found regarding the effect of AWB injections on quality of life when compared with placebo in patients with plantar fasciopathy.
Return to sport (important)		No studies	-	**No GRADE**	No evidence was found regarding the effect of AWB injections on return to sport when compared with placebo in patients with plantar fasciopathy.

Reasons for downgrading certainty of evidence (levels of downgrading -1 or -2)

1. Risk of Bias: Potential RoB mainly due to lack of detailed information on allocation, blinding and potential loss to follow up (-1 level)
   Imprecision: due to overlap of the 95% CI with the minimal clinically important difference, i.e. boundary of CI includes possibility of benefit or harm (-1 level)
2. Risk of Bias: Potential RoB mainly due to lack of detailed information on allocation, blinding and potential loss to follow up (-1 level)
   Imprecision: results included patients from only one study, limited sample size; not reaching the optimal information size (-1 level)
3. Risk of Bias: Potential RoB. mainly due to lack of detailed information on allocation and blinding (-1 level)
   Inconsistency: large heterogeneity with no overlap in confidence intervals (-1 level)
   Imprecision: due to overlap of the 95% CI with the minimal clinically important difference, i.e. boundary of CI includes possibility of benefit and harm (-2 levels)

Kennisvragen

Tijdens de ontwikkeling van deze module is systematisch naar onderzoeken gezocht die de zoekvraag kunnen beantwoorden. Door gebruik te maken van een systematische literatuuranalyse met beoordeling van de bewijskracht is duidelijk geworden dat er binnen deze module nog kennisvragen bestaan. De werkgroep meent dat (vervolg)onderzoek wenselijk is om in de toekomst een duidelijker antwoord te kunnen geven op vragen uit de praktijk.

Tijdens de ontwikkeling van de module autologe bloedproducten is gebleken dat er binnen deze sub module over ABI geen kennisvragen zijn.

Literatuur

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Oct;55(19):1106-1118. doi: 10.1136/bjsports-2019-101970. Epub 2021 Mar 30. PMID: 33785535; PMCID: PMC8458083.

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Implementatietabel

<table>
<tr><td colspan="4">Aanbeveling 2: Pas autologe bloed injecties niet toe voor patiënten met fasciopathie plantaris.
Bespreek met de patiënt het beperkte bewijs dat ABI niet effectief is en de onbekende risico’s van een autologe bloed injectie.</td></tr>
<tr><td>1. Wat was het onderliggende probleem om deze uitgangsvraag uit te werken?</td><td colspan="3">■ Ongewenste praktijkvariatie

Toelichting:

Het onderliggende probleem is de ongewenste praktijkvariatie in de behandeling van fasciopathie plantaris, waarbij autologe bloedinjecties (ABI) nog steeds worden toegepast ondanks het gebrek aan wetenschappelijk bewijs voor effectiviteit. Dit leidt tot onnodige behandelingen, mogelijke risico’s voor patiënten en ondoelmatige financiële uitgaven voor de patiënt.</td></tr>
<tr><td>2. Maak een inschatting over hoeveel patiënten het ongeveer gaat waar de aanbeveling betrekking op heeft?</td><td colspan="3">■ 5000-40.000</td></tr>
<tr><td>3. Maakt de aanbeveling deel uit van een set van interventies voor hetzelfde probleem?</td><td colspan="3">■ Ja: hoe verhoudt deze aanbeveling zich tot de andere aanbevelingen uit deze module/ richtlijn of uit andere richtlijnen(modules)? Dient hier rekening mee gehouden te worden bij de implementatie of kan dit worden gezien als een losstaande aanbeveling?

Toelichting: het betreft een losstaande aanbeveling. ABI blijkt niet effectief terwijl de alternatieven dat mogelijk wel zijn.</td></tr>
<tr><td>4. Belemmeringen en kansen op verschillende niveaus voor landelijke toepassing van de aanbeveling:</td><td>Voorbeelden</td><td>Wat zijn mogelijke belemmerende factoren?</td><td>Wat zijn mogelijke bevorderende factoren?</td></tr>
<tr><td>a) Richtlijn/ klinisch traject (innovatie)</td><td>Voortschrijding/vooruitgang in de praktijk, haalbaarheid, geloofwaardigheid, toegankelijkheid, aantrekkelijkheid</td><td>ABI is eenvoudig te bereiden

ABI is een lichaamseigen product

Mogelijk bestaande protocollen die ABI nog als optie noemen.

Gewenning aan het gebruik van injectiebehandelingen in de praktijk.</td><td>Een injectiebehandeling wordt geassocieerd met risico’s, waardoor er een zekere terughoudendheid is

Toename van wetenschappelijk bewijs tegen de effectiviteit van ABI</td></tr>
</table>

b) **Zorgverleners (artsen en verpleegkundigen)**	*Bewustzijn, kennis, houding, motivatie om te veranderen, gedragsroutines*	*Ervaring en voorkeur van zorgverleners die ABI als een mogelijke behandeling zien.* *Onvoldoende kennis over de ineffectiviteit van ABI* *Beperkt aanbod van alternatieve evidence-based behandelingen*	*Opleidingen en nascholing die de ineffectiviteit van ABI benadrukken* *Toename van focus op conservatieve behandelingen zonder injectie*
c) **Patiënt/ cliënt (naasten)**	*Kennis, vaardigheden, houding, compliance*	*Patiënten die actief zoeken naar injectiebehandelingen als snelle oplossing* *Geloof dat het lichaamseigen bloed een helende werking heeft. Misvattingen over de effectiviteit van lichaamseigen bloed* *Verwachtingen op basis van anekdotisch bewijs of eerdere ervaringen*	*Terughoudendheid voor injectie behandeling wegens risico's* *Goede voorlichting over de ineffectiviteit en onbekende risico's van ABI* *Vergroting van de bewustwording over veiligere en effectievere behandelingen*
d) **Sociale context**	*Mening van collega's, cultuur van het netwerk, samenwerking, leiderschap*	*Gebruik van ABI door collega's of in andere instellingen kan druk geven om het toch toe te passen* *Associatie van ABI met PRP kan het moeilijk maken om zorgverleners te overtuigen van de verschillen*	*Leiderschap binnen vakgroepen die het belang van evidence-based practice benadrukken* *Bespreking in multidisciplinaire overleggen om richtlijnconform te handelen*
e) **Organisatorische context**	*Organisatie van zorgprocessen, personeel, capaciteiten, middelen, structuren*	*Huidige infrastructuur en routine waarin ABI eenvoudig kan worden toegepast*	*Betere implementatie van de aanbeveling doordat er geen extra materialen voor bloedafname en injectie nodig zijn*

		Mogelijke weerstand binnen instellingen als ABI een gevestigde behandeling is	*Opname van de richtlijn in zorgprotocollen van ziekenhuizen en klinieken*
f) **Economische en politieke context**	*Financiële regelingen, regelgeving, beleid (vergoede zorg, betaaltitel)*	*Mogelijke financiële prikkels voor zorgverleners om ABI aan te blijven bieden* *Geen extra kosten voor dure apparatuur en materialen zoals PRP-kits* *Patiënten die bereid zijn om zelfstandig de kosten te dragen*	*Beleidsmatige besluiten om ABI niet als verzekerde zorg te vergoeden*

5. Welke personen/partijen zijn van belang bij het toepassen van de aanbeveling in de praktijk?	■ Patiënt/ cliënt (naaste) ■ Professional ■ Beroepsvereniging
6. Wat zouden deze personen/ partijen moeten veranderen in hun gedrag of organisatie om de aanbeveling toe te passen?	*Om de aanbeveling succesvol te implementeren, moeten verschillende personen en partijen hun gedrag of organisatie aanpassen. Hieronder volgen de belangrijkste veranderingen per groep:* *a) Zorgverleners (artsen en verpleegkundigen)* • *Stoppen met aanbieden van ABI als behandelingsoptie voor fasciopathie plantaris.* • *Bij- en nascholing volgen over de nieuwste richtlijnen en het gebrek aan effectiviteit van ABI.* • *Actief informeren en overtuigen van collega's die nog vasthouden aan ABI als behandeling.* • *Patiënten goed voorlichten over de ineffectiviteit en de onbekende risico's van ABI.* • *Alternatieve behandelingen aanbieden en patiënten daarin begeleiden.* *b) Patiënten en hun naasten* • *Geen ABI verwachten of eisen bij fasciopathie plantaris.* • *Openstaan voor evidence-based behandelopties die volgens de richtlijn worden geadviseerd.* • *Kritischer kijken naar niet-wetenschappelijk onderbouwde behandelingen en niet afgaan op anekdotisch bewijs of online informatie zonder wetenschappelijke basis.* *c) Wetenschappelijke en professionele verenigingen (zoals de VSG)* • *Actief uitdragen van de richtlijn en de bijbehorende wetenschappelijke onderbouwing.* • *Organiseren van symposia, webinars en publicaties om zorgverleners bewust te maken van de nieuwe aanbeveling.* • *Monitoren en evalueren van de implementatie om te kijken of ABI daadwerkelijk minder wordt toegepast.*
7. Binnen welk tijdsbestek moet de aanbeveling zijn geïmplementeerd?	■ < 2 jaar
8. Conclusie: is er extra aandacht nodig voor implementatie van de aanbeveling (anders dan publicatie van deze richtlijnmodule)?	■ **Ja*** **Toelichting:**

	De implementatie kan worden bevorderd door nascholing en training voor zorgverleners, zodat zij goed geïnformeerd zijn over de ineffectiviteit en risico's van ABI. Aanpassing van richtlijnen en protocollen binnen ziekenhuizen en beroepsverenigingen helpt om de aanbeveling breed te verankeren. Patiëntenvoorlichting via folders, websites en consultgesprekken zorgt ervoor dat patiënten realistische verwachtingen hebben over behandelingen.

**Deze aanbeveling komt in aanmerking voor plaatsing op de Implementatie Agenda van het programma Zorg Evaluatie & Gepast Gebruik (ZE&GG). In het programma ZE&GG werken patiënten, zorgverleners, zorgaanbieders, zorgverzekeraars en overheid samen aan de bewezen beste zorg voor de patiënt. Daarmee is ZE&GG een programma van alle betrokken partijen in de Medisch Specialistische Zorg. FMS is één van deze betrokken partijen.*

De implementatieagenda van ZE&GG bevat onderwerpen over wat de bewezen beste zorg is en die in de dagelijkse zorgpraktijk geïmplementeerd zouden moeten worden. Zorgverzekeraars Nederland (ZN) en de Nederlandse Vereniging voor Ziekenhuizen (NVZ) hebben landelijke afspraken gemaakt over de implementatie van de onderwerpen van de implementatieagenda. Deze afspraken zijn onderdeel van de zorginkoopafspraken tussen zorgverzekeraars en zorgaanbieders.

Vanuit FMS worden sterke, goed onderbouwde aanbevelingen, getoetst op de behoefte aan een implementatie impuls aangedragen. Voor de beoordeling van onderwerpen uit richtlijnen wordt gekeken naar bovenstaande tabel voor een inschatting van de implementatie impuls. Met de ingevulde implementatietabel kunnen we vanuit FMS de andere HLA-MSZ partijen goed informeren om zo samen te beslissen of de aanbeveling daadwerkelijk op de implementatie agenda zal worden geplaatst.

Risk of bias table for intervention studies (randomized controlled trials; based on Cochrane risk of bias tool and suggestions by the CLARITY Group at McMaster University)

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?**	**Was the allocation adequately concealed?**	**Blinding: Was knowledge of the allocated interventions adequately prevented? |Were patients blinded? | Were healthcare providers blinded? | Were data collectors blinded? | Were outcome assessors blinded? | Were data analysts blinded?**	**Was loss to follow-up (missing outcome data) infrequent?**	**Are reports of the study free of selective outcome reporting?**	**Was the study apparently free of other problems that could put it at a risk of bias?**	**Overall risk of bias If applicable/necessary, per outcome measure** **LOW/Some concerns/ HIGH**
Digra (2023)	Probably no Reason: No details given, just stated: "patients were divided into three groups by simple randomization"	Probably no Reason: no information provided on concealment of allocation	Probably no Reason: no description of blinding of patients, healthcare providers, data collectors/assessors/analysts	Probably no Seems no loss to follow up (short period) but no desription of any loss to follow up given	Probably yes Reason: All outcomes reported, though not clearly pre specified in methodology so difficult to assess	Probably no: Reason: potential bias due to lack of detailed information on chosen methodology to	HIGH (all outcome measures) Reason: Unclear allocation and blinding procedure, missing info on loss to follow up, selective

						assess the completeness of reporting, but no baseline characteristics reported for main outcome or reporting of adverse events.	reporting or completeness
Wheeler (2022)	Probably yes; Reason: Allocation and randomization by study nurse practitioner independent from the rest of the study	Definitely yes Reason: allocation with sealed envelopes	Probably yes: Reason: blinding of participants, data collectors and outcome assessors but administering clinician and study nurse practitioner not blinded though the administering clinician had no further participant contact	Probably yes: Reason: Loss to follow up (6m) 1 patient and a small (max n=5) number of interim apppointments missed but no other reasons for loss to follow up	Probably yes: Reason: All predefined outcomes have been reported (partly in supplementary material)	Probably yes: Reason: seems no other risks of biases, but detailed information for its assessment is lacking and sample size is small for the assessment of several outcomes	Some concerns (for all outcome measures) Reason: Blinding not complete, No detailed / missing information on performance of home exercise program in both groups
Kalaci (2009)	Probably no: Reason: No allocation sequence predefined, based on order of presentation	Probably no: Reason: no description of allocation	Probably no Reasos: patients were blinded, and reviewers were blinded, other groups not blinded.	Probably yes Reason: no loss to follow up but 2 additional groups (saline & peppering and AB & peppering) were excluded based due to to much pain caused by the procedure	Probably no Reason all outcomes reported though not clearly pre specified in methodology so difficult to assess	Probably no; Reason: study reports all important features yet lacks a clear well predefined methodology section so difficult to assess (f.e. in abstract a multicenter approach is	High (all outcome measures) Reason: Blinding not complete, unclear allocation, methodology briefly described, seems not based on well pre-defined choices.

						stated but in article no mentioning of any centers at all) or stop of procedure for 2 additional groups due to pain when was decided to stop procedures and exclude patients	
Kiter (2022)	Probably yes; Reason: Allocation by drawing lots, but no further specification given	Probably no; No description of allocation concealment	Probably no: Reason: no data on blinding of patients/ healthcare providers/ data collectors/ analysts/ outcome assessors/	Probably yes: Reason: 1 patient was lost to follow up but no further data or reasons provided.	Probably yes; Reason: all outcomes have been reported but no detailed description of these outcomes in methods	Probably no: Reason: the number of injections differed largely, without further specification on reasons or potential impact on outcomes	High (all outcome measures) Reason; allocation, blinding, loss to fu all poorly described and a different number of injections per patient/ group

Table of excluded studies

Reference	Reason for exclusion
Johnson-Lynn S, Cooney A, Ferguson D, Bunn D, Gray W, Coorsh J, Kakwani R, Townshend D. A Feasibility Study Comparing Platelet-Rich Plasma Injection With Saline for the Treatment of Plantar Fasciitis Using a Prospective, Randomized Trial Design. Foot Ankle Spec. 2019 Apr;12(2):153-158. doi: 10.1177/1938640018776065. Epub 2018 May 21. PMID: 29779399.	No data presented to provide effect estimates
Shetty SH, Dhond A, Arora M, Deore S. Platelet-Rich Plasma Has Better Long-Term Results Than Corticosteroids or Placebo for Chronic Plantar Fasciitis: Randomized Control Trial. J Foot Ankle Surg. 2019 Jan;58(1):42-46. doi: 10.1053/j.jfas.2018.07.006. Epub 2018 Nov 15. PMID: 30448183.	No data presented to provide effect estimates
de Vos RJ, van Veldhoven PL, Moen MH, Weir A, Tol JL, Maffulli N. Autologous growth factor injections in chronic tendinopathy: a systematic review. Br Med Bull. 2010;95:63-77. doi: 10.1093/bmb/ldq006. Epub 2010 Mar 2. PMID: 20197290.	Wrong population (FP and others) and wrong control group (no placebo with/without exercise therapy)
Karimzadeh A, Raeissadat SA, Erfani Fam S, Sedighipour L, Babaei-Ghazani A. Autologous whole blood versus corticosteroid local injection in treatment of plantar fasciitis: A randomized, controlled multicenter clinical trial. Clin Rheumatol. 2017 Mar;36(3):661-669. doi: 10.1007/s10067-016-3484-6. Epub 2016 Dec 12. PMID: 27957618.	Wrong control group (no placebo with/without exercise therapy)
Chew KT, Leong D, Lin CY, Lim KK, Tan B. Comparison of autologous conditioned plasma injection, extracorporeal shockwave therapy, and conventional treatment for plantar fasciitis: a randomized trial. PM R. 2013 Dec;5(12):1035-43. doi: 10.1016/j.pmrj.2013.08.590. Epub 2013 Aug 22. PMID: 23973504.	Wrong control group (no placebo with/without exercise therapy)
Gao R, Sun J, Zhang L, Chen S, Dong W, Yu H, Han B, Tan M, Li X. Comparative Effectiveness of Minimally Invasive Nonsurgical Treatments for Plantar Fasciitis: A Network Meta-analysis of 30 Randomized Controlled Trials. Pain Physician. 2021 Nov;24(7):E955-E971. PMID: 34704707.	Wrong comparison (no direct comparison PRP with placebo with/without exercise therapy)
Li H, Lv H, Lin T. Comparison of efficacy of eight treatments for plantar fasciitis: A network meta-analysis. J Cell Physiol. 2018 Jan;234(1):860-870. doi: 10.1002/jcp.26907. Epub 2018 Aug 4. PMID: 30078188.	Wrong control group (no placebo with/without exercise therapy, 1 RCT already included)
Guimarães JS, Arcanjo FL, Leporace G, Metsavaht LF, Conceição CS, Moreno MVMG, Vieira TEM, Moraes CC, Gomes Neto M. Effects of therapeutic interventions on pain due to plantar fasciitis: A systematic review and meta-analysis. Clin Rehabil. 2023 Jun;37(6):727-746. doi: 10.1177/02692155221143865. Epub 2022 Dec 26. PMID: 36571559.	Wrong comparison (no direct comparison PRP with placebo with/without exercise therapy)
Franchini M, Cruciani M, Mengoli C, Marano G, Pupella S, Veropalumbo E, Masiello F, Pati I, Vaglio S, Liumbruno GM. Efficacy of platelet-rich plasma as conservative treatment in orthopaedics: a systematic review and meta-analysis. Blood Transfus. 2018 Nov;16(6):502-513. doi: 10.2450/2018.0111-18. Epub 2018 Sep 3. PMID: 30201082; PMCID: PMC6214820.	Wrong population (FP and others) and wrong control group (no placebo with/without exercise therapy)
Assad S, Ahmad A, Kiani I, Ghani U, Wadhera V, Tom TN. Novel and Conservative Approaches Towards Effective Management of Plantar Fasciitis. Cureus. 2016 Dec 5;8(12):e913. doi: 10.7759/cureus.913. PMID: 28083457; PMCID: PMC5215813.	Wrong control group (no placebo with/without exercise therapy, 1 RCT already included)
Yu T, Xia J, Li B, Zhou H, Yang Y, Yu G. Outcomes of platelet-rich plasma for plantar fasciopathy: a best-evidence synthesis. J Orthop Surg Res. 2020 Sep 21;15(1):432. doi: 10.1186/s13018-020-01783-7. PMID: 32958046; PMCID: PMC7504858.	Wrong control group (no placebo with/without exercise therapy, 1 RCT already included)
Herber A, Covarrubias O, Daher M, Tung WS, Gianakos AL. Platelet rich plasma therapy versus other modalities for treatment of plantar fasciitis: A systematic review and meta-analysis. Foot Ankle Surg. 2024 Jun;30(4):285-293. doi: 10.1016/j.fas.2024.02.004. Epub 2024 Feb 15. PMID: 38395675.	Wrong control group (no placebo with/without exercise therapy, 1 RCT already included)

Masiello F, Pati I, Veropalumbo E, Pupella S, Cruciani M, De Angelis V. Ultrasound-guided injection of platelet-rich plasma for tendinopathies: a systematic review and meta-analysis. Blood Transfus. 2023 Mar;21(2):119-136. doi: 10.2450/2022.0087-22. Epub 2022 Oct 17. PMID: 36346880; PMCID: PMC10072988.	Wrong population (FP and others) and wrong control group (no placebo with/without exercise therapy)

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Fasciopathie Plantaris - UV8 Autologe factoren	
Uitgangsvraag/modules: Wat is de plaats van autologe bloedproducten bij de behandeling van patiënten met fasciopathie plantaris?	
Database(s): Embase.com, Ovid/Medline	Datum: 28-3-2024
Periode: vanaf 2000	Talen: geen restrictie
Literatuurspecialist: Esther van der Bijl	Rayyan review: https://rayyan.ai/reviews/980355
BMI-zoekblokken: voor verschillende opdrachten wordt (deels) gebruik gemaakt van de zoekblokken van BMI-Online https://blocks.bmi-online.nl/ Bij gebruikmaking van een volledig zoekblok zal naar de betreffende link op de website worden verwezen.	
Toelichting: Voor deze vraag is gezocht op de elementen fasciopathie plantaris EN autologe bloedproducten. → De sleutelartikelen worden gevonden met deze search. • Platelet-Rich Plasma Has Better Long-Term Results Than Corticosteroids or Placebo for Chronic Plantar Fasciitis: Randomized Control Trial. Shetty SH, Dhond A, Arora M, Deore S. J Foot Ankle Surg. 2019 Jan;58(1):42-46. • Autologous Blood Injection With Dry-Needling vs Dry-Needling Alone Treatment for Chronic Plantar Fasciitis: A Randomized Controlled Trial. Wheeler PC, Dudson C, Gregory KM, Singh H, Boyd KT. Foot Ankle Int. 2022 May;43(5):646-657.	
Te gebruiken voor richtlijntekst: In de databases Embase.com en Ovid/Medline is op 28 maart 2024 systematisch gezocht naar systematische reviews en RCTs over de plaats van autologe bloedproducten bij de behandeling van patiënten met fasciopathie plantaris. De literatuurzoekactie leverde 155 unieke treffers op.	

5 ***Zoekopbrengst 28-3-2024***

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	58	43	62
RCT	86	48	93
~~Observationeel~~			
Totaal	144	91	**155***

****in Rayyan***

Zoekstrategie Embase.com 28-3-2024

No.	Query	Results
#1	'plantar fasciitis'/exp OR 'plantar fasciopathy'/exp OR 'heel spur'/exp OR 'policeman heel'/exp OR (((calcane* OR heel* OR subcalcane*) NEAR/3 (spur* OR exostos* OR pain* OR policeman* OR jogger*)):ti,ab,kw) OR ((plant* NEAR/3 (fasciitis OR fasciopath* OR fascios* OR inflam*)):ti,ab,kw) OR (((baxter* OR plant* OR calcane* OR heel) NEAR/3 neuropath*):ti,ab,kw) OR calcaneodyn*:ti,ab,kw OR 'calcane* periostitis':ti,ab,kw	6372
#2	'thrombocyte rich plasma'/exp OR 'platelet-rich plasma cell'/exp OR 'blood autotransfusion'/exp OR (((blood OR plasma) NEAR/3 (autotransfusion* OR autologous	47371

	OR 'platelet rich*' OR 'thrombocyte rich*')):ti,ab,kw) OR ((prp NEAR/3 inject*):ti,ab,kw) OR 'autoh*emotransfusion':ti,ab,kw	
#3	#1 AND #2	292
#4	#3 AND [2000-2024]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	249
#5	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	1014761
#6	'clinical trial'/exp OR 'randomization'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR 'placebo'/exp OR 'prospective study'/exp OR rct:ab,ti OR random*:ab,ti OR 'single blind':ab,ti OR 'randomised controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti	4001894
#7	#4 AND #5 **– SR's**	58
#8	#4 AND #6 NOT #7 **– RCT's**	86
#9	#7 OR #8	144

Zoekstrategie Ovid/Medline 28-3-2024

#	Searches	Results
1	exp Fasciitis, Plantar/ or exp Heel Spur/ or ((calcane* or heel* or subcalcane*) adj3 (spur* or exostos* or pain* or policeman* or jogger*)).ti,ab,kf. or (plant* adj3 (fasciitis or fasciopath* or fascios* or inflam*)).ti,ab,kf. or ((baxter* or plant* or calcane* or heel) adj3 neuropath*).ti,ab,kf. or calcaneodyn*.ti,ab,kf. or calcane* periostitis.ti,ab,kf.	4416
2	exp Platelet-Rich Plasma/ or exp Blood Transfusion, Autologous/ or ((blood or plasma) adj3 (autotransfusion* or autologous or 'platelet rich*' or 'thrombocyte rich*')).ti,ab,kf. or (prp adj3 inject*).ti,ab,kf. or 'autoh*emotransfusion'.ti,ab,kf.	32277
3	1 and 2	155
4	limit 3 to yr="2000 -Current"	155
5	4 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	144
6	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	735289

7	exp clinical trial/ or randomized controlled trial/ or exp clinical trials as topic/ or randomized controlled trials as topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial or multicenter study or clinical trial).pt. or random*.ti,ab. or (clinic* adj trial*).tw. or ((singl* or doubl* or treb* or tripl*) adj (blind$3 or mask$3)).tw. or Placebos/ or placebo*.tw.	2706138
8	5 and 6 **– SR's**	43
9	(5 and 7) not 8 **– RCT's**	48
10	8 or 9	91

Module 9 Chirurgische interventie

Search and select

A systematic review of the literature was performed to answer the following question(s):

What is de efficacy of surgical gastrocnemius lengthening or recession in individuals with plantar fasciopathy compared to non-surgical treatment, no treatment or placebo?

Table 1. PICO

Patients	Individuals with plantar fasciopathy with a shortened gastrocnemius complex
Intervention	Surgical treatment: gastrocnemius lengthening and gastrocnemius recession
Control	1. Non-surgical interventions (stretching, corticosteroid injections, platelet-rich plasma injections) 2. Wait and see 3. Placebo
Outcomes	Pain, function, participation, adverse events
Other selection criteria	Study design: systematic reviews and randomized controlled trials Minimal number of participants: 20 per arm

Relevant outcome measures

The guideline panel considered pain and function as **crucial** outcome measures for decision making, and participation and adverse events as **important** outcome measures for decision making.

A priori, the guideline panel did not define the outcome measures listed above but used the definitions used in the studies.

The working group defined a 10% difference for both continuous outcome measures and dichotomous outcome measures informing on relative risk (RR ≤ 0.91 and ≥ 1.1) as clinically relevant differences.

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until May 23rd, 2024. The detailed search strategy is listed under the tab 'Literature search strategy'. The systematic literature search resulted in 54 hits. Studies were selected based on the following criteria

- Systematic reviews (searched in two databases, detailed search strategy with search date, clear description of in- and exclusion criteria, table with excluded studies, evidence table for included studies, risk of bias assessment performed) or randomized controlled trials (RCT);
- Full-text English language publication;
- Studies according to the PICO.

Initially, seven studies were selected based on title and abstract screening. After reading the full text, five studies were excluded (see the exclusion table under the tab 'Evidence tabellen'), and two studies were included.

Summary of literature

Description of studies

Two studies, describing one trial were included in the analysis of the literature. Important study characteristics and results are summarized in table 2. The assessment of the risk of bias is summarized in the risk of bias tables (under the tab 'Evidence tabellen').

Molund (2018) compared the results of proximal medial gastrocnemius recession and stretching with stretching alone for heel pain lasting more than 1 year in a randomized controlled trial. They included 40 individuals (20 per arm) aged 18 to 70 with plantar fasciitis for more than one year and unresponsive to conservative treatment. They described the results up to one year follow-up.

In a second article, the results of the six-year follow-up of this trial were reported (Riiser, 2024). This article describes three groups, the group initially assigned to the surgery (n=20), the crossover group to surgery (n=7) and the group that never underwent surgery (n=13). For the sake of this module, we compare the operative treatment group with the group that never underwent surgery. At six years, 5 out of 20 participants in the surgery group were lost to follow-up and 1 out of 13 in the control group.

Table 2. Characteristics of included studies

Study	Participants	Comparison	Follow-up	Outcome measures	Comments	Risk of bias (per outcome measure)*
Individual studies						
Molund, 2018 Riiser, 2024 *Norway*	N at baseline I: 20 | C: 20 Age (median [range]) I: 46 [29 to 68] C: 45 [22 to 63] Sex (%female) I: 75 | C: 80 Symptoms (months, median [range] I: 31 [12 to 252] C: 33 [12 to 396] VAS (median [range]) I: 7.6 [3.9 to 10] C: 7.1 [1.5 to 9.5]	I: proximal medial gastrocnemius recession and stretching as in C. C: stretching of the plantar fascia, triceps surae, and hamstrings. Twice a day for at least 60 sec per muscle group	1 year 6 year	Pain (VAS) Function (SF-36 (physical function domain and Manchester Oxford foot questionnaire) AOFAS ankle hindfoot scale	At 6 years, 5 out of 20 participants in the surgery group were lost to follow up and 1 out of 13 in the control group.	Some concerns

Abbreviations: I – intervention; C – control; SF-36 - 36-Item Short Form Health Survey; VAS – Visual Analogue Scale

*For further details, see risk of bias table in the appendix

Results

Results for the 6 year follow-up were presented by Riiser (2024) as intention to treat (20 per arm), per protocol (27 in the operative group and 13 in the nonoperative group) and per protocol excluding crossovers (20 in the operative group and 13 in the nonoperative group). In this paragraph we report the values per protocol excluding crossovers since the goal is to describe differences between the two original groups, and this does not include individuals receiving operative treatment at a later timepoint.

1. Pain (crucial)

Molund (2018) reported on pain with the visual analog score (VAS) asking patients to describe “the worst pain you have experienced in your foot within the last 24 hours.” The scale ranges from 0 to 10 points, where 0 represents no pain and 10 the worst imaginable pain. They reported a lower (i.e. better) VAS score in the group that underwent surgery (median [range]: 2.8 [0 to 8.1]) compared to the nonoperative group (median [range]: 7.4 [0.2 to 9.3]). This difference is clinically relevant.

At 6 years, reported pain is still lower in the group that underwent surgery (marginal mean (95%CI): 2.5 (1.4 to 3.6) compared to the nonoperative group (marginal mean (95%CI): 5.5 (4.3 to 6.7). This difference is also clinically relevant.

2. Function (crucial)

Molund (2018) report on the SF-36 physical function domain. This scale ranges from 0 to 100 with 100 representing best physical function. At 1 year follow-up, physical function was higher in the group that underwent surgery (median [range]: 90 [55 to 100]) compared to the nonoperative group (median [range]: 63 [15 to 100]). This difference is clinically relevant.

At 6 years, the SF-36 is not reported. However, function was reported by the Manchester Oxford foot questionnaire - walking/standing domain. This scale ranges from 0 to 100 with 0 being the best possible score. Walking standing domain was lower (i.e. better) in the group that underwent surgery (mean (sd): 24.4 (7.0)) compared to the nonoperative group (mean (sd): 45.9 (7.8)). This difference is clinically relevant. No baseline values for this measure were reported.

3. Participation (important)

No studies reported on the effect of surgical treatment on participation in patients with plantar fasciitis.

4. Complications (important)

Molund (2018) reported no major complications from the surgery. Minor complications were prolonged swelling or pain at the operative site (n=3), which did not resolve in 1 year in one person and increased cramping in the calf (n=1). At 6 years, no new complications were reported.

Summary of Findings

Population: Individuals with plantar fasciitis >1 year , Intervention: Surgical treatment and stretching , Comparator: Stretching alone

Outcome	Study results and measurements	Absolute effect estimates Stretching alone Surgical treatment and stretching	Certainty of the evidence (Quality of evidence)	Summary
Pain (crucial)	Measured by: VAS Scale: 0 - 10 Lower better Based on data from 40 participants in 1 study Follow up 1 year	Molund (2018) reported a median [range]: 7.4 [0.2 to 9.3]) in the nonoperative group and a median [range]: 2.8 [0 to 8.1]) for the group that underwent surgery.	**Low** Due to serious risk of bias, Due to serious imprecision[1]	Operative treatment may improve pain in individuals with chronic plantar fasciitis to no operative treatment for heel pain lasting more than 1 year. *(Molund, 2018; Riiser, 2024)*
	Measured by: VAS Scale: 0 - 10 Lower better Based on data from 33 participants in 1 study Follow up 6 years	Riiser (2024) reported a mean difference of 3.0 lower (95%CI: 4.17 to 1.83 lower) for the group that underwent surgery compared to the nonoperative group.		
Function (crucial)	Measured by: SF-36 physical function domain Scale: 0 - 100 High better. Based on data from 40 participants in 1 study Follow up 1 year	Molund (2018) reported a median [range]: 90 [55 to 100]) in the nonoperative group and a median [range]: 63 [15 to 100]) for the group that underwent surgery.	**Low** Due to serious risk of bias, Due to serious imprecision[1]	Operative treatment may improve function in individuals with chronic plantar fasciitis when compared to no operative treatment for heel pain lasting more than 1 year *(Molund, 2018; Riiser, 2024)*
	Measured by: the Manchester Oxford foot questionnaire - walking/standing domain. Scale: 0 to 100, lower better. Based on data from 33 participants in 1 study Follow up 6 years	Riiser (2024) reported a mean difference of 28.20 lower (95%CI: 33.90 to 22.50 lower) for the group that underwent surgery compared to the nonoperative group.		
Participation (important)	-	-	**No grade**	No evidence was found regarding the effect of operative treatment when compared to no operative treatment on participation in individuals with chronic plantar fasciitis.
Complications (Important)	Follow-up 6 years	Molund (2018) reported no major complications and four minor complications in the group that underwent surgery. No complications were reported in the nonoperative group.	**Very low** Due to serious risk of bias, Due to very serious imprecision[2]	We are uncertain whether operative treatment may lead to more or less complications in individuals with chronic plantar fasciitis when compared to no operative treatment for heel pain lasting more than 1 year *(Molund, 2018; Riiser, 2024)*

1. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Imprecision: serious.** Low number of patients, data from one trial (described in two articles);
2. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Imprecision: very serious.** Only data from one study, Low number of patients, no major complications occurred, confidence interval crosses both boundaries of clinical relevance for minor complications;

Kennisvragen

What is de efficacy of surgical gastrocnemius lengthening or recession in individuals with plantar fasciopathy compared to non-surgical treatment, no treatment or placebo?

Patients	Individuals with plantar fasciopathy with a shortened gastrocnemius complex
Intervention	Surgical treatment: gastrocnemius lengthening and gastrocnemius recession
Control	1. Non-surgical interventions (stretching, corticosteroid injections, platelet-rich plasma injections) 2. Wait and see 3. Placebo
Outcomes	Pain, function, participation, adverse events

5

Implementatietabel

Aanbeveling 1 en 3	**1. Verricht in het eerste jaar adequate conservatieve behandeling.** **3. Bespreek samen met de patiënt de relatieve effectiviteit van operatief ingrijpen ten opzichte van andere (adequate) conservatieve behandelingen en de potentiële complicaties/mogelijke restklachten van een operatieve ingreep.**		
1. Wat was het onderliggende probleem om deze uitgangsvraag uit te werken?	□ **Ongewenste praktijkvariatie** **Toelichting:** Veel patiënten komen bij de orthopedisch chirurg terwijl ze op dat moment niet voor tenminste een jaar lang adequaat conservatief behandeld zijn. De werkgroep is van mening dat een jaar lang adequaat behandelen de standaard moet zijn, evenals het bespreken van de relatieve effecten van operatief ingrijpen ten opzichte van andere conservatieve behandelingen.		
2. Maak een inschatting over hoeveel patiënten het ongeveer gaat waar de aanbeveling betrekking op heeft?	□ **5000-40.000**		
3. Maakt de aanbeveling deel uit van een set van interventies voor hetzelfde probleem?	**Er zijn meerdere aanbevelingen binnen deze module geformuleerd. De eerste en derde aanbeveling zijn beiden sterk geformuleerd.**		
4. Belemmeringen en kansen op verschillende niveaus voor landelijke toepassing van de aanbeveling:	***Voorbeelden***	**Wat zijn mogelijke belemmerende factoren?**	**Wat zijn mogelijke bevorderende factoren?**
a) **Richtlijn/ klinisch traject (innovatie)**	*Voortschrijding/vooruitgang in de praktijk, haalbaarheid, geloofwaardigheid, toegankelijkheid, aantrekkelijkheid*	Het kan lastig zijn om een patiënt te overtuigen van effect 1 jaar conservatieve therapie bij in beginne al wens tot ingreep.	Patiënteducatie, meenemen in literatuur en achtergrond succesvolle studies
b) **Zorgverleners (artsen en verpleegkundigen)**	*Bewustzijn, kennis, houding, motivatie om te veranderen, gedragsroutines*	Achtergrondkennis van aandoening en behandelmogelijkheden	Goed uitvoeren van diagnostiek, waarvan de Silversköld test een essentiële is.
c) **Patiënt/ cliënt (naasten)**	*Kennis, vaardigheden, houding, compliance*	Compliance van het trainingsschema, tijdsinvestering	therapie trouwheid, dagboek bijhouden

d) **Sociale context**	*Mening van collega's, cultuur van het netwerk, samenwerking, leiderschap*	Zorgverleners die te snel naar elkaar verwijzen	Adequaat de stappen en conservatieve therapie doorlopen
e) **Organisatorische context**	*Organisatie van zorgprocessen, personeel, capaciteiten, middelen, structuren*	Nog onduidelijk zorgpad	Indelen zorgpad Fasciopathie Plantaris met stapsgewijze behandelingen
f) **Economische en politieke context**	*Financiële regelingen, regelgeving, beleid (vergoede zorg, betaaltitel)*	Zorgkosten langdurige fysiotherapie, werkverzuim door klachten	Adequate begeleiding en patiënt educatie
5. Welke personen/partijen zijn van belang bij het toepassen van de aanbeveling in de praktijk?		x Patiënt/ cliënt (naaste) x Professional	
6. Wat zouden deze personen/ partijen moeten veranderen in hun gedrag of organisatie om de aanbeveling toe te passen?		Achtergrondkennis van aandoening en behandelingen. Met name het conservatieve traject	
7. Binnen welk tijdsbestek moet de aanbeveling zijn geïmplementeerd?		□ < 2 jaar	
Conclusie: is er extra aandacht nodig voor implementatie van de aanbeveling (anders dan publicatie van deze richtlijnmodule)?		□ **Nee**	

**Deze aanbeveling komt in aanmerking voor plaatsing op de Implementatie Agenda van het programma Zorg Evaluatie & Gepast Gebruik (ZE&GG). In het programma ZE&GG werken patiënten, zorgverleners, zorgaanbieders, zorgverzekeraars en overheid samen aan de bewezen beste zorg voor de patiënt. Daarmee is ZE&GG een programma van alle betrokken partijen in de Medisch Specialistische Zorg. FMS is één van deze betrokken partijen.*

De implementatieagenda van ZE&GG bevat onderwerpen over wat de bewezen beste zorg is en die in de dagelijkse zorgpraktijk geïmplementeerd zouden moeten worden. Zorgverzekeraars Nederland (ZN) en de Nederlandse Vereniging voor Ziekenhuizen (NVZ) hebben landelijke afspraken gemaakt over de implementatie van de onderwerpen van de implementatieagenda. Deze afspraken zijn onderdeel van de zorginkoopafspraken tussen zorgverzekeraars en zorgaanbieders.

Vanuit FMS worden sterke, goed onderbouwde aanbevelingen, getoetst op de behoefte aan een implementatie impuls aangedragen. Voor de beoordeling van onderwerpen uit richtlijnen wordt gekeken naar bovenstaande tabel voor een inschatting van de implementatie impuls. Met de ingevulde implementatietabel kunnen we vanuit FMS de andere HLA-MSZ partijen goed informeren om zo samen te beslissen of de aanbeveling daadwerkelijk op de implementatie agenda zal worden geplaatst.

Implementatietabel

Aanbeveling 2: Overweeg een operatieve ingreep alleen bij patiënten met een verkort gastrocnemius complex volgens de Silverskjöld test die niet herstellen na minimaal 1 jaar adequate conservatieve behandeling.	Op basis van de beschikbare evidentie en ervaring uit de praktijk kon er onvoldoende richting aan de besluitvorming worden gegeven. Om die reden is er geen beschrijving van belemmeringen en kansen voor implementatie van de aanbeveling toegevoegd. Disseminatie van de kennis in deze module verloopt via de standaard route. De module wordt gepubliceerd op de Richtlijnendatabase.

Risk of bias table for intervention studies (randomized controlled trials; based on Cochrane risk of bias tool and suggestions by the CLARITY Group at McMaster University)

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?**	**Was the allocation adequately concealed?**	**Blinding: Was knowledge of the allocated interventions adequately prevented? Were patients/healthcare providers/data collectors/outcome assessors/data analysts blinded?**	**Was loss to follow-up (missing outcome data) infrequent?**	**Are reports of the study free of selective outcome reporting?**	**Was the study apparently free of other problems that could put it at a risk of bias?**	**Overall risk of bias** **If applicable/necessary, per outcome measure** **LOW** **Some concerns** **HIGH**
Molund, 2018 and Riiser 2024	No information	Probably yes Reason: Sealed envelopes were drawn (unclear by who).	Definitely no Reason: open label trial, patients and surgeons were not blinded.	Probably yes Reason: For the one-year follow-up no data was missing. At 6 years loss-to follow-up is comparable between groups.	Probably yes Reason: All relevant outcome measures were reported.	Probably no Reason: no baseline values were reported for the Manchester Oxford foot questionnaire. Many outcome measures are reported compared to group size.	Some concerns (pain, function at 1 y, complications) Reason: self-reported measures in an open-label trial, HIGH (Function at 6 y) Reason: self-reported measures in an open-label trial and missing baseline values.

5

Table of excluded studies

Reference	Reason for exclusion
Arshad Z, Aslam A, Razzaq MA, Bhatia M. Gastrocnemius Release in the Management of Chronic Plantar Fasciitis: A Systematic Review. Foot Ankle Int. 2022 Apr;43(4):568-575. doi: 10.1177/10711007211052290. Epub 2021 Nov 12. PMID: 34766860; PMCID: PMC8996295.	Systematic review that only includes one relevant RCT, this RCT is described separately.
Bandyopadhyay A, Kumar S, Mandal P. Isolated Gastrocnemius Contraction and Gastroc Recession Surgery in Case of Planter Fasciitis: A Systemic Review and Meta-Analysis. Indian J Orthop. 2023 Aug 4;57(9):1359-1375. doi: 10.1007/s43465-023-00939-x. PMID: 37609028; PMCID: PMC10441881.	Systematic review that only includes one relevant RCT, this RCT is described separately.
Chimera NJ, Castro M, Manal K. Function and strength following gastrocnemius recession for isolated gastrocnemius contracture. Foot Ankle Int. 2010 May;31(5):377-84. doi: 10.3113/FAI.2010.0377. PMID: 20460063.	Wrong design: pre-post study.
Escalada Barrado J, Saiz Modol C, Llombart Blanco R. Medial gastrocnemius proximal fasciotomy in patients with chronic plantar fasciitis: A systematic review. Rev Esp Cir Ortop Traumatol. 2023 Sep 18:S1888-4415(23)00191-1. English, Spanish. doi: 10.1016/j.recot.2023.08.017. Epub ahead of print. PMID: 37730117.	Systematic review that only includes one relevant RCT, this RCT is described separately.
Pickin CC, Elmajee M, Aljawadi A, Fathalla I, Pillai A. Gastrocnemius Recession in Recalcitrant Plantar Fasciitis: A Systematic Review. J Foot Ankle Surg. 2022 Mar-Apr;61(2):396-400. doi: 10.1053/j.jfas.2021.10.029. Epub 2021 Nov 1. PMID: 34838458.	Systematic review that only includes one relevant RCT, this RCT is described separately.

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Fasciopathie Plantaris - UV9 Operatieve ingreep	
Uitgangsvraag/modules: Wat is de plaats van een operatieve ingreep bij de behandeling bij patiënten met fasciopathie plantaris?	
Database(s): Embase.com, Ovid/Medline	Datum: 23 mei 2024
Periode: vanaf 2000	Talen: geen restrictie
Literatuurspecialist: Esther van der Bijl	Rayyan review: https://rayyan.ai/reviews/1041689
BMI-zoekblokken: voor verschillende opdrachten wordt (deels) gebruik gemaakt van de zoekblokken van BMI-Online https://blocks.bmi-online.nl/ Deduplication: voor het ontdubbelen is gebruik gemaakt van http://dedupendnote.nl/	
Toelichting: Voor deze vraag is gezocht op de elementen fasciopathie plantaris EN operatieve ingreep (specifiek gastrocnemius recession/ lengthening). Het sleutelartikel wordt gevonden met deze search. In het zoekformulier wordt specifiek gevraagd naar operatieve ingrepen van de gastrocnemius. Vanwege de kleine opbrengst is overleg geweest over deze specifieke aanpak. Afgesproken is om de search in eerste instantie zo te houden en de systematische reviews, RCTs en observationele studies voor te leggen aan de werkgroep.	
Te gebruiken voor richtlijntekst: In de databases Embase.com en Ovid/Medline is op 23 mei 2024 systematisch gezocht naar systematische reviews, RCTs en observationele studies over de plaats van een operatieve ingreep bij de behandeling bij patiënten met fasciopathie plantaris. De literatuurzoekactie leverde 54 unieke treffers op.	

Zoekopbrengst 23 mei 2024

	EMBASE	OVID/MEDLINE	Ontdubbeld
SR	6	9	9
RCT	16	4	18

Observationele studies	21	24	27
Totaal	43	37	**54***

in Rayyan

Zoekstrategie Embase.com 23 mei 2024

No.	Query	Results
#1	'plantar fasciitis'/exp OR 'plantar fasciopathy'/exp OR 'heel spur'/exp OR 'policeman heel'/exp OR (((calcane* OR heel* OR subcalcane*) NEAR/3 (spur* OR exostos* OR pain* OR policeman* OR jogger*)):ti,ab,kw) OR ((plant* NEAR/3 (fasciitis OR fasciopath* OR fascios* OR inflam*)):ti,ab,kw) OR (((baxter* OR plant* OR calcane* OR heel) NEAR/3 neuropath*):ti,ab,kw) OR calcaneodyn*:ti,ab,kw OR 'calcane* periostitis':ti,ab,kw	6447
#2	'gastrocnemius recession'/exp OR (('gastrocnemius muscle'/exp OR 'triceps surae muscle'/exp) AND (recession:ti,ab,kw OR lengthening:ti,ab,kw OR release:ti,ab,kw OR surger*:ti,ab,kw OR surgical*:ti,ab,kw OR slide:ti,ab,kw OR operation*:ti,ab,kw)) OR (((gastroc* OR 'calf' OR 'gastro soleus' OR 'gastrocsoleus' OR 'triceps surae') NEAR/3 (recession OR lengthen* OR releas* OR surger* OR surgical* OR slide OR operat*)):ti,ab,kw) OR (((modified OR procedure* OR technique* OR operat*) NEAR/3 (baumann* OR strayer* OR vulpius)):ti,ab,kw)	6304
#3	#1 AND #2	96
#4	#3 AND [2000-2024]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	75
#5	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	1030954
#6	'clinical trial'/exp OR 'randomization'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR 'placebo'/exp OR 'prospective study'/exp OR rct:ab,ti OR random*:ab,ti OR 'single blind':ab,ti OR 'randomised controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti	4038071
#7	'major clinical study'/de OR 'clinical study'/de OR 'case control study'/de OR 'family study'/de OR 'longitudinal study'/de OR 'retrospective study'/de OR 'prospective study'/de OR 'comparative study'/de OR 'cohort analysis'/de OR ((cohort NEAR/1 (study OR studies)):ab,ti) OR (('case control' NEAR/1 (study OR studies)):ab,ti) OR (('follow up' NEAR/1 (study OR studies)):ab,ti) OR (observational NEAR/1 (study OR studies)) OR ((epidemiologic NEAR/1 (study OR studies)):ab,ti) OR (('cross sectional' NEAR/1 (study OR studies)):ab,ti)	8241761
#8	'case control study'/de OR 'comparative study'/exp OR 'control group'/de OR 'controlled study'/de OR 'controlled clinical trial'/de OR 'crossover procedure'/de OR 'double blind procedure'/de OR 'phase 2 clinical trial'/de OR 'phase 3 clinical trial'/de OR 'phase 4 clinical trial'/de OR 'pretest posttest design'/de OR 'pretest posttest control group design'/de OR 'quasi experimental study'/de OR 'single blind procedure'/de OR 'triple blind procedure'/de OR (((control OR controlled) NEAR/6 trial):ti,ab,kw) OR (((control OR controlled) NEAR/6 (study OR studies)):ti,ab,kw) OR (((control OR controlled) NEAR/1 active):ti,ab,kw) OR 'open label*':ti,ab,kw OR (((double OR two OR three OR multi OR trial) NEAR/1 (arm OR arms)):ti,ab,kw) OR ((allocat* NEAR/10 (arm OR arms)):ti,ab,kw) OR placebo*:ti,ab,kw OR 'sham-control*':ti,ab,kw OR (((single OR double OR triple OR assessor) NEAR/1 (blind* OR masked)):ti,ab,kw) OR nonrandom*:ti,ab,kw OR 'non-random*':ti,ab,kw OR 'quasi-experiment*':ti,ab,kw OR crossover:ti,ab,kw OR 'cross over':ti,ab,kw OR 'parallel group*':ti,ab,kw OR 'factorial trial':ti,ab,kw OR ((phase	15113335

	NEAR/5 (study OR trial)):ti,ab,kw) OR ((case* NEAR/6 (matched OR control*)):ti,ab,kw) OR ((match* NEAR/6 (pair OR pairs OR cohort* OR control* OR group* OR healthy OR age OR sex OR gender OR patient* OR subject* OR participant*)):ti,ab,kw) OR ((propensity NEAR/6 (scor* OR match*)):ti,ab,kw) OR versus:ti OR vs:ti OR compar*:ti OR ((compar* NEAR/1 study):ti,ab,kw) OR (('major clinical study'/de OR 'clinical study'/de OR 'cohort analysis'/de OR 'observational study'/de OR 'cross-sectional study'/de OR 'multicenter study'/de OR 'correlational study'/de OR 'follow up'/de OR cohort*:ti,ab,kw OR 'follow up':ti,ab,kw OR followup:ti,ab,kw OR longitudinal*:ti,ab,kw OR prospective*:ti,ab,kw OR retrospective*:ti,ab,kw OR observational*:ti,ab,kw OR 'cross sectional*':ti,ab,kw OR cross?ectional*:ti,ab,kw OR multicent*:ti,ab,kw OR 'multi-cent*':ti,ab,kw OR consecutive*:ti,ab,kw) AND (group:ti,ab,kw OR groups:ti,ab,kw OR subgroup*:ti,ab,kw OR versus:ti,ab,kw OR vs:ti,ab,kw OR compar*:ti,ab,kw OR 'odds ratio*':ab OR 'relative odds':ab OR 'risk ratio*':ab OR 'relative risk*':ab OR 'rate ratio':ab OR aor:ab OR arr:ab OR rrr:ab OR ((('or' OR 'rr') NEAR/6 ci):ab)))	
#9	#4 AND #5 **– SR's**	6
#10	#4 AND #6 NOT #9 **– RCT's**	16
#11	#4 AND (#7 OR #8) NOT (#9 OR #10) **– Observationele studies**	21
#12	#9 OR #10 OR #11	43

Zoekstrategie Ovid/Medline 23 mei 2024

#	Searches	Results
1	exp Fasciitis, Plantar/ or exp Heel Spur/ or ((calcane* or heel* or subcalcane*) adj3 (spur* or exostos* or pain* or policeman* or jogger*)).ti,ab,kf. or (plant* adj3 (fasciitis or fasciopath* or fascios* or inflam*)).ti,ab,kf. or ((baxter* or plant* or calcane* or heel) adj3 neuropath*).ti,ab,kf. or calcaneodyn*.ti,ab,kf. or calcane* periostitis.ti,ab,kf.	4464
2	(((gastroc* or 'calf' or 'gastro soleus' or 'gastrocsoleus' or 'triceps surae') adj3 (recession or lengthen* or releas* or surger* or surgical* or slide or operat*)) or ((modified or procedure* or technique* or operat*) adj3 (baumann* or strayer* or vulpius))).ti,ab,kf.	1046
3	1 and 2	54
4	limit 3 to yr="2000 -Current"	54
5	4 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	50
6	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	747755
7	exp clinical trial/ or randomized controlled trial/ or exp clinical trials as topic/ or randomized controlled trials as topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial or multicenter study or clinical trial).pt. or random*.ti,ab. or (clinic* adj trial*).tw. or ((singl* or doubl* or treb* or tripl*) adj (blind$3 or mask$3)).tw. or Placebos/ or placebo*.tw.	2728770
8	Epidemiologic studies/ or case control studies/ or exp cohort studies/ or Controlled Before-After Studies/ or Case control.tw. or cohort.tw. or Cohort analy$.tw. or (Follow up adj (study or studies)).tw. or (observational adj (study or studies)).tw. or Longitudinal.tw. or Retrospective*.tw. or prospective*.tw. or consecutive*.tw. or Cross sectional.tw. or Cross-sectional studies/ or historically controlled study/ or interrupted time series analysis/ [Onder exp cohort studies vallen ook longitudinale, prospectieve en retrospectieve studies]	4731601
9	Case-control Studies/ or clinical trial, phase ii/ or clinical trial, phase iii/ or clinical trial, phase iv/ or comparative study/ or control groups/ or controlled before-after studies/ or controlled clinical trial/ or double-blind method/ or historically controlled study/ or matched-pair analysis/ or single-blind method/ or (((control or controlled) adj6 (study or studies or trial)) or (compar* adj (study or studies)) or ((control or controlled) adj1 active) or "open label*" or ((double or two or three or multi or trial) adj (arm or arms)) or (allocat* adj10 (arm or arms)) or placebo* or "sham-control*" or ((single or double or triple or assessor) adj1 (blind* or masked)) or nonrandom* or	5695443

	"non-random*" or "quasi-experiment*" or "parallel group*" or "factorial trial" or "pretest posttest" or (phase adj5 (study or trial)) or (case* adj6 (matched or control*)) or (match* adj6 (pair or pairs or cohort* or control* or group* or healthy or age or sex or gender or patient* or subject* or participant*)) or (propensity adj6 (scor* or match*))).ti,ab,kf. or (confounding adj6 adjust*).ti,ab. or (versus or vs or compar*).ti. or ((exp cohort studies/ or epidemiologic studies/ or multicenter study/ or observational study/ or seroepidemiologic studies/ or (cohort* or 'follow up' or followup or longitudinal* or prospective* or retrospective* or observational* or multicent* or 'multi-cent*' or consecutive*).ti,ab,kf.) and ((group or groups or subgroup* or versus or vs or compar*).ti,ab,kf. or ('odds ratio*' or 'relative odds' or 'risk ratio*' or 'relative risk*' or aor or arr or rrr).ab. or (("OR" or "RR") adj6 CI).ab.))	
10	5 and 6 **– SR's**	9
11	(5 and 7) not 10 **– RCT's**	4
12	(5 and (8 or 9)) not (10 or 11) **– Observationele studies**	24
13	10 or 11 or 12	37