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Review Article

The Effectiveness of Combined Extracorporeal Shockwave Therapy and Exercise for Plantar Heel Pain: A Systematic Review

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Abstract

Plantar heel pain (PHP) is a common musculoskeletal disorder that is effectively treated with extracorporeal shockwave therapy (ESWT) and exercise. This review aimed to evaluate the effectiveness of combined ESWT and exercise versus other interventions in treating PHP. A systematic review of effectiveness was conducted, adhering to the PRISMA guidelines. Five databases were searched for studies published between January 2000 and September 2021 with 12 studies (n = 861) meeting the inclusion criteria, which compared ESWT and stretching to various other treatments. High-quality evidence indicates that combined ESWT and stretching interventions are more effective than their individual use or botulinum toxin injections, and low-quality evidence of superiority versus ultrasound and stretching. There was moderate quality evidence that combined ESWT and stretching is no more effective than corticosteroid injection, and high-quality evidence that the combination is no more effective than blood-derived injection therapies, custom orthotics, or low-level laser therapy combined with stretching. There is high-quality evidence that topical corticosteroid or laser therapy in combination with ESWT and stretching increases its effectiveness and moderate-quality evidence for the additive effectiveness of dry needling. Overall, combined ESWT and stretching treatments are effective and may be recommended where they are available and practical to implement. Further high-quality studies comparing combined interventions for PHP, including different exercise activities like resistance training, are required. *PROSPERO registration number:* CRD42020213286

Introduction

Recent research highlights musculoskeletal disorders as a leading contributor to the global burden of disability and chronic pain.[1] Musculoskeletal disorders impact a broad demographic spectrum of the population, resulting in extensive expenditures by healthcare systems and, thus, have become a substantial societal problem.[2] However, service-level and health policy responses to this issue are inadequate, therefore requiring an integrated research and policy agenda, including prioritising evidence-based effective treatments.[3] Chronic foot pain constitutes a large proportion of the musculoskeletal diseases, among which Plantar Heel Pain (PHP) causes up to 15% of all foot-related pain complaints and occurs in 10% of the population.[4] Symptoms of PHP include sharp heel pain commonly felt in the morning, which can limit functionality, with or without the presence of calcaneal heel spurs or nerve entrapment.[5] The disorder, which may result from excessive weight bearing or biomechanical abnormalities, presents like tendinopathy and results in chronic degeneration of plantar fascia collagen fibres rather than an acute inflammatory response.[6] Several commonly used clinical treatments for PHP include exercise therapy, orthotics, injection therapies, taping, manual therapy, ultrasound, low level laser therapy and extracorporeal shockwave therapy (ESWT).[7] Of all currently-available treatments, ESWT and exercise approaches appear to have the best evidence of long-term effectiveness.[8] Traditionally, plantar fascia stretching has been the most evidence-based exercise approach for PHP; however, resist-

Keywords: Exercise; Muscle Stretching Exercises; Extracorporeal Shockwave Therapy; High-Energy Shock Waves; Fasciitis; Plantar.

Abbreviations: ACP, Autologous conditioned plasma; BoTN-A, Botulinum toxin type-A; CFO, Custom fabricated orthotics; CSI, Corticosteroid injection; ESWT, Extracorporeal shock wave therapy; FFI, Foot Function Index; FFI-PS, Foot Function Index pain subscale; GRADE, Grading of Recommendations, Assessment, Development and Evaluation; HSRT, Heavy slow resistance training; LLLT, Low-level laser therapy; NHS, National Health Service; NRS, Numeric Rating Scale; NSAIDS, Non-steroidal anti-inflammatory drugs; PBMT, Photo-biomodulation therapy; PFSS, Plantar fascia specific stretching; PHP, Plantar heel pain; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analysis; RCTs, Randomised controlled trials; RMS, Roles and Maudsley score; UK, United Kingdom.

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ance training has been shown to be a more effective form of exercise in recent years.[9]

For several decades, evidence of the effectiveness of ESWT has been increasing, particularly for lower limb tendinopathies and PHP.[10] Recalcitrant PHP that is unresponsive to conservative treatment are considered appropriate candidates for ESWT, which has shown long-term safety and effectiveness.[11] In addition, recent evidence suggests that ESWT combined with exercise may be a more effective PHP treatment compared with either treatment in isolation.[12] In clinical practice, ESWT is often combined with exercise, yet a detailed comparison of combined treatment approaches is needed in future studies.[13] Current research recommends that combined, rather than isolated, treatments be used in PHP treatment, whereby ESWT or exercise as individual treatments potentially have inadequate long-term outcomes.[6] However, there is a dearth of studies on combined approaches and lack of clinical recommendations, despite indications of combined treatment being superior.[14] In this work, a search in PROSPERO, the Cochrane Library, and PubMed revealed no systematic reviews comparing the effectiveness of combined ESWT and any type of exercise for PHP. Therefore, the aim of this systematic review was to assess the effectiveness of combined ESWT and exercise interventions compared with other treatments in treating plantar heel pain based on pain and function outcomes. The conclusions allow for recommendations regarding the combination of ESWT and exercise interventions for treating PHP.

Methods

This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA, Supplementary File 1) guidelines and was conducted in accordance with an a priori protocol, which was registered in the PROSPERO database (CRD42020213286).[15]

This review considered studies with adult participants aged 18 years old and over who were formally diagnosed with PHP. Studies using local anaesthesia were excluded, as research has demonstrated that it can diminish ESWT effectiveness.[16] Studies in which participants have the one of following ESWT contraindications were also excluded: diabetes mellitus, systematic inflammatory disease, previous foot surgery or fractures, malignancy, neurological disorders, or pregnancy.[17] This review included studies that investigated the effectiveness of a combined intervention of any type of ESWT and any type of exercise in the treatment of PHP, undertaken in any healthcare setting. Any active treatment method for PHP was considered for comparators. For a full list of comparators, please see the PROSPERO review protocol (Supplementary File 2, Appendix 1). Primary outcomes included heel pain and foot function. Heel pain evaluated by any validated scale, such as the Visual Analogue Scale (VAS), Numeric Rating Scale (NRS), verbal rating scales or Foot Function Index pain subscale (FFI-PS).[18] Foot function was evaluated by any validated scale for PHP, such as the Foot Function Index (FFI).[19] The review was restricted to randomized controlled trials (RCTs) with two or more arms, in which combined ESWT and exercise formed one arm of the trial. The use of active co-interventions, such as pain medication (NSAIDs), education, orthotics and exercise, was acceptable if used in all trial arms to limit confounding variables.[20] The authors' preliminary work had identified several potentially eligible RCTs, which were chosen for inclusion over less robust study designs in this study due to the availability of RCTs on this topic. Any deviation from the standard RCT design, such as crossover or cluster designed trials, was also permitted.

Search strategy

The search strategy sought to identify published and unpublished trials utilizing a three-step search strategy. An initial scoping search of Medline was conducted, followed by analysis of text words contained in the title and abstract and article index terms. A comprehensive systematic search using all identified keywords and index terms was conducted using the following databases: Medline, CINAHL, AMED, and SPORTDiscus (Supplementary File 2, Appendix 2–3). The search for unpublished studies included EThOS Networked Digital Library of Theses and Dissertations and the NICE Guidelines ESWT recommendations. The trial registers that were searched included: ClinicalTrials.gov, UK clinical trials gateway, and EU trials registry. Finally, in addition to the comprehensive search, supplementary searches were undertaken by reviewing bibliographies of articles selected for critical appraisal and related systematic reviews to find those not initially identified. The search strategy was adapted to each database and was limited to the year 2000 onwards. The year 2000 was chosen to ensure that seminal work was not missed as research on ESWT for PHP first began around this time. Studies published in a language other than English were only considered if a translation was available, as translation services are not available to the authors.

Study selection

All identified citations from the systematic search were uploaded into RefWorks (Proquest LLC), with duplicates removed. Two reviewers independently screened the titles and abstracts of all studies obtained against the identified inclusion criteria. Full-text versions of eligible studies were accessed and reviewed against the inclusion criteria. Studies were removed from the screening process if the information provided did not meet the criteria. The details of studies meeting the criteria were imported to Covidence.[15]

Assessment of methodological quality

Included studies were critically appraised by two independent reviewers at the study level for methodological quality in the review using the standardized Cochrane risk of bias tool on Covidence.[21] Any disagreements that arose between the reviewers were resolved through discussion or with a third reviewer. The results of critical appraisal are reported in narrative form and in a graph. All studies meeting the inclusion criteria, regardless of their methodological quality, underwent data extraction and synthesis and were included in the review. Seven criteria were appraised for RCTs. Item three, which pertained to blinding, was included but not considered highly relevant in the final scoring and grading of recommendations, given that interventions could not be blinded. Therefore, a maximum high-quality score of 6 or 7 could be achieved, with all included studies scoring at least 4/7, which was considered a moderate-quality score.

Data extraction

Data were extracted from studies included in the review using the standardised data extraction tool available on Covidence by two in-

dependent reviewers.[15] The data extracted included specific details relative to the interventions, comparators, populations, study methods and outcomes of significance to the review question pertaining to heel pain and foot function. Any disagreements between the reviewers were resolved through discussion or with a third reviewer.

Data synthesis

Statistical pooling and meta-analysis were not possible due to clinical and methodological heterogeneity; therefore, findings are presented as a narrative synthesis. Although some studies used the same outcome measures, none employed the exact same clinical intervention protocol or comparator with wide variances in intervention protocols, outcome measures and follow-up times.

Assessing certainty of findings and quality of evidence

A summary table of the findings was created following the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach for assessing the quality of evidence.[22] Evidence from RCTs starts at high-quality, and the certainty is increased or decreased for several reasons, such as risk of bias.[22] The outcomes reported in the summary of findings table include heel pain and foot function for the interventions. For each outcome, a ranking of 'high', 'moderate', 'low' or 'very low' was assigned to the quality of evidence based on the risk of bias. There is, by necessity, a considerable amount of subjectivity in each decision as GRADE cannot be implemented mechanically. However, GRADE does provide a reproducible and transparent framework for grading certainty in evidence.[23]

Results

Search results and study inclusion

The initial search strategy identified a total of 405 studies, which was reduced to 20 studies obtained in full text after screening and removal of duplicates. Reasons for excluding studies obtained in full text included wrong study design, such as not being RCTs (three studies), duplication of results (two studies), wrong intervention (two studies), and wrong outcomes (one study) (Supplementary File 2, Appendix 4). The remaining 12 RCTs underwent quality appraisal and were included in the review (Fig. 1).

Methodological quality

Item 3 from the Cochrane risk of bias tool, which pertains to blinding, was considered not highly relevant as blinding is not possible for ESWT and exercise interventions. Therefore, the highest RCT score was considered to be 6 or 7, with seven studies achieving this score (Fig. 2).[12,14,24–28] Three studies scored 5,[29–31] and the remaining two scored 4.[32,33] These five studies were unclear about randomization methods and if concealed allocation to treatment groups was used. Two studies did not disclose if outcome assessors were blind to the group assignment (Fig. 3).[32,33]

Characteristics of included studies

The 12 included RCTs (Table 1[12,14,24-33]) were conducted in a range of countries: Turkey (four), Iran (two), Egypt, Brazil, Germany, Singapore, Canada, and Spain. All included studies were performed within a healthcare setting, which comprised a total of 861 participants. Although all participants were diagnosed with PHP, there were wide variances in the duration of the condition, ranging from 1 month to 12 months.[12] All studies investigated the effects of the interventions on heel pain, and ten studies utilized VAS scales. The studies also investigated foot function using a variety of outcome measures. Four studies used the full FFI,[26,29,31,33] and three used the FFI-PS.[12,14,24] The only exercise intervention used in the studies were stretching interventions, with all studies using combined PFSS and gastrocnemius stretching, with only one study using PFSS alone.[12] No studies used any other type of exercise, such as strengthening exercises. The studies also employed a variety of comparator interventions, some of which incorporated three or four trial arms comparing multiple combined interventions.

Findings

The findings are presented in relation to the primary outcomes of heel pain and foot function from combined ESWT and stretching interventions versus other interventions.

Stretching exercise alone

Four studies contained a comparator group involving stretching exercise alone.[14,24,25,33] Chew *et al*.[25] found clinically and statistically significant VAS pain improvement with combined ESWT and stretching versus stretching at month one (−2 points vs −0.75, $p = 0.017$), three (−3.25 points vs 1.0, $p = 0.022$) and six (−5.5 points vs 3.0, $p = 0.042$). Akinoglu *et al*.[33] found clinically and statistically significant improvement in FFI in the combined group compared to stretching alone ($p < 0.05$). Takla *et al*.[24] reported that the combined group was clinically and statistically superior to the stretching only group measured by VAS (7.8 to 1.7 = 48.48% decrease vs 7.8 to 8.1 = 3.8% increase) and FFI scores (41.8 to 28.9 = 30.8% decrease vs 43.8 to 43.5 = 0.6% increase) at 12 weeks ($p = 0.0001$). Only, Cinar *et al*.[14] discovered the combined group not to be superior for reducing pain at 3 weeks, but it was statistically significantly superior at 3 months ($p = 0.035$). Patients having clinically meaningful FFI-PS improvements were also higher for ESWT (61% vs 50%).

ESWT alone

One study compared combined ESWT and PFSS without gastrocnemius stretching with ESWT alone.[12] Two months after baseline, the FFI-PS score was clinically and statistically improved for the combined group (−20.1 vs −12.2 points) compared with ESWT alone ($p \leq 0.001$). Statistically significant but not clinically important differences remained at 4 and 24 months ($p \leq 0.01$).

Ultrasound combined with stretching

Three studies compared combined ESWT and stretching with ultrasound and stretching.[30,32–33] Akinoglu *et al*.[33] found that, although both groups had improved FFI-PS scores, the improvements were more clinically meaningful (28.25 vs 43.28) in the ultrasound group at one month, which was statistically significant ($p \leq 0.05$). Grecco

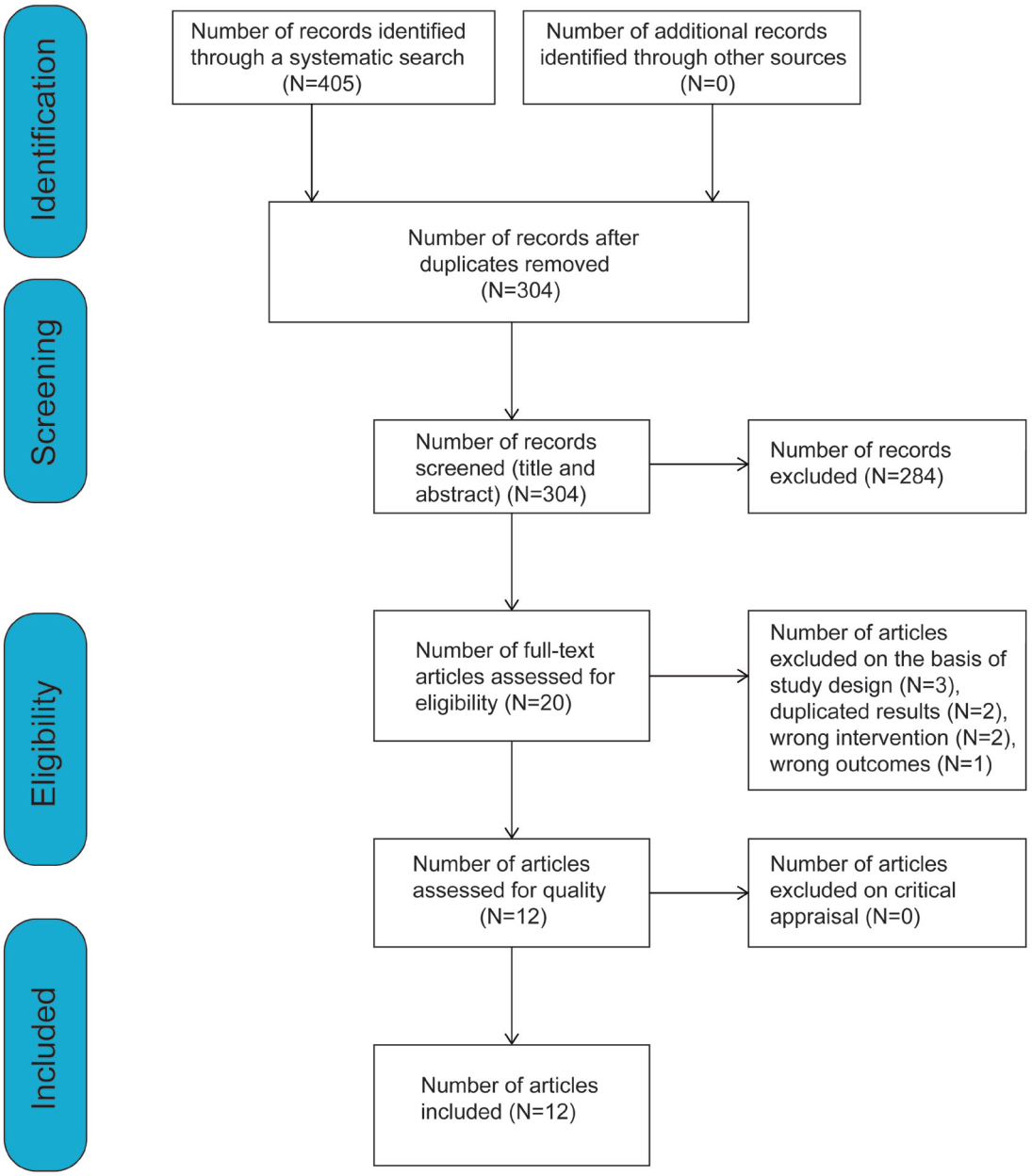

Fig. 1. PRISMA study flow diagram.

et al.[32] found clinically meaningful but no statistically significant differences between the groups for VAS pain at 3 (65% vs 70% good outcome) and 12 months (85% vs 80% good outcome), where a good outcome was defined as a VAS score of 1/10 or less. Ulusoy *et al*.[30] found ESWT and stretching to be statistically and clinically significantly superior after one month (success defined as 60% or more VAS improvement) compared to ultrasound and stretching (65% vs 23.5%) for pain measured with VAS ($p = 0.12$).

Autologous conditioned plasma (ACP) injection combined with stretching

One study used a single ACP injection combined with stretching.[25] At month one, three, and six, both ACP (−2.0, −3.0, −5.0) and ESWT (−2.0, −3.25, −5.5) combined with stretching was found to be superior to stretching only (−0.75, −1.0, −3.0) based on the VAS score. These differences were statistically significant at each timepoint for both ESWT ($p = 0.017, 0.022, 0.042$) and ACP ($p = 0.037, 0.053, 0.080$) versus stretching alone. There was no significant difference at each time-point between ACP and ESWT and stretching in VAS scores ($p = 0.575, 0.947, 0.791$).

Single corticosteroid injection combined with stretching

One study found that ESWT and stretching had better scores in VAS and FFI compared to corticosteroid injection and stretching.[29]

Fig. 2. Risk of bias summary.

Although these changes were clinically meaningful, they were not statistically significant [FFI decreased to 19.65 from 60.25 points (67.4% improvement) in ESWT vs 31.50 from 60.25 points (47.7% improvement) in the injection group at week 8, ($p = 0.072$)]. Good or excellent results in the opinions of patients were achieved in 55% of ESWT and 30% of corticosteroid injection groups ($p = 0.11$).

Botulinum toxin type A injection combined with stretching

One study compared one session of ESWT with one injection of botulinum toxin type-A (BoNT-A), both combined with stretching.[28] In the ESWT group, the median (and interquartile range) of improvement in the VAS pain, when taking the first steps, was 2

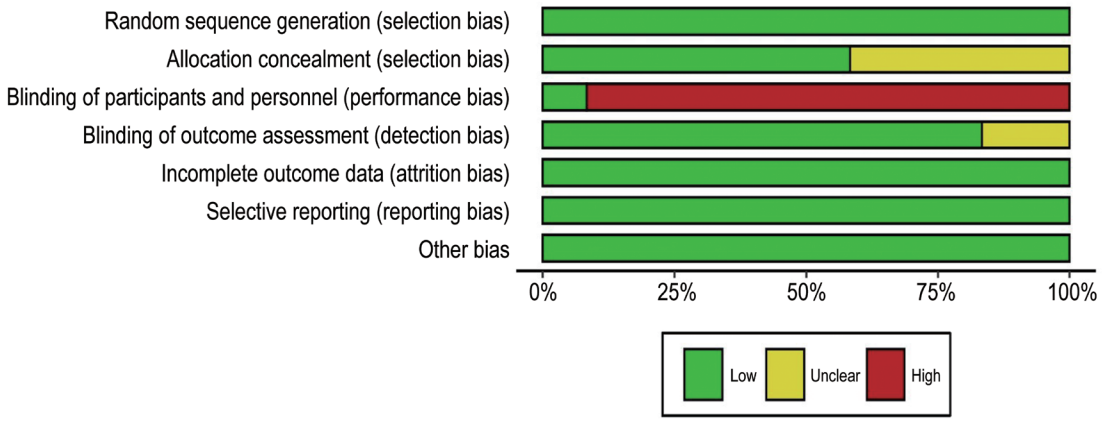

Fig. 3. Risk of bias graph.

(1–4) points, and in the BoNT-A group the same result was 1 (0–2) points (p = 0.009). In the ESWT group, the median (and interquartile range) of improvement in the Roles and Maudsley scale was 1 (0–1) points, and in the group of patients that received BoNT-A the same result was 0 (0–1) points (p = 0.006). In a multivariate analysis, use of ESWT was associated with improvement of pain and function, and combined ESWT and stretching treatment was found superior to BoNT-A.

Custom fabricated orthotics (CFO) combined with stretching

One study compared ESWT versus CFO, both combined with stretching.[26] Both groups achieved significant clinically important improvements in VAS and FFI scores at 4, 12, 24 and 48 weeks compared with their baseline values. CFO VAS scores over the five time-points (6.6, 5.2, 4.4, 3.9, 4.1) and FFI (82.5, 63.9, 59.3, 55.2, 51.8) were slightly better than ESWT VAS scores (6.3, 5.1, 4.6, 4.4, 4.8) and FFI (78.3, 65.2, 62.8, 62.4, 66.4). However, there was no statistically significant difference between treatments, and neither method was superior ($p < 0.001$).

Low level laser therapy (LLLT) combined with stretching

Three studies compared ESWT and stretching with LLLT and stretching.[14,24,30] Ulusoy *et al*.[30] found that, although LLLT had a higher clinically meaningful success rate than ESWT for pain and function (70.6% vs 65%), there was no statistically significant difference between the groups ($p = 0.717$) in terms of VAS scores. Takla *et al*.[24] reported that, while both groups had statistically significant and clinically meaningful improvements in VAS and FFI scores, combined ESWT and stretching was significantly superior ($p < 0.0001$). Cinar *et al*.[14] proposed that LLLT had statistically significant lower FFI-PS compared to ESWT and stretching at three months ($p = 0.003$). Patients having clinically meaningful FFI-PS improvements were also higher for LLLT than ESWT (79% vs 61%).

ESWT and stretching combined with dry needling

One study investigated the additive effect of dry needling with three sessions of ESWT combined with stretching.[31] In both groups, there were statistically significant improvements in VAS pain and FFI scores ($p \leq 0.001$). The intergroup comparison showed that VAS scores, and FFI pain subscale scores ($p = 0.034$) were statistically superior in the combined dry needling group. There was no statistically significant difference between the groups in FFI disability ($p = 0.081$), and FFI activity limitation subscale ($p = 0.226$) scores. ESWT, stretching, and dry needling combination therapy proved to be superior for pain improvement.

ESWT and stretching combined with topical corticosteroid

One study investigated the additive effect of topical corticosteroid to ESWT and stretching.[27] At one month, VAS pain showed a statistically significant improvement in the intervention group, but not at three months ($p = 0.006$). A 50% improvement in VAS scores was considered clinically successful, whereby 75% (vs 45%) of patients in the intervention group achieved this score at one month and 80% (vs 65%) at three months ($p = 0.135$).

ESWT and stretching combined with Photobiomodulation therapy (PBMT)

Both ESWT and PBMT (equivalent to LLLT) combined with stretching were effective in decreasing pain and improving function according to VAS and FFI scores compared to stretching and sham PBMT.[24] However, application of PBMT with ESWT and stretching was clinically superior over ESWT and PBMT with stretching alone, based on VAS and FFI scores, which was statistically significant ($p < 0.0001$). The study calculated overall VAS and FFI effect sizes of 85.452 (0.68 effect size) and 49.76 (0.56 effect size) for the combined interventions.

Discussion

This systematic review investigated the effectiveness of combined ESWT and exercise interventions versus other interventions for pain and function in PHP. The findings suggest that combined ESWT and stretching treatment is superior to using either therapy alone or botulinum toxin injection combined with stretching for improving pain and function in PHP. The combination of ESWT and stretching also appears to be more effective than combining ultrasound with stretching and has similar outcomes to combining

Table 1. Characteristics of included studies

Study	Country	Setting	Participant characteristics	Groups	Outcomes measured	Description of main results
Akinoglu B, *et al*.[33]	Turkey	Physical therapy and rehabilitation clinic	Adults with PHP for at least three months	(1) Radial shockwave therapy (R-ESWT) once per week for three weeks (3 sessions) and home plantar fascia and gastrocnemius stretching daily for four weeks (n=18); (2) Ultrasound (US)treatment twice per week for three weeks (7 sessions) and home stretching daily for four weeks (n=18); (3) Home stretching daily for four weeks (n=18)	Foot Function Index (FFI), a 10 cm pain visual analogue scale (VAS) and the American Orthopaedic Foot and Ankle Association (AOFAS) hind foot score.	FFI improved in all groups, but more in US group ($p < 0.05$). AOFAS improved in all groups, but less in the control group ($p < 0.05$). Static and dynamic balance increased in all groups ($p < 0.05$). Ankle proprioception sense increased only in the R-ESWT group ($p < 0.05$). R-ESWT and US groups symptoms improved more than stretching alone.
Chew KT, *et al*.[25]	Singapore	Sports medicine centre	Adults diagnosed with PHP of 4 months or longer.	(1) Autologous conditioned plasma (ACP) injection (once) and Conventional treatment: daily home gastrocnemius and plantar fascia stretching (n=19); (2) Shockwave therapy (ESWT) 2 sessions, 1 week apart and Conventional treatment: daily home stretching (n=19); (3) Conventional treatment alone: daily home stretching (n=16)	VAS, AOFAS, and ultrasound plantar fascia thickness	Significant VAS improved more in ACP group compared with conventional treatment at month 1 ($p = 0.037$) and ESWT group compared with conventional treatment at months 1, 3, and 6 ($p = 0.017$, $p = 0.022$, and $p = 0.042$). AOFAS improved in the ACP group at months 3 and 6 ($p = 0.004$ and $p = 0.013$) and, for the ESWT group, at months 1 and 3 ($p = 0.011$ and $p = 0.003$) compared with conventional treatment. ACP or ESWT plus stretching were superior to stretching alone.
Cinar E, *et al*.[14]	Canada	Outpatient physiotherapy department	Adults diagnosed with PHP for one month or longer.	(1) R-ESWT once weekly for 3 weeks & Full-length silicone insoles (3 months) & Home gastrocnemius and plantar fascia stretching (3 weeks) (n=25); (2) Laser therapy (LLLT), three times a week for ten sessions & insoles (3 months) & Home stretching (3 weeks) (n=24); (3) Control group: insoles (3 months) & Home stretching (3 weeks) (n=17)	Foot Function Index pain subscale (FFI-p). Functional pain was measured through 12-minute walking test and Numeric Rating Scale for Pain (NRS-p).	In NRS-p, LLLT group had significantly lower pain than ESWT ($p = 0.002$) at the third week and control ($p = 0.043$) and ESWT ($p = 0.003$) at third month. In FFI-p, ESWT group had higher pain than LLLT ($p = 0.003$) and control ($p = 0.035$) groups at third week and LLLT ($p = 0.010$) group at third month. When LLLT and ESWT were combined with usual care, LLLT was found to be more effective in reducing pain at short-term follow-up.
Vahdatpour B, *et al*.[27]	Iran	Physical medicine and rehabilitation clinic	Adults with PHP for at least six months	(1) Four sessions at weekly intervals of ESWT combined with topical corticosteroid and home gastrocnemius and plantar fascia stretching (n=40); (2) Four sessions at weekly intervals of ESWT combined with topical Vaseline (control) and home stretching (n=40)	VAS: Heel pain while taking the first steps in the morning (VAS morning). Heel pain while doing a daily activity (VAS daily). Modified Roles and Maudsley score (RMS).	At one month, VAS morning showed significant improvement in intervention group ($p = 0.006$) and RMS showed better improvement in intervention group ($p = 0.026$). There was no significant difference between the two groups after 3 months in RMS or VAS score. PF thickness was decreased significantly in both groups, but it was not significant between the two groups ($p = 0.292$). Combined treatment was more effective.

(continued)

Table 1. *(continued)*

Study	Country	Setting	Participant characteristics	Groups	Outcomes measured	Description of main results
Takla M, *et al*.[24]	Egypt	Private orthopaedic outpatient clinic	Adults diagnosed with PHP for 6 months or longer	(1) Combined ESWT (once weekly for three weeks) with PBMT (three times per week for three weeks) and daily home gastrocnemius and plantar fascia stretching for three weeks (n=30); (2) ESWT and daily home stretching for three weeks (once weekly for three weeks) (n=30); (3) PBMT (three times per week for three weeks) and daily home stretching for three weeks (n=30); (4) Sham-PBMT and daily home stretching for three weeks (n=30)	Pressure pain threshold (PPT), VAS, and foot function index disability subscale (FFI-d).	PPT, VAS, and FFI-d values improved in all treatment groups ($p < 0.0001$). Both ESWT and PBMT were effective in increasing PPT values, decreasing pain and increasing functional ability. Additionally, application of PBMT after ESWT was shown to be superior to ESWT and PBMT alone, and ESWT was superior to PBMT in terms of reducing pain sensitivity and increasing function.
Grecco MV, *et al*.[32]	Brazil	Institute of Orthopaedics and Traumatology	Adults aged 20 or over diagnosed with PHP for 3 months or longer	(1) Conventional physiotherapy: Ultrasound x ten sessions with home plantar fascia and gastrocnemius stretching (n=20); (2) R-ESWT × 3 sessions at weekly intervals, with home stretching (n=20)	VAS, Fischer's algometer to quantify the painful pressure at the insertion of the plantar fascia.	At the 12-months, both treatments were effective for improving pain and function, however improvement with R-ESWT was faster.
Eslamian F, *et al*.[29]	Iran	Physical medicine and rehabilitation research centre	Adults diagnosed with PHP	(1) Five sessions at 3-day intervals of R-ESWT) and home gastrocnemius and plantar fascia stretching (n=20); (2) Single Local methylprednisolone injection and home stretching (n=20)	VAS, FFI, treatment satisfaction	VAS and FFI improved in both groups ($p < 0.001$), but more so in the R-ESWT group, but these changes were insignificant statistically ($p = 0.072$). Good or excellent results in the opinions of patients were achieved in 55% of ESWT and 30% of corticosteroid injection groups ($p = 0.11$).
Rompe JD, *et al*.[12]	Germany	Orthopaedic hospital	Adults diagnosed with PHP for at least 12 months.	(1) Three sessions at weekly intervals of Shockwave therapy (ESWT) and daily Plantar fascia stretching for 8 weeks (n=79); (2) Three sessions at weekly intervals of Shockwave therapy (ESWT) (n=73)	PS-FFI, Patient-relevant outcome measures (SROM) questionnaire.	At two months after baseline, the Foot Function Index sum score PS-FFI improved more in the combined group than those managed with ESWT alone ($p < 0.001$), as well as individually for item 2 ($p < 0.001$). 24 patients in Group 1 (32%) versus 47 in Group 2 (59%) were satisfied with the treatment ($p < 0.001$). Significant differences persisted at four months, but not at 24 months.

(continued)

Table 1. *(continued)*

Study	Country	Setting	Participant characteristics	Groups	Outcomes measured	Description of main results
Ulusoy A, *et al*.[30]	Turkey	University physical medicine and rehabilitation department	Adults diagnosed with PHP for at least 6 months	(1) 5 sessions per week for 3 weeks (15) of LLLT and home gastrocnemius and plantar fascia stretching (n=20); (2) 5 sessions per week for 3 weeks (15) of ultrasound (US) and home stretching (n=20); (3) Once weekly for 3 weeks (3 sessions) of ESWT and home stretching (n=20)	VAS, heel tenderness index (HTI), AOFAS, RMS and MRI	The treatment success rate was 70.6% in the LLLT group, 65% in the ESWT group, and 23.5% in the US group. LLLT and ESWT proved significantly superior to US therapy using the primary efficacy criterion (p = 0.006 and p = 0.012, respectively), with no significant difference between the LLLT and ESWT groups ($p > 0.05$). LLLT and ESWT resulted in similar outcomes, and both were more successful than US therapy.
Çağlar Okur S, *et al*.[26]	Turkey	Outpatient physiotherapy clinic	Adults ages 30–60 years diagnosed with PHP.	(1) 3 sessions (once weekly) of R-ESWT and daily plantar fascia and gastrocnemius stretching for 4 weeks (n=40); (2) Custom fabricated orthotics (CFO) and plantar fascia and gastrocnemius stretching for 4 weeks (n=43)	VAS, FFI and Foot Health Status Questionnaire (FHSQ).	Both groups improved at 4, 12 and 24 weeks compared with their baseline values ($p < 0.001$), and significant improvement observed in the CFO group continued at 48 weeks ($p < 0.05$); however, there was no significant difference between groups, with neither treatment being superior ($p > 0.05$).
Bagcier F, *et al*.[31]	Turkey	Physical medicine and rehabilitation outpatient clinic	Adults aged between 18 and 70 years, with PHP for at least 6 weeks.	(1) Three sessions at weekly intervals of ESWT followed by cold application for 15 minutes and home Plantar fascia and gastrocnemius stretching (n=20); (2) Three sessions at weekly intervals of ESWT followed by dry needling of gastrocnemius muscle and cold application for 15 minutes and home stretching (n=20)	VAS, FFI	VAS, maximum painless standing time (p = 0.002), maximum painless walking distance ($p \leq 0.001$), and FFI pain subscale scores (p = 0.034) were statistically superior in the ESWT plus dry needling group. There was not statistically difference between the groups in pressure pain threshold (p = 0.132), FFI disability (p = 0.081), and FFI activity limitation subscale (p = 0.226) scores. ESWT and dry needling combination therapy was superior for pain scores.
Roca B, *et al*.[28]	Spain	General hospital	Adults older than 15 years; diagnosed with PHP for at least 6 months.	(1) One session of ESWT and daily Plantar fascia and gastrocnemius stretching (n=37); (2) One injection of Botulinum toxin type A and daily stretching (n=37)	VAS pain and activity, RMS	The median (and interquartile range) of improvement in the VAS of pain result, when taking the first steps, was 2 (1–4) points in ESWT group, and in the BoNT-A group the same result was 1 (0–2) points (p = 0.009). The median (and interquartile range) of improvement in the RMS of pain result was 1 (0–1) points in ESWT group, and in the BoNT-A group the same result was 0 (0–1) points (p = 0.006). ESWT was superior to BoNT-A for pain improvement.

BoNT-A: Botulinum toxin type-A; VAS: visual analogue scale; RMS: Roles and Maudsley score; AOFAS: American orthopaedic foot and ankle society scale; FFI: Foot Function Index; ESWT: Extracorporeal shockwave therapy; CFO: Custom fabricated orthotics: LLLT: Low-Level laser therapy; PHP: Plantar heel pain; FHSQ: Foot health status questionnaire; US: Ultrasound.

LLLT or custom orthotics with stretching. When comparing ESWT and stretching with more invasive injection therapies, such as ACP or corticosteroid injection, no significant difference between interventions was found. Combining ESWT and stretching with topical corticosteroid, dry needling, or LLLT also led to superior outcomes. The GRADE strength of the evidence rating was initially considered high for each of these outcomes due to having high-quality RCT evidence. However, the superiority of ESWT and stretching to ultrasound was downgraded to a 'low' strength of evidence because of potential bias (Table 2). These three studies were all unclear about randomization methods and if concealed allocation to treatment groups was used.[30,32–33] Two of these studies also did not disclose if outcome assessors were blind to the group assignment.[32–33] and, as a result, may have introduced potential sampling and measurement bias.[34] Both studies were still included in the review as they still maintained an overall moderate score of 4/7 but reduced the strength of the evidence compared to other interventions. Strength of evidence was downgraded from high to moderate for the comparison of ESWT and stretching to corticosteroid injection and the addition of dry needling due to risk of bias regarding unclear randomization methods and use of concealed allocation.[29,31]

Recent systematic reviews have also suggested similar outcomes with ESWT and CSI and ACP injection therapies for PHP.[35] These reports indicate that these invasive injection therapies may be unnecessary if ESWT is available as a treatment option as it is associated with less side effects and a better safety profile.[36] Participants were also significantly more satisfied with ESWT vs CSI (55% vs 30%) as a PHP treatment in the included study.[29] There was no significant difference between ESWT and stretching versus CFO and stretching; however CFO or standard orthotics are recommended as an earlier intervention strategy over ESWT.[37] Although earlier systematic reviews have suggested no benefits of standardised orthotics for PHP, recent RCTs have demonstrated the effectiveness of CFO for PHP.[38] The effectiveness of combined ESWT and stretching was also found to be increased when topical corticosteroid was used prior to ESWT and when LLLT was used following ESWT.[24,27] This is in agreement with previous studies, as both LLLT and CSI have been shown to be effective for treating PHP, despite not being as effective as ESWT.[36] Although LLLT induces tissue regeneration and anti-inflammatory effects like ESWT, it is believed to work by a different mechanism targeting cellular mitochondria.[39] While CSI has shown to be effective for short-term pain reduction and inflammation reduction in PHP, reported side effects include heel pad atrophy and plantar fascia rupture.[40] Studies on tendinopathy have also found that CSI can reduce the effectiveness of exercise interventions and may, therefore, not be an optimal treatment combination.[41]

Combined PHP treatments can increase intervention effectiveness, but may be impractical and not cost-effective in many clinical settings.[14] Out of all PHP treatments, ESWT appears to be the most effective treatment option to combine with exercise, the most practical, and safest.[8] It is less invasive, has less side effects, and has better long-term effectiveness than ACP or CSI injection therapies.[36] It also requires less treatment sessions – only 3 are recommended – compared to LLLT and ultrasound that typically require 10–15 treatment sessions.[30] All the studies that investigated exercise alongside ESWT as an intervention included stretching interventions, including the same PFSS protocol.[42] However, the use of a standardized 12-week heavy slow resistance training (HSRT) program targeting the plantar fascia was found to be more effective compared to this PFSS protocol for pain (VAS) and function (FFI) in am RCT.[9] A recent RCT reported that combining HSRT and PFSS protocols with CSI was significantly more effective than CSI or the combined exercise program alone for pain and function (VAS and FFI) in PHP.[43] Currently, no studies have investigated the effects of strengthening exercise combined with ESWT for PHP.[44]

Main limitations of included studies

The main limitations of the studies included in this review relate to small sample sizes, methodological and clinical heterogeneity in study designs, and the lack of blinding that led to a risk of bias. Some studies that conducted power calculations for sample sizes[12,14,24,27,29,30] were potentially underpowered to detect true statistically significant differences.[25–26,28,31,32] One study claimed to have used a power calculation, but details of the sample size were omitted.[33] There was a wide variation in intervention protocols, including different types of ESWT with different energy densities, different machines, and various numbers of treatment sessions, ranging from two[25] to five,[29] with three being most common. All these parameters are known to influence effectiveness of ESWT.

There were also wide variations in longest treatment follow-up times, ranging from 1 month[33] to 24 months,[12] with only three studies having a 12-month or longer follow-up.[12,26,32] Treatment interventions also varied in length, from three weeks[24,14,30] to eight weeks.[12] There were also variances in the participant criteria, such as duration of PHP and diagnostic methods. Duration of PHP ranged from 1 month[14] to 12 months,[12] with 3 months being the average. This is important as the duration of PHP is known to affect the outcomes of ESWT. The recommended length of PFSS intervention to achieve physiological effects is 8 weeks.[9] Although all studies referred to the same PFSS protocol, only one study implemented it with an eight-week intervention,[12] which resulted in uncertainty over the true effectiveness of PFSS or its additive effect to ESWT within these studies. Most studies also included gastrocnemius stretching alongside PFSS, which may have influenced outcomes. Some studies gave exercise instructions and adherence diaries, but were poorly reported and raised concerns on exercise adherence. Although most studies used VAS scales to measure pain, various outcome measures were applied to evaluate foot function. FFI was the only outcome measure used, which has been specifically validated for the PHP population; however, only four studies used the complete FFI.[26,29,31,33]

Limitations of the review

Due to study heterogeneity in interventions used and outcome measures, statistical pooling and meta-analysis were not possible. This limits the conclusions that can be drawn regarding the effectiveness of combined ESWT and exercise interventions versus other interventions in treating PHP. A few non-English articles were excluded, which influences the generalizability of findings since treatment methods may differ by country. Half of the included studies (6 of 12) originated from either Turkey or Iran, thereby influencing the global generalizability of findings. Although a thorough search of the literature was conducted, it is still possible that relevant literature may have been missed, which may have affected the review outcomes.

Implications and future directions

The evidence from this systematic review suggests that combined ESWT and stretching interventions are an effective treatment for PHP compared to other treatments. There is high- and low-quality

Table 2. Summary of findings

Outcomes	Impact	№ of participants (studies)	Certainty of the evidence (GRADE)
ESWT and stretching compared to other treatments for plantar heel pain. *Patient or population:* plantar heel pain. *Setting:* any clinical setting. *Intervention:* ESWT and stretching. *Comparison:* other treatments			
Pain and function in PHP with combined ESWT and stretching versus stretching alone follow up: range 1 month to 6 months	ESWT and stretching statistically significantly superior for improving pain and function	173 (4 RCTs)	⊕⊕⊕⊕ HIGH
Pain and function in PHP with combined ESWT and stretching versus ESWT alone follow up: range 2 months to 24 months	ESWT and stretching statistically significantly superior for improving pain and function	152 (1 RCT)	⊕⊕⊕⊕ HIGH
Pain and function in PHP with combined ESWT and stretching versus ultrasound combined with stretching follow up: range 1 month to 12 months	ESWT and stretching statistically significantly superior for improving pain and function	116 (3 RCTs)	⊕⊕◯◯ LOW[a]
Pain and function in PHP with combined ESWT and stretching versus ACP injection combined with stretching follow up: 6 months	Mixed findings - neither treatment statistically significantly superior for improving pain and function	54 (1 RCT)	⊕⊕⊕⊕ HIGH
Pain and function in PHP with combined ESWT and stretching versus corticosteroid injection combined with stretching follow up: 2 months	Mixed findings - neither treatment statistically significantly superior for improving pain and function	40 (1 RCT)	⊕⊕⊕◯ MODERATE [b]
Pain and function in PHP with combined ESWT and stretching versus LLLT combined with stretching follow up: range 1 month to 3 months	Mixed findings - neither treatment statistically significantly superior for improving pain and function	149 (3 RCTs)	⊕⊕⊕⊕ HIGH
Pain and function in PHP with combined ESWT and stretching versus CFO combined with stretching follow up: 11 months	Mixed findings - neither treatment statistically significantly superior for improving pain and function	83 (1 RCT)	⊕⊕⊕⊕ HIGH
Pain and function in PHP with combined ESWT and stretching versus botulinum toxin type A injection combined with stretching follow up: 2 months	ESWT and stretching statistically significantly superior for improving pain and function	72 (1 RCT)	⊕⊕⊕⊕ HIGH
Pain and function in PHP with dry needling combined with ESWT and stretching versus dry needling and stretching follow up: 1 month	Dry needling combined with ESWT and stretching statistically significantly superior for improving pain and function	40 (1 RCT)	⊕⊕⊕◯ MODERATE[b]
Pain and function in PHP with topical corticosteroid combined with ESWT and stretching versus ESWT and stretching follow up: 3 months	Topical corticosteroid combined with ESWT and stretching statistically significantly superior for improving pain and function	80 (1 RCT)	⊕⊕⊕⊕ HIGH
Pain and function in PHP with LLLT combined with ESWT and stretching versus ESWT and stretching follow up: 3 months	LLLT combined with ESWT and stretching statistically significantly superior for improving pain and function	60 (1 RCT)	⊕⊕⊕⊕ HIGH
GRADE Working Group grades of evidence			
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect. *Moderate certainty:* we are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. *Low certainty:* our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect. *Very low certainty:* we have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.			

[a]Unclear randomization methods and if concealed allocation was used. Did not disclose if outcome assessors were blinded to group assignment. Potential sampling and measurement bias. [b]Unclear allocation concealment (potential selection bias). ACP, autologous conditioned plasma; CFO, custom fabricated orthotics; ESWT, extracorporeal shock wave therapy; LLLT, Low-level laser therapy; PHP, plantar heel pain; RCT, Randomised controlled trial.

evidence that this combined approach is more effective than either treatment used alone and ultrasound. Therefore, combined ESWT and stretching should be clinically recommended in favour of either treatment alone or ultrasound. Although there were no significant differences in effectiveness between combined ESWT and stretching with injection therapies (ACP, CSI), ESWT may be recommended over them due to its better safety profile and fewer side effects. Topical corticosteroid may be a safer option, which has shown to have an additive short-term effect when combined with ESWT and stretching, and may be recommended where available.[27] Although there was no difference between combined ESWT and stretching and CFO, standard or custom orthotics are consistently recommended alongside or prior to ESWT.[45]

There are conflicting and mixed findings when ESWT and stretching is compared with LLLT and stretching, with neither method appearing superior. However, ESWT should be considered a more practical and cost-effective method compared to LLLT, as the recommended standardized ESWT protocol requires 3 sessions to be effective, whereas LLLT requires 10–15 sessions.[24] Given that LLLT requires up to 15 sessions and the side effects associated with corticosteroids, a combined ESWT (3 sessions) and stretching protocol may be the most practical, cost-effective, safest, and evidence-based conservative treatment currently available for PHP. The review findings support the recommendations from recent PHP research that combined, rather than single, interventions should be recommended for treating PHP.[14]

Further large-scale RCTs should be conducted with large sample sizes and robust methods to control for assessor bias, such as ensuring blinding of those assessing outcome measures. Longer-term follow-up times are required to determine the long-term effectiveness of combined PHP interventions. Future studies should also investigate and compare combined interventions using validated measures, which is reflective of clinical physiotherapy practice that often combines treatments.[14,46] Exercises other than stretching should be combined with ESWT, such as HSRT, and methods for individualising exercise interventions should be considered to improve outcomes compared to standardised interventions.[9,47] Using standardized intervention protocols and validated outcome measures would also allow better translation of findings. Future studies should also emphasise the importance of completing and returning exercise diaries to monitor adherence.[48]

Conclusions

Plantar heel pain is a common musculoskeletal disorder that affects the lives of many individuals worldwide. This systematic review investigated the effectiveness of combined ESWT and exercise treatment versus other interventions in improving pain and function in PHP. Twelve RCTs met the inclusion criteria (n= 861) with various commonly-used comparator interventions. Given the clinical and methodological heterogeneity of the included studies, statistical pooling of data for meta-analysis was not possible. Therefore, a narrative synthesis of findings is presented with quality of evidence assessed by GRADE. Much evidence demonstrates that combined ESWT and stretching interventions are more effective than either treatment used alone or BoNT-A injection. There are limited reports on this combined treatment versus ultrasound interventions and its better effectiveness than corticosteroid injection. Numerous studies show that the combination is no more effective than autologous conditioned plasma injection, custom orthotics, or low-level laser therapy combined with stretching. However, ESWT and stretching should be considered as a safer and more practical treatment option than these methods. Further, the use of topical corticosteroid or LLLT in combination with ESWT and stretching has proven to increase effectiveness compared to ESWT and stretching alone, yet more evidence is needed to investigate dry needling in combination with ESWT and stretching. The combined treatments for PHP with quality evidence may be recommended where they are available and practical to implement. The combination of ESWT and stretching may be the most practical and effective treatment based on the currently-available high-quality evidence. Strengthening exercises have not been investigated either combined with or compared against ESWT as a PHP treatment in RCTs. Further high-quality RCTs with robust methodological design, larger sample sizes, and longer follow-up durations comparing combined interventions for PHP, including strengthening exercises, are required to determine and recommend the most optimal treatment strategy.

Supporting information

Supplementary material for this article is available at https://doi.org/10.14218/ERHM.2021.00059.

Supplementary File 1. PRISMA checklist for this article.

Supplementary File 2. Appendix 1–4.

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Conflict of interest

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Author contributions

IB conceptualised the work and wrote the first draft of the manuscript. IB and AM revised the manuscript and approved the final manuscript.

Data sharing statement

No additional data are available.

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