

Interventions for treating plantar heel pain (Review)

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ABSTRACT

Background

Ten percent of people may experience pain under the heel (plantar heel pain) at some time. Injections, insoles, heel pads, strapping and surgery have been common forms of treatment offered. The absolute and relative effectiveness of these interventions are poorly understood.

Objectives

The objective of this review was to identify and evaluate the evidence for effectiveness of treatments for plantar heel pain.

Search strategy

We searched the Cochrane Musculoskeletal Injuries Group specialised register (September 2002), the Cochrane Central Register of Controlled Trials Register (The Cochrane Library issue 3, 2002), MEDLINE (1966 to September 2002), EMBASE (1988 to September 2002) and reference lists of articles and dissertations. Four podiatry journals were handsearched to 1998. We contacted all UK schools of podiatry to identify dissertations on the management of heel pain, and investigators in the field to identify unpublished data or research in progress. No language restrictions were applied.

Selection criteria

Randomised and quasi-randomised trials of interventions for plantar heel pain in adults.

Data collection and analysis

Two reviewers independently evaluated randomised controlled trials for inclusion, extracted data and assessed trial quality. Additional information was obtained by direct contact with investigators. No poolable data were identified. Where measures of variance were available we have calculated the weighted mean differences based on visual analogue scale (VAS) scores.

Main results

Nineteen randomised trials involving 1626 participants were included. Trial quality was generally poor, and pooling of data was not conducted. All trials measured heel pain as the primary outcome. Seven trials evaluated interventions against placebo/dummy or no treatment. There was limited evidence for the effectiveness of topical corticosteroid administered by iontophoresis, i.e. using an electric current, in reducing pain. There was some evidence for the effectiveness of injected corticosteroid providing temporary relief of pain. There was conflicting evidence for the effectiveness of low energy extracorporeal shock wave therapy in reducing night pain, resting pain and pressure pain in the short term (6 and 12 weeks) and therefore its effectiveness remains equivocal. In individuals with chronic pain (longer than six months), there was limited evidence for the effectiveness of dorsiflexion night splints in reducing pain. There was no evidence to support the effectiveness of therapeutic ultrasound, low-intensity laser therapy, exposure to an electron generating device or insoles with magnetic foil. No randomised trials evaluating surgery, or radiotherapy against a randomly allocated control population were identified. There was limited evidence for the superiority of corticosteroid injections over orthotic devices.

Authors' conclusions

Although there is limited evidence for the effectiveness of local corticosteroid therapy, the effectiveness of other frequently employed treatments in altering the clinical course of plantar heel pain has not been established in randomised controlled trials.

At the moment there is limited evidence upon which to base clinical practice. Treatments that are used to reduce heel pain seem to bring only marginal gains over no treatment and control therapies such as stretching exercises. Steroid injections are a popular method of treating the condition but only seem to be useful in the short term and only to a small degree. Orthoses should be cautiously prescribed for those patients who stand for long periods; there is limited evidence that stretching exercises and heel pads are associated with better outcomes than custom made orthoses in people who stand for more than eight hours per day.

Well designed and conducted randomised trials are required.

PLAIN LANGUAGE SUMMARY

Effectiveness of treatments for heel pain still unclear

Pain and tenderness under the heel (plantar heel pain) on weight bearing can cause impairment of activity and significant disability. A wide range of treatments are used including corticosteroid injections, low energy shock wave therapy and night splints.

At the moment there is limited evidence upon which to base clinical practice. Treatments that are used to reduce heel pain seem to bring only marginal gains over no treatment and control therapies such as stretching exercises. Steroid injections are a popular method of treating the condition but only seem to be useful in the short term and only to a small degree. Orthoses should be cautiously prescribed for those patients who stand for long periods; there is limited evidence that stretching exercises and heel pads are associated with better outcomes than custom made orthoses in people who stand for more than eight hours per day.

This review found there is only limited evidence to support the use of these treatments and no evidence to support the effectiveness of ultrasound or insoles with magnetic foil.

Further research is needed, particularly into the use of orthoses (devices used to modify position or motion) and radiotherapy.

BACKGROUND

Plantar heel pain (plantar heel pain syndrome or plantar fasciitis), is a common condition which is estimated to affect 10% of runners, and to occur in a similar proportion of the general population at some time during life (D'Maio 1993). The clinical features are pain and tenderness under the heel on weight bearing, with associated limitation of activity. Typically, this pain is worst first thing in the morning. Heel pain is also associated with other conditions most notably, polyarthritis; in this condition other features will also present in the history and on examination. Plantar fasciitis has also been called jogger's heel, tennis heel, calcaneodynia and, in the past, gonorrhoeal heel (an incorrect association which prevailed in the early 20th century). Healthcare providers involved in the treatment of painful heels may include general medical practitioners, podiatrists, rheumatologists, physiotherapists, orthopaedic surgeons, orthotists, and osteopaths.

Little is known of the underlying disease process or the clinical course of the condition. Although often eventually self-limiting in untreated individuals, it can be a source of morbidity over several months and occasionally, in the worst instances, years. The pain is thought to arise from an acute or chronic injury (enthesopathy) of the origin of the plantar fascia and/or intrinsic muscles arising from the plantar tuberosity of the calcaneum. Occasionally, radiological changes of soft tissue calcification are seen in the

tissues around the heel resulting in a so called 'spur', the clinical significance of which is unclear. Some treatments that have been used reflect the different causal theories while others have simply tried to control the pain. These include pain medication, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, therapeutic ultrasound, heel pads, in-shoe orthoses, and fascial release surgical procedures (Bruno 1976; Weil 1994). For the purposes of this review, we have concentrated only on the treatments for patients who have a confirmed diagnosis of plantar heel pain. We have not been concerned with the prevention of plantar heel pain in those in individuals who may have a predisposition to the condition.

As we were unable to locate a previous systematic review that addressed the effectiveness of treatments for the painful heel, we conducted this review of evidence from randomised trials.

OBJECTIVES

This review examined the evidence from randomised controlled trials for the effectiveness of interventions for the treatment of plantar heel pain. We tested the following null hypotheses:

A. There is no difference in patient outcomes between those individuals with plantar heel pain who receive a therapeutic intervention and those who do not.

B. There is no difference in patient outcomes between different therapeutic interventions for plantar heel pain.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Randomised or quasi-randomised (methods of allocating participants to an intervention which were not strictly random e.g. date of birth, hospital record number or alternation) controlled trials of heel pain treatments, which met the specifications below were considered.

Types of participants

Adult participants in any trial meeting the inclusion criteria for trial type, whether they were part of the general population, athletes, or individuals with seronegative arthropathies and enthesopathies, where this information was available. Any age group was admissible. It was our intention that trials involving children alone, or dealing specifically with young athletes, would be analysed separately.

Randomised controlled trials evaluating treatments for heel pain arising from calcaneal fractures, calcaneal tumours, post-operative pain as a result of foot surgery management, or posterior heel pain such as that involving the tendo Achilles or peroneus longus were excluded.

Types of intervention

We sought randomised and quasi randomised trials evaluating any intervention used to treat plantar heel pain.

Types of outcome measures

Binary and continuous measures were considered for the following outcomes:

1. Pain, including tenderness on palpation (principal outcome measure)
2. Any measure of disability
3. Quality of life measures (e.g. QALY's, SF36, patients' reports of improvement or non-improvement)
4. Return to activities (sport or work)
5. Independence from health services attendance - including discharge
6. Adverse effects of treatment : infection, plantar fascial rupture, heel pad atrophy, hyperesthesia.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Bone, Joint and Muscle Trauma Group methods used in reviews.

Randomised controlled trials were identified up to September 2002 as follows:

We searched the Cochrane Musculoskeletal Injuries Group specialised register of trials (September 2002), the Cochrane Central Register of Controlled Trials (The Cochrane Library issue 3, 2002), MEDLINE (from 1966 to September 2002), EMBASE (from 1988 to September 2002) and reference lists of articles and dissertations. Journals that were handsearched were the British Journal of Podiatric Medicine (formally The Chiropodist) (1957-1998); The Foot (1994-1998); Foot and Ankle International (1980-1998); The Journal of the American Podiatric Medical Association (1967-1998). We contacted known investigators in the field to identify unpublished data or research in progress. We contacted all 13 UK schools of podiatry for dissertations on the management of the painful heel (1998). Non-English language reports were included in the review.

In MEDLINE (SilverPlatter), the first two levels of the optimum search strategy (Dickersin 1994) were combined with the following subject-specific search terms:

1. HEEL* and SYNDROME*
2. (JOG* or TENNIS* or POLICE* or GONORRHOEAL) near HEEL*
3. PLANTAR near FASCI*
4. explode "FASCIITIS"/ all subheadings
5. (PLANTAR or HEEL* or CALCAN* or FOOT*) near PAIN*
6. HEEL near SPUR
7. "CALCANEUS"/ all subheadings
8. #1 or #2 or #3 or #4 or #5 or #6 or #7

METHODS OF THE REVIEW

Two reviewers (FC & CT) independently applied the inclusion/exclusion criteria to each randomised controlled trial located and conducted data extraction and rated methodological quality. Disagreements were resolved by discussion of the articles by the reviewers. We wrote to trialists for additional information on trial methodology (method of randomisation) and results (usually standard deviations or some other measure of variance).

We developed and piloted a quality assessment tool. This was based on the following items:

1. Was the randomisation procedure described
2. Was the allocation schedule concealed
3. Was an intention to treat analysis used
4. What number of patients were lost to follow-up
5. Was the outcome assessment blind.

This led to each trial being attributed a quality score out of a maximum of 5 points.

When a pooled estimate of the impact of intervention made practical sense and the data were available it was intended that

meta-analysis would be conducted for direct comparisons. We intended to present relative risk and 95% confidence intervals for dichotomous outcomes for each randomised controlled trial and group them in relevant sub-groups according to the specific question they addressed. We assessed homogeneity across the results of trials within relevant sub groups (DerSimonian 1986) and intended to provide a pooled relative risk for each subgroup of trials. If we had found no reason to doubt our 'a priori' assumption of a single underlying effect in sub groups of trials we intended to use a fixed effects model to estimate the pooled effect as our primary analysis (Whitehead 1991). However, if evidence of heterogeneity was found to be present we intended to use a random effects model (DerSimonian 1986). In either case it was our intention to undertake both analyses and assess the potential impact of assumptions on the model for pooling trials for treatment effect.

DESCRIPTION OF STUDIES

Twenty five reports of randomised controlled trials were considered for inclusion in this review. Eighteen reports of RCTs were identified from the MEDLINE search (Batt 1996; Buchbinder 2002; Caselli 1997; Crawford 1996; Crawford 1999; Fauno 1993; Gudeman 1997; Hammer 2002; Krischek 1998; Lynch 1998; Martin 2001; Ogden 2001; Pfeffer 1999; Powell 1998; Probe 1999; Rompe 1996a; Rompe 2002; Turlik 1999). A further seven randomised trials were located from the following sources: three unpublished dissertations (Black 1996; Kriss 1990; Nolan 1990) through direct contact with UK schools of podiatry; one through direct contact with investigators (Rompe 1996b); one published report from the Cochrane Musculoskeletal Injuries trial database (Noble 1981); and two trials from other sources (Basford 1998; Blockey 1956).

Six randomised controlled trials (Batt 1996; Fauno 1993; Hammer 2002; Noble 1981; Rompe 2002; Turlik 1999) were excluded (see Characteristics of Excluded Studies).

The remaining nineteen randomised controlled trials included in this review involved 1626 patients. All included randomised controlled trials involved adults from the general population rather than specific groups such as athletes or dancers. Mean ages of participants, where reported, were 42 years (Gudeman 1997) and 48 years (Powell 1998) with over all age ranges from 21 to 80 years (Black 1996; Blockey 1956; Caselli 1997).

The diagnostic features of heel pain in participants varied between trials. Authors reported a range of diagnostic criteria from planar heel pain (Blockey 1956), pain on the plantar aspect of the heel (Crawford 1996), typical inflammatory characteristics (Black 1996), a calcaneal spur (Rompe 1996b), medial plantar calcaneal spur (Gudeman 1997), an ultrasound confirmed lesion (Buchbinder 2002) to "tenderness to pressure at the origin of the plantar fascia, on the midanterior inferior border of the calcaneus as

well as complaints of sharp shooting or localised inferior foot pain made worse with activity and on rising in the morning" (Basford 1998).

Details of individual trials are given in the Characteristics of Included Studies Table, and are summarised below:

Steroid injections and pads

Steroid injection versus Viscoheel Sofspot heel pads (Black 1996): 17 patients. Patients were randomised to receive either a Viscoheel heel pad or a heel injection of triamcinolone hexacetonide (Lederspan) 20 mg with 2% lignocaine. The injection group were advised to rest for 48 hours after the procedure.

Steroid injections versus saline injection (Blockey 1956): 19 patients. Painful heels were either injected with 25 mg hydrocortisone acetate or saline injection. All patients were also given a sponge heel pad.

Steroid injections and orthosis versus steroid injections alone versus orthosis alone (Kriss 1990): 80 patients. In this three arm trial patients received either an anti-pronatory insole or a steroid injection of triamcinolone hexacetonide (Lederspan) 20 mg mixed with 2% lignocaine or both.

Steroid injections versus local anaesthetic (Crawford 1999): 91 patients. This was a 2x2 factorial design; patients received a heel injection of either 1 ml of 25 mg prednisolone acetate with 1 ml local anaesthetic or 2 ml of local anaesthetic. Patients were also randomised to receive a tibial nerve block or not prior to heel injection.

Steroid injections versus visco elastic heel cup versus low-Dye strapping (Lynch 1998): 85 patients. A three arm trial in which patients received: anti inflammatory therapy of 1 ml of 0.5% bupivacaine hydrochloride without epinephrine (adrenaline); accommodative therapy with a visco elastic heel pad; mechanical therapy of low-Dye strapping with a metatarsal pad and a custom-made orthosis.

Physical therapies

Low intensity laser versus dummy laser (Basford 1998): 32 patients. Affected feet were irradiated either with 30 mW continuous-wave 0.83 mm GaAlAs IR diode laser or a disabled laser probe. Treatment consisting of three periods of 33 second 'sweeps' at both the origin of the plantar fascia and the medial border.

Ultrasound versus placebo (Crawford 1996): 19 patients. Episodes of heel pain were allocated to either true ultrasound at a dosage of 0.5 W/cm², pulsed 1:4, 3 Mz for eight minutes, or placebo ultrasound when only the timer was set. All patients received eight treatments in four weeks.

Iontophoresis with steroids versus iontophoresis with saline (Gudeman 1997): 39 patients. Iontophoresis is a process by which ions of a medication are introduced into tissues by means of an

electric current. Group 1 patients were treated with placebo iontophoresis (buffered saline) while group 2 patients received iontophoresis with Dexamethasone. All patients also received six sessions of ice and stretching programmes over a two to three week period.

Bioelectron MKII electron generating device versus placebo device (Nolan 1990): 27 patients. This experimental device produced a beam of electrons, delivered onto the surface of the skin via a probe. The manufacturers claimed this reduced tissue acidity and restored the inflamed area to normal pH. Patients were randomised to receive either a functioning or a disabled device. After instruction patients used the device at home administering treatment for five minutes three times daily over 21 days.

Low-energy extracorporeal shock wave therapy (ESWT) versus placebo (Rompe 1996a): 36 patients. ESWT was applied using an experimental device, the Siemens Osteostar. The device made contact with feet in the treatment group only, feet in the placebo group had the device held at a 1 cm distance. In the treatment group the energy density was 0.06 mJ/mm² three times in weekly intervals.

Low energy extracorporeal shock wave therapy 1000 impulses versus 10 impulses (Rompe 1996b): 119 patients. ESWT was applied using an experimental device, the Siemens Osteostar. Patients received either 1000 impulses three times at weekly intervals or 10 impulses in the same time period.

Low energy shock wave therapy 3 X 500 impulses versus 3 X 100 (Krischek 1998): 50 patients. A two arm trial in which one group of patients received 3 X 500 impulses of 0.08 mJ/mm² ESWT whilst the second group received 3 X 100 impulses of 0.08 mJ/mm² ESWT.

Extra corporeal shock wave therapy (Ogden 2001): 260 patients. Patients assigned to active treatment received 1500 impulses at an 18 kV power setting. Patients who received the placebo treatment also had 1500 shocks delivered at 18 kV but a physical barrier of a Styrofoam block was placed between the foot and the treatment head to absorb the shock-waves.

Ultrasound-guided extracorporeal shock wave therapy (Buchbinder 2002): 166 patients. Each patient in both the placebo and experimental groups received a total of three treatments given at weekly intervals. For the placebo group this consisted of 100 shock waves per treatment of energy 0.02 mJ/mm². The experimental group received either 2000 or 2500 shock waves per treatment of energy levels varying between 0.02 mJ/mm² and 0.33 mJ/mm².

Insoles and night splints

Moulded (PPT) insole and magnetic foil versus moulded (PPT) insole (Caselli 1997): 40 patients. Patients in the treatment group wore PPT Rx (type of mass produced insole) firm moulded insoles containing a Nikken magnetic foil placed in the heel. Control

group patients wore the same insole without the magnetic foil. All patients wore the insole for four weeks, with no co-interventions.

Custom made orthoses versus heel pads versus stretching exercises (Pfeffer 1999): 236 patients. A five arm trial in which patients were randomised to receive a custom made orthosis, or a silicone heel pad, or a felt pad, or a rubber heel cup, or stretching exercises alone.

Custom made orthoses versus over the counter arch supports versus tension night splints (Martin 2001): 255 patients. A three-arm trial received custom made orthoses made from 5 mm Polydur plastic material; the second group received over-the-counter arch supports (Foot Soldiers); the third group received a posterior tension night splint dorsi-flexed 5 degrees of ankle dorsi flexion.

Night splints versus control (no intervention) (Powell 1998): 37 patients. In their allocated intervention month each patient received a night splint made of polypropylene with the ankle placed in five degrees of dorsiflexion. Foam was used distally on the splint to give 30 degrees dorsiflexion at the metatarsophalangeal joints.

Night splints versus oral anti inflammatory drugs and stretching exercises (Probe 1999): 116 patients. A two arm trial in which one group received 1 month of oral anti inflammatory medication, Achilles stretching exercises and shoe recommendations whilst the second group received 1 month of oral anti inflammatory medication, Achilles tendon stretching exercises and shoe recommendations plus a night splint dorsi flexed at the ankle joint (5 degrees).

Outcome measures

With the exception of the randomised controlled trial by Blockey 1956, all trials measured pain on visual analogue pain scales (VAS) as the primary outcome. The mean differences presented in this systematic review are based on those. Only two used a generic outcomes measure SF36 (Buchbinder 2002; Probe 1999). Five trials only measured the primary outcome; patients perception of pain (Blockey 1956; Crawford 1996; Crawford 1999; Kriss 1990; Nolan 1990). Basford 1998 also measured pain on palpation, toe walking and windlass testing., he reported using an 1000mm VAS [sic]. Black 1996 used the Ritchie Tenderness Scale but did not give details of this outcome measurement. Two trials used the Maryland Foot Scale (Gudeman 1997; Buchbinder 2002); this tool assesses pain and function on a 100 point scale but gives a combined score. Caselli 1997 and Pfeffer 1999 used the Foot Function Index; this measures pain, disability and activity restriction using a 100 mm visual analogue scale.

In addition to a visual analogue pain scale Lynch 1998 and Martin 2001 both measured the effect of heel pain on three types of activity (leisure, work and exercise) on a 1 to 4 Likert scale where 1 = no effect and 4 = constant effect. First step pain was defined on a 1 to 4 scale where 1 = no pain and 4 = constant. Patients were also categorised as having excellent, fair and poor outcomes related to their VAS score. Powell 1998 used the Mayo Clinical Scoring System; this tool measures pain, activity limitations, footwear or

orthotic requirements, plantar heel pain tenderness, neuropathy and antalgic gait. Patients score from a possible maximum of 100 points which denoted normal function and absence of pain. The higher the score, the less pain.

Rompe 1996a used a scale where 100 points equalled maximal pain and zero indicated no pain. Night pain, resting pain and pressure pain were measured in this way. In the larger studies, Rompe 1996b again used a 100 point VAS and categorised the duration of pain free walking ability into five grades where 1 = less than 15 minutes, 2 = less than 30 minutes, 3 = less than 45 minutes, 4 = less than 60 minutes, 5 = more than 60 minutes.

Rompe 1996b also rated patients' pain post intervention compared to their pre treatment conditions into four groups (excellent, good, fair, poor). Krischek 1998 used visual analogues scales to measure pain plus minutes of pain free walking and patient satisfaction from 1-3 categories.

Ogden 2001 measured five outcomes:

1. Investigator heel pain assessment: pressure sensor applied to the site of maximum sensitivity.
2. Minimum 50% improvement over baseline with a VAS score of 4.0 or greater.
3. Subject self assessment of pain; minimum of 50% improvement over pre treatment baseline score of 4.0 or greater. Subjects self assessment of pain on first walking in the morning: minimum of 50% improvement over pre treatment baseline and a VAS score of .0.
4. Subjects self assessment of activity: Distance measured without heel pain.- improvement of one point on a five point scale, or maintain a 0/1 baseline level (no pain minimal pain).
5. Use of pain medications: no prescription analgesics were given after treatment. If patients self-treated with over the counter analgesic medications it was noted.

Buchbinder 2002 measured six outcomes;

1. Overall pain on a 100 mm VAS (Primary outcome measure)
2. Morning and activity pain on a 100 mm VAS
3. Walking ability without need for rest
4. The Maryland Foot score
5. Problem elicitation technique
6. SF36 (generic health measure)

METHODOLOGICAL QUALITY

The overall quality scores can be found in the Characteristics of Included Studies Table and Table 02.

Was the randomisation procedure described?

Methods by which the allocation schedule were generated was not stated in the majority of the reports (Basford 1998; Black 1996; Blockey 1956; Caselli 1997; Crawford 1996; Gudeman 1997; Ogden 2001; Rompe 1996a; Rompe 1996b). However,

Powell 1998, Crawford 1999, Probe 1999 and Buchbinder 2002 reported using computer generated random numbers allocations. Kriss 1990 reported using sealed envelopes.

Was the allocation schedule concealed?

Nine randomised controlled trial (Black 1996; Kriss 1990; Martin 2001; Lynch 1998; Pfeffer 1999; Powell 1998; Probe 1999; Rompe 1996a; Rompe 1996b) were not double blind. Although Rompe 1996b intended this larger trial to be double blind he acknowledged that patients could probably determine their treatment allocation due to the painful nature of the treatment. Mechanisms used to provide placebo controls were well described in all other trials. One trial reported the allocation codes were kept by the departmental secretary (Crawford 1999). One further trial (Buchbinder 2002) reported that both the patients and a single outcome assessor were blinded to the allocation schedule which was created by the trial biostatistician using computer generated numbers list. The single therapist was informed of treatment allocation by central telephone call just prior to commencement of treatment. But otherwise this information and the period over which blinding, if used, was applied was not stated in any of the other trials.

Was an intention to treat analysis used?

Intention to treat analysis was only used in the randomised controlled trial by Buchbinder 2002.

What number of patients were lost to follow up?

All trials contained reports of the numbers of patients who were lost to follow-up except Basford 1998 and Crawford 1996.

Was the outcome assessment blind?

Assessor blinding was reported in seven randomised controlled trials (Basford 1998; Blockey 1956; Buchbinder 2002; Crawford 1996; Crawford 1999; Gudeman 1997; Nolan 1990; Rompe 1996b).

RESULTS

The number of different interventions and the differences in the type of data that was collected in the trials included in the review prevented the pooling of data. A particular barrier to the statistical integration of data was the absence of summary statistics from nine trials. Ten trials did present summary data (Buchbinder 2002; Crawford 1996; Crawford 1999; Gudeman 1997; Krischek 1998; Kriss 1990; Lynch 1998; Nolan 1990; Pfeffer 1999; Rompe 1996b). Eight trials reported significant reduction in pain in one or more treatment group.

Steroid injection

The evaluation of iontophoresis and Dexamethasone compared with iontophoresis and saline (Gudeman 1997) showed an improvement in the outcomes of the Dexamethasone group in the immediate (2-3 weeks) post treatment period (WMD 3.80; 95%

CI 0.76 to 6.84). Outcomes taken four weeks after the end of the intervention did not reach statistical significance (WMD 2.30; 95% CI -2.16 to 6.76).

In Kriss 1990 the results showed patients who received steroid injections alone had the greatest improvement in pain levels compared to a pad and a combination of the pad and injection (WMD -45.01; 95% CI -59.12 to -30.90). The main threat to the internal validity of this trial was the patients', health professionals and evaluators' knowledge of the allocation and the lack of control group.

In the 2x2 factorial trial of steroid injections versus local anaesthetic and tibial nerve block anaesthesia versus no tibial nerve block anaesthesia, Crawford 1999 reported a statistically different improvement in pain scores at one month on 10 cm visual analogue scales (WMD -1.94; 95% CI -3.06 to -0.82). Neither the patient or the outcome assessor were aware of the treatment allocation.

Extra corporeal shock wave therapy

In two trials of extra corporeal shock wave therapy (ESWT) (Rompe 1996a; Rompe 1996b), the health professionals were aware of the treatment allocation. The authors suggest that the painful nature of ESWT therapy meant it was unlikely that patients were unaware of the treatment allocation in the larger study and in the smaller trial the equipment did not make contact with the feet of patients in the placebo group. The larger trial (Rompe 1996b) showed a significant reduction improvement in pressure pain between 0 to 12 weeks (WMD -47.30; 95% CI -54.38 to -40.22) for the active treatment arm. A protocol deviation occurred between week 12 and 52 when patients from both groups who were unresponsive to the allocated treatment were given NSAIDs, corticosteroid infiltrations or surgery. This confounding has led to the trial's outcomes at 52 weeks being excluded from the review.

Krischek 1998 was unable to detect a statistically significant difference in two doses of ESWT; 3 X 500 impulses and 3 X 100 impulses (WMD -0.90; 95% CI -2.54 to 0.74). Ogden 2001 did not present summary statistics and measures of variance for the data collected from people receiving either 1500 impulses or placebo making further analysis impossible. The authors reported significantly more patients in the active treatment arm met all four rigid success criteria (investigator heel pain assessment, subject self assessment of pain, use of pain medications, $p = 0.08$). The mean differences for a reduction in pain scores between the two groups was 6%.

Night splints

Although the cross-over trial of night splints (Powell 1998) reported improvements in patients' heel pain during the two treatment phases, there were statistical differences between groups at baseline according to the Mayo Clinical Scoring System. Both patients and health professionals were aware of the treatment allocation and it is not reported whether the evaluator of outcomes was

objective. At the conclusion of the trial, 36% of patients were pain free. Probe 1999 did not detect a statistically significant difference in heel pain reduction between a group who were given a night splint and the control group who were not.

Orthoses/heel pads

In the trial by Pfeffer 1999 custom made orthoses were not found to produce a greater reduction in heel pain than stretching exercises (OR 0.82 95% CI 0.30 to 2.24) however when prefabricated shoe inserts were compared with stretching exercises an odds ratio of 2.93 (95% CI 1.22 to 7.08) favoured the use of stretching. Pfeffer 1999 performed a subgroup analysis of patients who stood for more or less than 8 hours per day. We decided not to present these data because the analyses were post hoc; the authors did not report that such a stratification had taken place at the time of randomisation. However the data may have identified time spent standing as a potentially important prognostic indicator (see implications for research).

Outcomes (pain reduction)

Twelve randomised controlled trials did not detect a statistical difference between the interventions for the principal outcomes of heel pain between at least one of the compared interventions. What follows is a list of evaluations which did not detect a statistical difference in outcomes: lasers (Basford 1998; data not available); ultrasound (Crawford 1996; weighted mean difference WMD 0.15; 95% CI -1.89 to 2.19); steroid injections versus heel pads (Black 1996; data not available); steroid injections versus saline (Blockey 1956; relative risk 0.52; 95% CI 0.15 to 1.78); Bioelectron MKII versus sham (Nolan 1990; WMD -0.85; 95% CI -3.11 to 1.41); insoles with and without magnetic foil (Caselli 1997; data not available); night splints versus over the counter arch supports (Martin 2001; WMD 0.40; 95% CI -0.66 to 1.46) or night splints versus custom made orthoses (Martin 2001; WMD 0.60; 95% CI -0.43 to 1.63); night splints versus anti inflammatory drugs, stretching exercises and shoe advice (Powell 1998; WMD 1.2; 95% CI 0.51 to 2.41); steroid injections versus heel cups (Lynch 1998; WMD 0.20; 95% CI -0.82 to 1.22); steroid injections versus custom made orthoses (Lynch 1998; WMD -1.20; 95% CI -2.79 to 0.39); 3 X 500 impulses versus 3 X 100 impulses of ESWT (Krischek 1998; WMD -0.90; 95% CI -0.74 to 2.54); ESWT 3 weekly treatments of 2000-2500 impulses versus 100 impulses (Buchbinder 2002; WMD -1.9; 95% CI -11.9 to 8.1 after 6 weeks and WMD 0.6; 95% CI -10.3 to 11.5 after 12 weeks). In the trial evaluating a variety of shoe inserts with stretching exercises rubber heel pads versus stretching exercises for people standing more than 8 hours per day were not found to differ significantly (Pfeffer 1999; WMD -2.80; 95% CI -11.7 to 6.17). For those people who stood for less than 8 hours per day no statistical differences were detected between custom made orthoses and heel pads (all types) (WMD 0.00; 95% CI -3.72 to 3.72). Crawford 1999 found no advantage to patients in having a tibial nerve block prior to a steroid injection: this procedure did not make the heel

injection more comfortable. Mean differences in VAS scores of heel pain at three months (WMD -0.90; 95% CI -2.62 to 0.82) and six months (WMD 0.20; 95% CI -1.08 to 1.48) were not statistically significant.

Weighted Mean Differences are presented in the data tables for randomised controlled trials whose standard deviations were reported. This data was not available for the following trials: (Basford 1998; Black 1996; Caselli 1997; Powell 1998; Rompe 1996a).

Adverse events

Few adverse effects were reported in either group. Adverse events were not universally reported. Ten randomised controlled trials did not mention adverse events anywhere in their reports (Black 1996; Caselli 1997; Crawford 1996; Crawford 1999; Gudeman 1997; Rompe 1996a; Kriss 1990; Lynch 1998; Martin 2001; Nolan 1990). Basford 1998 reported negligible adverse events with 4% of patients reporting mild sensations during or after laser treatment. Blockey 1956 reported that there were no adverse events in patients in either the saline or the steroid group. Powell 1998 found 19% of patients were dissatisfied with the night splint with many reporting an inability to tolerate the device. Rompe 1996b concluded that ESWT was considered to be unpleasant by all patients, though not as unpleasant as local infiltration. It is unclear from the report how many patients had previous experience of local infiltration. Buchbinder 2002 noted that one participant from each group reported pain for one week after treatment, one participant in the active group reported heat and numbness, one participant in the placebo group reported pain and burning in the heel and ankle also bruising after the first treatment by one patient in the active group.

Ogden 2001 reported 38 episodes of adverse events in the trial of ESWT versus placebo. Eighteen of these were in the active treatment group. Adverse events or complication were; pain after treatment, numbness and tingling. One patient experienced a plantar fascial tear which was attributed to previous treatment with multiple corticosteroid injections.

Outcomes (other than pain)

The ten randomised controlled trials which reported measuring outcomes other than pain recorded the following: in Basford 1998 no significantly different outcomes except the control group could walk further without limping at one month and had more painful toe walking at the time of last treatment. Black 1996 found the Ritchie Tenderness Score for the steroid group was 1.9 pre-intervention, and 0.7 at three months post intervention whilst the heel pad group scored 1.4 pre-intervention which decreased to 0.5 after three months. Buchbinder 2002 found no statistically differences in the degree of improvement between treatment groups for any of the five additional outcomes measures; morning and activity pain, walking ability, Maryland Foot Score, Problem Elicitation Technique and SF36 at six weeks and twelve weeks. Statistically significant differences between the Mayo Clinical scores for the

groups at one, two and six months were detected by Powell 1998. Rompe 1996a found walking ability was significantly improved in the treatment group at three and six weeks but does not report outcomes for walking ability at 24 weeks. In Rompe 1996b improvement in pain free walking ability was reported as significantly different for outcomes compared between weeks zero and twelve. There was also a significant difference in the patients' satisfaction with the treatment in favour of the high dose therapy. Caselli 1997 did not report secondary outcomes despite using the Foot Function Index. In addition to pain measurement Pfeffer 1999 measured the time to improvement and change in activity. No data for these outcomes were presented: "because they are qualitatively similar to those presented for response rates and over all changes in pain score". Martin 2001 collected data about whether the pain score affected exercise, leisure activities, and work activities at baseline but did not present post intervention data. Lynch 1998 collected data on the effect of heel pain on three types of activities: leisure, work and exercise but no data were presented relating to the outcomes post intervention. Powell 1998 used SF36 (short-form 36 health status questionnaire). He found the baseline showed lower scores for bodily pain, general health change, role performance, social functioning and physical functioning compared with age matched averages from the USA. Three months after treatment these values had returned to normal, the gains were symmetrical. The improvement in both groups over time (pre and post intervention) were statistically significant ($p = 0.005$). Ogden 2001 found a 35% difference in the use of analgesia in the two groups of patients but only small differences in pain reduction (6%) and activity (1%).

DISCUSSION

The treatments for the painful heel which have undergone evaluation in randomised controlled trials are extracorporeal shock wave therapy, steroid injections, heel pads, orthoses and night splints.

Extracorporeal shock wave therapy has been evaluated in five randomised controlled trials using different doses (Buchbinder 2002; Ogden 2001; Rompe 1996a; Rompe 1996b; Krschek 1998). The results of the ESWT studies are equivocal; Ogden 2001 concludes that ESWT is more effective than placebo but only reports a mean difference of 6% (reduction in heel pain). In common with the report of the trial by Rompe 1996a, Ogden 2001 does not present measures of variance making alternative analyses of the data from these two placebo controlled trials difficult. The two trials evaluated different doses of active treatment of ESWT (Rompe 1996b; Krschek 1998). Rompe 1996b found that better outcomes were associated with the higher dose 3 X 1000 weekly, but in a smaller trial, Krschek 1998 did not detect a statistical difference between 3 x 100 impulses weekly or 3 x 10 impulses of ESWT weekly and is consistent with the findings of Buchbinder 2002. Buchbinder 2002 compared 3 x 2000-2500 impulses with 3 x 100 impulses

given at weekly intervals and found no statistically significant differences in the degree of improvement in the two groups for any of the measured outcomes namely: overall, morning and activity pain, walking ability, Maryland Foot Score, Problem Elicitation Technique and SF36 at six weeks and 12 weeks.

Steroid injections have been evaluated in five randomised controlled trials (Black 1996; Blockey 1956; Crawford 1999; Kriss 1990; Lynch 1998). The results from trials comparing steroid injections with placebo substances show either no advantage in the active substance or only a short term improvement over placebo. Blockey 1956 found no differences in pain reduction between the active treatment and placebo groups and Crawford 1999 only detected a statistically significant difference at one month. At outcomes taken at later times (3 and 6 months), no statistical differences in pain outcomes were detected although the authors note that the loss to follow up at 6 months was so high (50%), that it was not possible for them to reach conclusions about the effectiveness of the therapy at the longer outcomes. Patients who received a tibial nerve block prior to injection did not experience more comfort during the steroid injection procedure than those whose heels were not anaesthetised (Crawford 1999).

The relative effectiveness of steroid injections compared to heel pads and orthoses is unclear; Black 1996 found no evidence of greater effectiveness of pads over steroid injections but had a very small sample of patients. Even though statistical significance was not detected the group who received the viscogel pads had twice the pain reduction of the steroid injection group. Kriss 1990 found steroid injections alone to be statistically more effective than orthoses alone, or steroid injections plus orthoses at outcomes taken after one month. As outcomes were collected at longer times the effectiveness of the steroid injections diminished until no statistical differences were found at six months. These data also suggest the effectiveness of steroid injections is short term. Lynch 1998 did not find a statistical difference in pain reduction between steroid injections and heels cups or steroid injections and custom made orthoses. The differences in conclusions produced by the trial by Kriss 1990 and the trial by Lynch 1998 may be as a result of differences in the materials used to manufacture the orthoses: those used by Kriss 1990 were made from flexible materials whilst those used by Lynch 1998 were manufactured from rigid materials.

The results of the Pfeffer 1999 trial produced some evidence of the benefits of stretching exercises over prefabricated shoe inserts, but did not find stretching to produce greater reductions in pain over custom made orthoses.

The evidence for the effectiveness of night splints is not conclusive. Powell 1998 found evidence of effectiveness of a night splint which provided dorsi flexion (flexion) at the metatarsophalangeal joints of the toes. Probe 1999 was not able to detect a difference in pain reduction for people treated with a night splint dorsi flexed at the ankle and people treated with a combination of non-steroidal anti inflammatory drugs, stretching exercises and shoe modifica-

tions. We suggest two possible reasons for these observed data: different trial designs were used; cross over trials require that the condition under investigation is stable and not given to spontaneous fluctuations. The evidence from the randomised controlled trials in this review suggests that heel pain spontaneously recovers in a proportion of the population. Indeed the continued improvement in the heel pain of the participants in the cross over trial (Powell 1998) four months after the end of treatment with the night splint supports this view. The second possible explanation for the different conclusions from evaluations of night splints might be the differences in the design of the splints: dorsi flexion of the MTP joints (Powell 1998) would theoretically induce 'the windlass effect' (i.e. place tension on the elongated plantar fascia). This effect would not be achieved with dorsi flexion at the ankle joint (Probe 1999). More randomised evaluations of night splints which consider design issues (both trial design and splint design) are required to evaluate the effect of this treatment.

The review found some indirect evidence that patients' heel pain improves spontaneously (see Table 01). Patients in all trial arms improve regardless of their treatment allocation. This confirms the personal beliefs of some clinicians that the condition is self limiting for some patients (Singh 1997), and prescribed diagnostic investigations and management strategies should be considered in the light of this evidence .

The review included nineteen randomised controlled trials evaluating interventions for the management of heel pain. The quality assessment scores were generally poor and only one trial met all five quality criteria (see Characteristics of included studies table). The failure of the majority of authors to clearly report the concealment of the treatment allocation from the health professionals represents a serious threat to the validity of their conclusions. Health professionals who are involved in trials can influence patients' estimates of the effectiveness of treatment simply through interaction with patients when their own beliefs and expectations are (silently) communicated (Gracely 1985).

Standardisation of the tools used to measure outcomes would aid comparisons between therapies. All the trials included in this review used some version of a visual analogue scale in order to assess pain. Some authors additionally measure outcomes of questionable relevance. Nocturnal pain and resting pain in the heel are not well-documented common symptoms of heel pain, yet one trial collected these outcomes (Rompe 1996b). Greater use of tools to assess functional outcomes would be an important consideration in future trials. The reports of the trials also gave minimal information about the randomisation procedure and numbers lost to follow-up. Failure to report the randomisation procedure has been associated with over-estimates of treatment effects by reviewers of literature of pregnancy and childbirth (Schulz 1995).

None of the randomised controlled trials reported evaluations for athletes, patients with seropositive or seronegative rheumatological conditions, children or any other sub group within the population.

Little is therefore known about the response of these individuals to the treatments evaluated in the included studies.

The lack of reported standard deviations associated with mean pain scores and other outcomes made alternative analyses impossible for some trials. Although we wrote to authors who omitted this information, only two (Martin 2001; Rompe 1996b) responded to our request. We are therefore unable to produce relative risks or weighted mean differences for all trials.

All trials had small sample sizes which may have resulted in beneficial or detrimental effects being undetected. In future, trials evaluating treatments for the painful heel may need to be multi-centred to recruit enough patients to ensure adequate statistical power is achieved. Reports of all future trials should also include detailed summary statistics to enable pooling of data. Although all trialists used visual analogue scales of some description to assess patients' pain, the variety of tools used to measure secondary outcomes need to be standardised. We also suggest that journal editors and authors should be more aware of the CONSORT guidelines for the reporting of randomised controlled trials.

AUTHORS' CONCLUSIONS

Implications for practice

At the moment there is limited evidence upon which to base clinical practice. Treatments that are used to reduce heel pain seem to bring only marginal gains over no treatment and control therapies such as stretching exercises. Steroid injections are a popular method of treating the condition but only seem to be useful in the short term and only to a small degree. Extra corporeal shock wave therapy has been evaluated in five randomised trials four of which were conducted in Germany (Krischek 1998; Ogden 2001; Rompe 1996a; Rompe 1996b), where the therapy was developed. The equipment was distributed free to clinicians to undertake clinical trials (Fritze 1998). The strict criterion of a positive x-ray identification of a heel spur before including patients in these four trials limits the generalisability of the findings. It is also worth noting that ESWT was considered to be unpleasant by all patients (Rompe 1996b). Dissatisfaction has also been expressed with night splints with patients experiencing and inability to tolerate the device (Powell 1998).

Clinicians should refrain from using a tibial nerve block to anaesthetise the heel prior to performing a steroid injection. It does not appear to confer any additional comfort during the procedure.

There is limited evidence that stretching exercises are associated with better outcomes than prefabricated shoe inserts but not custom made orthoses.

Implications for research

More randomised controlled trials are needed to evaluate interventions to treat plantar heel pain. The subgroup analysis of people who stood for more than eight hours each day suggest that stretching exercises alone may be more effective in managing the condition than clinically established interventions (Pfeffer 1999). It is important that custom made orthoses undergo further evaluation to establish the true harms and benefits associated with this therapy in people with heel pain who stand for long periods. Indeed future trialists may consider collecting data on the length of time that trial patients stand each day. It would be worthwhile to also evaluate the effectiveness of stretching in a large placebo controlled RCT.

All randomised controlled trials included in the review contained dimensions associated with biased estimates of treatment effects as a result of either trial design or small sample sizes. Multi-centre trials should be considered to improve the statistical power of studies evaluating interventions for this condition. The quality of reporting of trials included in the review is generally poor and future trialists need to incorporate the items concerned with maintaining internal validity when designing RCTs. Some standardisation of outcomes used for the assessment of the painful heel would improve the homogeneity of data from trials. Incorporating binary outcomes into trials would help establish the proportions of people who are not cured by therapies.

POTENTIAL CONFLICT OF INTEREST

Fay Crawford was the principal investigator in two of the included studies in the review.

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* Indicates the major publication for the study

T A B L E S**Characteristics of included studies**

Study	Basford 1998
Methods	Randomisation: block randomisation into one of two groups. Allocation concealment: not clear. Assessor blinding: assessment performed by one of two blinded physicians. Loss to follow up: not clear. Intention to treat: No. QA score 2/5
Participants	Rochester MN, USA. Number of patients: 32 subjects entered the study

Characteristics of included studies (Continued)

Sex: 25 females, 7 males

Age: Control group median 42 (33 -51) treatment group median 42.5 (26 -64) years

Symptom duration: control group median 6.5 (0.5 -90) months, treatment group median 12.0 (3 -180) months.

Inclusion criteria: age 18 to 70, plantar fasciitis for more than 30 days.

Exclusion criteria: Treatment within the previous 30 days, recent change in activity, use of gluco corticoids, pre-menopausal females were required to use adequate birth control. Foot orthoses, analgesics, NSAIDs were permitted and analysed as a variable.

Interventions	<p>1. Low intensity laser. Irradiation with a 30 mW continuous wave 0.83 microns GaAlAs IR diode laser used for 33 seconds at the origin of the plantar fascia, and then 2 x 33 second sweeps along the medial border of the plantar fascia.</p> <p>2. Dummy laser. (All 'treatments' performed with a non energised probe). Both groups treated 3 x per week for 4 weeks.</p>
Outcomes	<p>Follow-up: session 6 (week 2) and session 12 (week 4) and 1 month after last treatment.</p> <p>1. Pain: 1000 mm VAS; first steps in the morning, duration of pain and effects of pain on daily activities.</p> <p>2. Distance walked before limping: findings only significantly different between groups in two categories; the control group could walk a significantly greater distance before limping at 1 month follow-up and this group experienced more pain with toe walking</p> <p>3. Orthotic use (no data)</p> <p>4. Side effects: Reported as negligible; 4% of patients reported minimal sensations before and after treatment.</p>
Notes	
Allocation concealment	B – Unclear

Study

Black 1996

Methods	<p>Randomisation: method not clear. Allocation concealment: not known. Assessor blinding: not stated. Loss to follow up: 3 (18%). Intention to treat: no. QA score 1/5</p>
Participants	<p>Northern Ireland. 17 patients entered the trial. Sex: 10 males and 4 females with 21 episodes of heel pain were retained. Age: range 21-73 years No differences in baseline age, duration of pain or initial pain scores. Exclusion criteria: rheumatoid arthritis.</p>
Interventions	<p>1. Triamcinolone (Lederspan) 20 mg with 2% plain lignocaine and advice to rest for 48 hours. 2. Viscoheel sofspot (a viscoelastic heel orthosis) 6mm thick with a lower dual durometer plug of 15 mm width placed to correspond with the medial calcaneal tubercle</p> <p>Co-interventions: all participants received an insole for both feet even when their condition was unilateral in order to avoid limb length discrepancies. Patients in the heel aid group were advised to change their shoes to accommodate the device as required.</p>
Outcomes	<p>Follow up: 1, 2 and 3 months.</p> <p>1. 10 cm VAS. Mean pain score before treatment with steroid = 6.4 which decreased to 4.0 after treatment. Mean pain score before treatment with heel pad =6.2 before treatment and reduced to 2.5 at follow up.</p> <p>2. Ritchie tenderness scale. Steroid group pre intervention = 1.90 and at 3 month follow up = 0.70 while the orthotic group 1.4 pre intervention and 0.5 at follow up.</p> <p>3. Adverse events: not reported.</p>

Characteristics of included studies (Continued)

Notes Only means reported, standard deviations unavailable.

Allocation concealment B – Unclear

Study **Blockey 1956**

Methods	Randomisation: not stated. Allocation concealment held by senior registrar. Assessor blinding: outcomes taken by consultant. Loss to follow-up: no. Intention to treat: no. QA score 2/5
Participants	Salford, UK 19 patients with 22 painful heels. Sex: 10 females and 9 males. Age: range 40-80 years, mean 55.7 years Exclusion criteria: patients with peri-articular joint pains; those in whom a local cause could be found; "abnormal" foot structure. (Patients with hallux valgus, hammer-toes and plantar callosity were included in the study).
Interventions	1. Plantar heel injection of 25 mg hydrocortisone acetate (steroid). 2. Saline injection. Co-interventions: All patients were also given a sponge heel pad.
Outcomes	Follow-up: 1, 2, 3 and 4 weeks and 6 months. Final assessments were made between 6 and 18 months. 1. Only primary outcomes were noted: the complete resolution of pain 2. Adverse events: reported no patients in either groups experienced adverse events.
Notes	Dichotomous outcomes only
Allocation concealment	B – Unclear

Study **Buchbinder 2002**

Methods	Randomisation: Computer generated numbers conveyed to single therapist by central telephone call (remote randomisation). Assessor blind: yes. Loss to follow-up: 5 (6%). Intention to treat: yes, baseline data given. Q/A score 5/5
Participants	Melbourne, Australia. 166 patients Sex: 93 females 68 male Age range Exclusion: general inflammatory arthropathy, wound lesion, pregnancy, severe infection, malignancy, bleeding disorder, pacemaker, previous heel surgery or previous ESWT Exclusion
Interventions	1. ESWT: 2-2500 impulses 3 x weekly treatments 2. ESWT: 100 impulses 3 x weekly treatments ESWT was applied using an experimental device, the Siemens Osteostar. Patients received 1000 impulses three times at weekly intervals or 10 impulses in the same period. Both at an energy flux density of 0.08 mJ/mm ² . All patients had the transducer head placed under the guidance of ultrasound which identified the origin of the plantar fascia adjacent to the calcaneum.

Characteristics of included studies (Continued)

Outcomes	Follow-up: 6 and 12 weeks. 1. Overall pain, morning and activity pain 2. Walking ability 3. Maryland foot score 4. Problem elicitation technique 5. SF36 Adverse events Pain for 1 week after treatment reported by one participant from each group. Heat and numbness was reported by 1 participant in the active group. A burning sensation in the heel by 1 participant in the placebo group. Bruising after the first treatment by a participant in the active group.
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Notes

Allocation concealment A – Adequate

Study Caselli 1997

Methods	Randomised: “randomly divided” between two groups. Allocation concealment: unknown. Assessor blinding: not stated. Loss to follow-up: 6 (15%). Intention to treat: no, baseline data not given for 6 excluded patients. QA score 1/5
Participants	New York, USA. Patients attending foot clinics were screened for plantar heel pain. 40 patients were recruited, results obtained for 34. Exclusion criteria: diabetes, peripheral vascular disease, rheumatoid arthritis, seronegative spondylopathy and allergy to any of the materials used to construct the insoles. Sex: 12 males and 22 females. Age: range 28 - 59 years
Interventions	1. PPT/Rx Firm Moulded insoles containing a Nikken magnetic foil placed in the heel. 2. PPT/Rx Firm Moulded Insole without the magnetic foil. Subjects were requested to wear an enclosed shoe. No co-interventions were used.
Outcomes	Follow-up: 4 weeks 1. Foot Function Index 2. Adverse events: Not reported
Notes	Baseline characteristics not given for all patients randomised. No standard deviations were reported.
Allocation concealment	B – Unclear

Study Crawford 1996

Methods	Randomisation: shuffled cards. Allocation concealment: envelopes held by independent observer. Assessor blinding: the ultrasound machine was covered with a drape by an independent observer to prevent the treatment allocation being revealed to the therapist who took outcome measurements. Loss to follow-up: all patients completed treatment. Intention to treat: not applicable. QA score 3/5
Participants	London, UK 19 patients with 26 episodes of heel pain. Sex: Treatment group: 7 males and 6 females Placebo group: 5 females and 8 male Age: treatment group 50 years (range 20-71), placebo group 55 years (range 20-79).

Characteristics of included studies (Continued)

	Exclusion criteria: those who had previously been treated with ultrasound, presence of fluffy calcaneal spur on x-ray, generalised joint pain the use of analgesics, heel pads or orthoses.
Interventions	1. Ultrasound at a dosage of 0.5 w/cm ² , pulsed 1:4, 3 Mz. for eight minutes. 2. Placebo ultrasound when only the timer was set. All patients received eight treatments in four weeks. 10 cm visual analogue pain scales.
Outcomes	Follow-up: week 0 (pre intervention) and at the end of 8 treatments (week 4). 1. 10 cm VAS. No differences in pain outcomes detected between the two groups. 2. Adverse events: not reported
Notes	Authors note the possibility of a Type II error due to the small sample size.
Allocation concealment	A – Adequate

Study	Crawford 1999
Methods	Randomisation: computer generated random letters. Allocation concealment: schedule held by independent observer and departmental secretary. Assessor blinding: yes. Loss to follow up: 1 month 4% 3 months 25% 6 months 48% Intention to treat: no. QA score 3/5
Participants	London UK 91 patients with 106 episodes of heel pain. Sex: 69 females and 37 males. Age: range 30 - 87 years, mean age 57 yrs (SD 12.9)
Interventions	1. 1 ml of 25 mg/ml prednisilone acetate with 1% lignocaine. 2. 1 ml of 25% prednisilone acetate with 1ml of 2% lignocaine given under a posterior tibial nerve block. 3. 2 ml 1% lignocaine 4. 2 ml 1% lignocaine given under a posterior tibial nerve block.
Outcomes	Follow-up at baseline, 1,3 and 6 months. Pain (2 types): 1. heel pain measured on a 10cm VAS at baseline 1,3 and 6 months. 2. injection pain measured on 10cm VAS
Notes	
Allocation concealment	A – Adequate

Study	Gudeman 1997
Methods	Randomisation: random assignment to one of two groups. Allocation concealment: Unknown. Assessor blinding: outcomes taken by a blinded assessor. Loss to follow-up: 3 (8%). Intention to treat: outcomes for loss to follow-up patients not stated. QA score 2/5
Participants	Location; USA. 39 patients recruited, results available for 36. Sex: 32 female and 7 male Age: mean 42.1 ± 13.6 year

Characteristics of included studies (Continued)

	Exclusion criteria: history of diabetes, foot tumour or foot trauma such as fracture.
Interventions	1. Traditional modalities and placebo plus iontophoresis (buffered saline) 2. Traditional modalities and dexamethasone (steroid) iontophoresis. All patients also received six sessions of ice and stretching programmes over a 2-3 week period.
Outcomes	Follow-up: pre treatment, post treatment (1 month) and follow-up (2 months). 1. Maryland Foot Score (MFS) 100 point scale, scores increase as pain decreases and other outcomes improve (gait, stability, limb motion, ability to climb stairs). 2. Adverse events not reported
Notes	
Allocation concealment	B – Unclear

Study	Krischek 1998
Methods	Randomisation: not clear. Allocation concealment: not stated. Assessor blinding: not stated. Loss to follow up: 2. Intention to treat analysis: not stated. QA score 1/5
Participants	Germany: university hospital. Sex: 32 females, 18 males Age: Group I: 35-74 Group II: 36-79 Exclusion criteria: trapped nerve and/or peripheral neuropathy, knee or ankle joint problems, tumour or inflammatory arthritic conditions, pregnancy, less than 18 years of age.
Interventions	1. ESWT: 3 x 500 impulses at 0.08 mj/mm ³ once weekly for 3 weeks. 2. ESWT: 3 x 100 impulses at 0.08 mj/mm ³ once weekly for 3 weeks.
Outcomes	Follow-up: 12 months Outcomes: VAS (pain) minutes of pain free walking satisfaction using three categorical outcomes. Adverse events: none observed.
Notes	
Allocation concealment	B – Unclear

Study	Kriss 1990
Methods	Randomisation: cards in sealed envelopes. Allocation concealment: unknown. Assessor blinding: not applicable. Loss to follow-up: 4 Intention to treat: not clear. QA score 2/5
Participants	London, UK. 80 patients entered the trial, 76 patients completed. 70 (92%) patients had pain for no more than 12 months. The median duration of pain is presented as 3.5 months for the pad and injection only groups and 6 months for the injection and pad group.
Interventions	1. Steroid injections

Characteristics of included studies (Continued)

	2. Orthoses 3. Both steroids and orthoses Exclusion criteria: foot pain which radiated along the plantar fascia. All patient's anti inflammatory medication was stopped at least six weeks prior to the beginning of the study.
Outcomes	Follow up: 1, 4, 8, 12 and 24 weeks. 1. 100 mm VAS. 2. Adverse events: not reported
Notes	This work is an unpublished MPhil dissertation. The study lacks a control group.
Allocation concealment	B – Unclear

Study	Lynch 1998
Methods	Randomisation: not stated. Allocation concealment: not blind. Assessor blinding: not stated. Loss to follow-up: 18 patients lost to follow-up, additional 25 refused further treatment. Intention to treat analysis: no. QA score 1/5
Participants	USA. 103 patients enrolled. Sex: not stated. Age: 19 - 81 years (average 49). Duration of pain: left feet 46 weeks, right feet 26.5 weeks. Exclusion criteria: any self or professional treatment one month prior to entering the study, no radiological abnormalities.
Interventions	1. Anti inflammatory therapy 0.5 ml of dexamethasone sodium phosphate 4 mg/ml with 1 ml of 0.5% bupivacaine hydrochloride. Patients also took two 300 mg capsules of etodolac per day. After 2 weeks and 4 weeks patients with poor outcomes received a second injection. 2. A visco elastic heel cup and acetaminophen on an as needed basis. 3. Mechanical therapy from a custom-made orthosis after 4 weeks of strapping.
Outcomes	Follow-up: 2, 4, 6 weeks and 3 months. 1. Pain: 0-10 visual analogue scale to measure pain. 2. At the final outcome patients were asked to assess their condition as excellent, fair or poor. 3. Leisure: participants were asked to rate the effect of heel pain a) no effect, b) minimal effect c) occasional effect and d) constant effect. 4. Work (assessed as above). 5. Exercise (assessed as above). 6. First-step pain was assessed as a) none b) minimal c) occasional d) constant.
Notes	
Allocation concealment	B – Unclear

Study	Martin 2001
Methods	Randomisation: not stated. Allocation concealment: not stated. Assessor blinding: not stated. Loss to follow-up: 24%.

Characteristics of included studies (Continued)

	Intention to treat: no. QA score 1/5
Participants	USA. 255 recruited. 62 (24%) loss to follow-up. Sex: 195 females and 60 males. Age: average 47 years. Exclusion criteria: heel pain consistent with a diagnosis of bursitis, tendinitis, or neurological pain, received treatment within the previous month, radiological heel abnormalities.
Interventions	1. Custom made orthoses. 5mm polydur plastic material. 2. Over the counter arch supports made from rigid plastic. 3. Posterior tension night splint with 5° of dorsiflexion.
Outcomes	Follow-up: 12 weeks. 1. First-step pain using VAS (0-10). Excellent, good and poor: 0-2 = Excellent 3-5 = good 6-10 =Poor
Notes	
Allocation concealment	B – Unclear

Study **Nolan 1990**

Methods	Randomisation: randomly divided between two groups. Allocation concealment: codes held by third party. Assessor blinding: yes. Loss to follow-up: 17%. Intention to treat: no baseline data given for excluded patients. QA score 3/5
Participants	London, UK. 27 patients. Age: range 20 to 67 years. Exclusion criteria: recent history of injury, treatments with systemic therapies likely to mask the condition, pregnancy, patients inability to give informed consent.
Interventions	1. Functioning experimental device designed to deliver electrons. 2. Disabled version of device. Patients performed self treatment at home after demonstration from same therapist.
Outcomes	Follow-up: 21 days. 1. 10cm VAS; patients kept pain diary. 2. Adverse events: not reported
Notes	
Allocation concealment	A – Adequate

Study **Ogden 2001**

Methods	Randomisation: not stated. Allocation concealment: not concealed from clinician but concealed from the assessor. Assessor blinding: yes. Loss to follow-up: 1.5%. Intention to treat analysis: no. QA score: 1/5
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Characteristics of included studies (Continued)

Participants	North America. Number of patients: 260 Sex: female 66%, males 44%. Age: mean 50 years, range 20 to 79 years. Duration of symptoms: treatment group mean 2.65 years, placebo group mean 2.95 years. Exclusion: history of plantar fascial surgery, other pathophysiologies, neurologic -vascular or metabolic diseases, steroid induced rupture of plantar fascia.
Interventions	Both groups received an ankle block injection. 1. ESWT: 1500 shocks at an 18 kV power setting. 2. Placebo ESWT: a styrofoam block was placed against the treatment head and a fluid filled bag was placed between the styrofoam block and the subjects heel.
Outcomes	Follow-up: 1. Investigator heel pain assessment: pressure sensor applied to the site of maximum sensitivity. Minimum 50% improvement over baseline with a VAS score of 4.0 or greater. 2. Subject self assessment of pain: minimum of 50% improvement over pre-treatment baseline score of 4.0 or greater. 3. Subjects self assessment of pain on first walking in the morning: minimum of 50% improvement over pre-treatment baseline and a VAS score of 4.0. 4. Subjects self assessment of activity: distance measured without heel pain: improvement of one point on a five point scale, or maintain a 0/1 baseline level (no pain minimal pain). 5. Use of pain medications: no prescription analgesics were given after treatment. If patient self-treated with over the counter analgesic medications it was noted.
Notes	
Allocation concealment	B – Unclear

Study Pfeffer 1999

Methods	Randomisation: method of randomisation not stated. Allocation concealment: not stated. Assessor blinding: not stated. Loss to follow-up: 36. Intention to treat: no. QA score 1/5
Participants	Multicentre trial North America. Number of patients: 236 Sex: 160 females, 76 males. Age: mean 47 years, range 23 to 81. Duration of symptoms: the majority of patients had heel pain for 2 to 3 months across all treatment groups. Exclusion criteria: previous treatment for the condition, under 16 years of age.
Interventions	All groups had the control intervention in addition to the active allocation. 1. Control intervention: Achilles tendon and plantar fascia stretching for 10 minutes x 2 daily. 2. A silicone heel pad + stretching 3. A felt insert + stretching 4. A custom made polypropylene orthosis + stretching.

Characteristics of included studies (Continued)

Outcomes	<p>Follow-up: 8 weeks post intervention.</p> <p>1. Pain: a sub-scale of the foot Function Index</p> <p>2. Patients rated their heel pain as;</p> <p>a) all better</p> <p>b) much better</p> <p>c) slightly better</p> <p>d) unchanged</p> <p>e) worse</p>
Notes	
Allocation concealment	B – Unclear

Study	Powell 1998
Methods	<p>Randomisation: computer generated.</p> <p>Allocation concealment: not concealed.</p> <p>Assessor blinding: assessor not blind.</p> <p>Loss to follow-up: 7 (18%).</p> <p>Intention to treat: no.</p> <p>QA score 1/5</p>
Participants	<p>USA.</p> <p>Number of patients: 37 Number of episodes: 52.</p> <p>Sex: Group A: 4 males and 18 females</p> <p>Group B: 4 males and 11 females.</p> <p>Age: Group A: mean 46.7 (sd 2.8 years).</p> <p>Group B: mean 49.5 (sd 2.5 years).</p> <p>Duration of symptoms: mean 33.4 months.</p> <p>Inclusion criteria: heel pain > 6 months, pain described as severe first thing in the morning, with standing, prolonged sitting or with prolonged standing, tenderness localised to the origin of the plantar fascia on the medial tubercle of the calcaneus and failure of non-surgical treatment such as NSAIDs, orthoses, heel cups, activity modification, weight loss, steroid injections, physical therapy, casting and taping.</p> <p>Exclusion criteria: previous surgery to foot or lumbar sacral spine, specific metabolic or connective tissue disorders associated with the diagnosis of heel pain, ankylosing spondylitis, RA, gout, lupus or Reiter's disease, and radiographic evidence of local pathology other than plantar fasciitis.</p>
Interventions	<p>Cross over study. In intervention month patients received:</p> <p>1. night splint made of polypropylene with the ankle placed in 5 degrees of dorsiflexion. Foam was used distally on the splint to give 30 degrees dorsiflexion at the MTP joints.</p> <p>2. No treatment</p>
Outcomes	<p>Follow-up: 30 days, 60 days and 6 months.</p> <p>1. 10 cm visual analogue pain scales</p> <p>2. Patient interviews to establish walking distance, function, footwear and orthotic requirements.</p> <p>3. Physical examination evaluation of gait, ankle motion, plantar heel tenderness, presence or absence of neuropathy, and pain associated with the windlass manoeuvre.</p> <p>4. A foot 'type' assessment.</p> <p>5. Mayo Clinical scoring system (MCSS).</p> <p>6. Adverse events: 19% of patients were dissatisfied with the device.</p> <p>7. Ankle hindfoot rating system (AHRS)</p>
Notes	
Allocation concealment	B – Unclear

Study	Probe 1999
Methods	Randomisation:

Characteristics of included studies (Continued)

	<p>computer generated randomisation. Allocation concealment: not stated. Assessor blinding: yes. Loss to follow-up: 6. Intention to treat: no. QA score 3/5</p>
Participants	<p>Teaching hospital in North America. Number of patients: Sex: 81 females, 35 males. Age: 46 (SD 11 years). Duration of symptoms: 19 weeks. Exclusion criteria: previous hind foot surgery, systemic illness, heel pain due to fat pad atrophy, nerve entrapment.</p>
Interventions	<p>1. Ankle dorsi flexion exercises 10 x 10 seconds x 3 per day for 3 months + piroxicam 20 mg daily. Shoes with supportive arches. 2. As above plus a night splint with 5° ankle dorsiflexion for use at night during sleep.</p>
Outcomes	<p>Follow-up: 4, 8 and 12 weeks, then between 12 and 28 months. 1. Subjective pain scales: none, mild, moderate and severe. 2. SF36 3. Mailed questionnaire for long term outcomes.</p>
Notes	
Allocation concealment	B – Unclear

Study	Rompe 1996a
Methods	<p>Randomisation: randomly allocated. Allocation concealment: equipment did not touch patients in the placebo group. Assessor blinding: Loss to follow up: yes, all placebo patients after 6 weeks Intention to treat: Yes QA score 3/5</p>
Participants	<p>Location: Germany 36 patients originally recruited, six patients withdrew during follow-up. 15 patients received ESWT : 5 female and 10 males, 15 patients received placebo ESWT : 6 females and 9 males Age: Treatment group: range 47 years (range 26 - 61); Placebo group: 51 years (range 31 - 58 years). Duration of pain: Treatment group: median 16 months (12-64 months); Placebo group: median 22 months (12-38 months). Inclusion criteria: pain over a radiologically proven calcaneal spur. Exclusion criteria: dysfunction in the knee or the ankle, local arthritis, generalised poly-arthritis, rheumatoid arthritis, ankylosing spondylitis, Reiter's syndrome, neurologic abnormalities, nerve entrapment, age under 18 years, pregnancy, infectious or tumorous disease</p>
Interventions	<p>1. ESWT device made contact with feet in the treatment group (energy density was 0.06mJ/mm² three times in weekly intervals). 2. ESWT device did not make contact with feet in the placebo group.</p>
Outcomes	<p>Follow-up: 3, 6, 12 and 24 weeks after the last application. 1. 100mm VAS. 2. Digital scales were used to measure pain-free plantar pressure. 3. Pain-free walking ability was measured according to six ratings; 0 = less than 5 minutes, 1 = less than 15 minutes, 2 = less than 30 minutes, 3 = less than 45 minutes, 4 = less than 60 minutes, 5 = more than 60 minutes.</p>

4. Patients were asked to define their improvement using the following system; 1 = no pain, 2 = symptoms improved, 3 = symptoms identical, 4 = symptoms increased.
5. Adverse events: not reported

Notes	After 6 weeks all placebo treatments ceased and all patients from that allocation were given true ESWT until the end of the study. Thus only outcomes at 3 and 6 weeks are reported in this review. No summary statistics are reported.
Allocation concealment	B – Unclear

Study Rompe 1996b

Methods	Patients randomised into two groups using sealed numbered envelopes. Allocation concealment: No Assessor blinding: Yes Loss to follow-up: 16% Intention to treat: Not applicable QA score 3/5
Participants	Department of Orthopaedics Germany. 119 patients entered and 100 patients completed the study. Inclusion criteria: painful heel for more than six months. Exclusion criteria: problems with knee or ankle, local arthritis, generalised polyarthritis, rheumatoid arthritis, ankylosing spondylitis, Reiter's syndrome, neurological abnormalities, nerve entrapment syndrome, aged under 18, pregnancy, infections and tumours.
Interventions	Using an experimental device: Extra corporeal shock wave therapy (Siemens Osteostar, Siemens AG, 91052). 1. 3 x at weekly intervals 1000 impulses of shock waves. 1. 3 x at weekly intervals 10 impulses of shock waves.
Outcomes	Follow-up: 12 weeks. Outcomes taken at 52 weeks confounded by protocol deviation after 12 weeks. 1. 100mm VAS at weeks 0 and 12 used to assess night pain, resting pain, and pain on manual pressure. 2. Pain-free walking ability was measured according to six ratings; 0 = less than 5 minutes, 1 = less than 15 minutes, 2 = less than 30 minutes, 3 = less than 45 minutes, 4 = less than 60 minutes, 5 = more than 60 minutes. 3. Pain was also assessed using an excellent, good, fair, poor scale. 4. Adverse events: concludes that ESWT is considered to be unpleasant by all patients but not more unpleasant than local infiltration. However it is not clear how many of the patients had experienced local infiltration.
Notes	26% of patients in the treatment group required further treatment at the end of the study.
Allocation concealment	B – Unclear
ESWT: extracorporeal shock wave therapy PPT/Rx Firm Moulded Insoles: trade name QA: quality assessment VAS: visual analogue scale	

Characteristics of excluded studies

Study	Reason for exclusion
Batt 1996	Group outcomes assessed at different times.
Fauno 1993	Evaluated heel pads in the prevention rather than the treatment of heel pain.
Hammer 2002	Confusion regarding the two treatment groups. Both groups were given ESWT, group one immediately and group two after two weeks of conservative management. Not possible to compare the effect of ESWT in these two groups.
Noble 1981	Presented the data combined for 17 conditions, of which heel pain was one.

Characteristics of excluded studies (Continued)

Rompe 2002	Five year outcomes of included trial (Rompe 1996b), however these patients cannot be included because of the potential confounding effect of additional treatments (including corticosteroid infiltrations and surgery) that unresponsive patients in both groups could receive in the original 1996 (b) trial.
Torkki 2002	Doesn't separate the data for painful heels, so it is combined with other musculoskeletal conditions.
Turlik 1999	This RCT is a patient preference trial but hasn't been analysed as such. There is a risk of confounding from adjunctive therapies namely NSAIDs and steroid injections which patients were able to request in addition to the experimental therapy which was a shoe insert.

ADDITIONAL TABLES

Table 01. Overview of outcomes from all included trials

Author	Interventions	Treat' group outcome	Contr' group outcome	Contr' group outcome	Stat significance
Rompe 1996b	Extracorporeal shock wave therapy: 1000 vs 10 impulses	Improved	Improved		Yes
Basford 1998	Lasers vs placebo	Improved	Improved		No
Black 1996	Steroids vs pads	Improved	Improved		No
Blockey 1956	Steroids vs steroids	Improved	Improved		No
Caselli 1997	Insoles vs insoles with magnetic foil	Improved	Improved		Yes
Crawford 1996	Ultrasound vs placebo	Improved	Improved		No
Crawford 1999	Steroid injection vs local anaesthetic	Improved	Improved		Yes (at one month)
Gudeman 1996	Iontophoresis and saline vs iontophoresis and steroids	Improved	Improved		Yes (at one month)
Kriss 1990	Steroids vs insoles alone, steroids + insoles vs steroids alone, steroids + steroids vs insoles alone	Improved	Improved		Yes
Krischek 1998	Extracorporeal shock wave therapy: 3x500 impulses or 3x100 impulses	Improved	Improved		Yes (at 3 months)
Lynch 1998	Steroid injections vs pads vs custom made orthoses	Improved	Improved	Improved	No
Martin 2001	Custom made orthoses vs over-	Improved	Improved	Improved	Yes (comparison between heel pads)

Table 01. Overview of outcomes from all included trials (Continued)

Author	Interventions	Treat' group outcome	Contr' group outcome	Contr' group outcome	Stat significance
	the-counter-arch supports vs tension night splints				and custom made orthoses and tension night splints
Nolan 1990	Bioelectron MK II vs placebo	Improved	Improved		No
Ogden 2001	Extracorporeal shock wave therapy: 1500 shocks at 18kV vs placebo	Improved	Improved		No clear
Pfeffer 1999	Pad vs custom made insoles vs stretching exercises	Improved	Improved	Improved	Yes
Powell 1998	Night splints	Improved	Improved		Yes
Probe 1999	Night splints vs stretching exercises	Improved	Improved		No
Rompe 1996a	Extracorporeal shock wave therapy vs placebo	Improved	Improved		Yes
Buchbinder 2002	Extracorporeal shock wave therapy vs placebo	Improved	Improved		No

Table 02. Quality assessment scores

Author	Method of random	Allocation conceal	Assessor blind	Loss to follow-up	ITT analysis	QA score
Basford 1998	Block randomisation	Not clear	Yes	No	No	2/5
Black 1996	Not clear	Not clear	Not clear	3 (18%)	No	1/5
Blokey 1956	Not clear	Yes	Yes	No	No	2/5
Buchbinder 2002	Computer generated numbers	Remote randomisation	Yes	5 (6%)	Yes	5/5
Caselli 1997	Not clear	Not clear	Not clear	6 (15%)	No	1/5
Crawford 1996	Shuffled cards	Cards held by independant observer	Yes	No	No	3/5
Crawford 1996	Computer generated random letters	Schedule held by independent observer and departmental	Yes	1 month 4%, 3 months 25%, 6 months 48%	No	3/5

Table 02. Quality assessment scores (Continued)

Author	Method of random	Allocation conceal	Assessor blind	Loss to follow-up	ITT analysis	QA score
		secretary				
Gudeman 1997	Not clear	Not clear	Yes	3 (8%)	No	2/5
Krischek 1998	Not clear	Not clear	Not clear	2	Not clear	1/5
Kriss 1990	Cards in envelopes	Not clear	Not applicable	4	Not clear	2/5
Lynch 1998	Not clear	Not blind	Not clear	18 + further 25 refused treatment	No	1/5
Martin 2001	Not clear	Not clear	Not clear	24%	No	1/5
Nolan 1990	Not clear	Codes held by 3rd party	Yes	17%	No	3/5
Ogden 2001	Not clear	Not concealed from the clinician	Yes	1.5%	No	1/5
Pfeffer 1999	Not clear	Not clear	Not clear	36	No	1/5
Powell 1998	Computer generated schedule	Not blind	No	7 (18%)	No	1/5
Probe 1999	Computer generated schedule	Not clear	Yes	6	No	3/5
Rompe 1996a	Not clear	Not blind	Not clear	all placebo patients after 6weeks	Yes	1/5
Rompe 1996b	Sealed envelopes	No	Yes	16%	Not applicable	3/5

ANALYSES

Comparison 01. 25mg hydrocortisone versus saline solution

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 No relief of pain	1	22	Relative Risk (Fixed) 95% CI	0.52 [0.15, 1.78]

Comparison 02. Therapeutic ultrasound versus placebo ultrasound

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Pain: change in Visual Analogue Scale scores (100 mm)	1	26	Weighted Mean Difference (Fixed) 95% CI	0.15 [-1.89, 2.19]

Comparison 03. Steroid injection versus orthosis

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Pain: change in Visual Analogue Scale scores (100 mm)	1	48	Weighted Mean Difference (Fixed) 95% CI	-45.01 [-59.12, -30.90]

Comparison 04. Steroid injection and orthosis versus steroid injection

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Pain: change in Visual Analogue Scale scores (100 mm)	1	50	Weighted Mean Difference (Fixed) 95% CI	16.00 [0.72, 31.28]

Comparison 05. Steroid injection and orthosis versus orthosis

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Pain: change in Visual Analogue Scale scores (100 mm)	1	54	Weighted Mean Difference (Fixed) 95% CI	-29.01 [-44.38, -13.64]

Comparison 06. Bioelectron MKII (electrons)

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Pain: change in Visual Analogue Scale scores (100 mm)	1	25	Weighted Mean Difference (Fixed) 95% CI	-0.85 [-3.11, 1.41]

Comparison 07. Iontophoresis of 0.4% Dexamethasone versus placebo

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Maryland Foot Score (100 point max): change immediately after intervention	1	40	Weighted Mean Difference (Fixed) 95% CI	3.80 [0.76, 6.84]
02 Maryland Foot Score (100 point max): change after one month	1	40	Weighted Mean Difference (Fixed) 95% CI	2.30 [-2.16, 6.76]

Comparison 08. Extracorporeal shock wave therapy

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Night pain: change in VAS at 12 weeks	1	100	Weighted Mean Difference (Fixed) 95% CI	-18.13 [-21.93, -14.33]
02 Resting pain: change in VAS at 12 weeks	1	100	Weighted Mean Difference (Fixed) 95% CI	-16.72 [-21.68, -11.76]

03 Pressure pain: change in VAS at 12 weeks	1	100	Weighted Mean Difference (Fixed) 95% CI	-47.30 [-54.38, -40.22]
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Comparison 09. Steroid injection versus local anaesthetic

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Pain: change in VAS at 1 month	1	106	Weighted Mean Difference (Fixed) 95% CI	-1.94 [-3.06, -0.82]
02 Pain: change in VAS at 3 months	1	102	Weighted Mean Difference (Fixed) 95% CI	-0.90 [-2.62, 0.82]
03 Pain: change in VAS scores at 6 months	1	102	Weighted Mean Difference (Fixed) 95% CI	0.20 [-1.08, 1.48]

Comparison 10. Custom orthosis versus stretching exercises

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Pain: change in visual analogue scale for people who stand < 8 hrs per day.	1	25	Weighted Mean Difference (Fixed) 95% CI	-15.60 [-20.54, -10.66]
02 Pain: change in visual analogue scores for people who stand > 8 hrs per day	1	18	Weighted Mean Difference (Fixed) 95% CI	26.90 [14.92, 38.88]

Comparison 11. Over the counter arch supports versus night splint

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Pain: changes in visual analogue scores	1	122	Weighted Mean Difference (Fixed) 95% CI	0.40 [-0.66, 1.46]

Comparison 12. Custom-made orthoses versus night splints

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Pain: changes in visual analogue scores	1	131	Weighted Mean Difference (Fixed) 95% CI	0.60 [-0.43, 1.63]

Comparison 13. Custom made orthoses versus over-the counter arch supports

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Pain: changes in visual analogue scores	1	133	Weighted Mean Difference (Fixed) 95% CI	0.20 [-0.82, 1.22]

Comparison 14. Steroid injection versus heel cup

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Pain: change in visual analogue scales (0 to 10)	1	57	Weighted Mean Difference (Fixed) 95% CI	-1.20 [-2.79, 0.39]

Comparison 15. Steroid injection versus custom-made orthoses

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Pain: change in visual analogue scores (0 to 10)	1	59	Weighted Mean Difference (Fixed) 95% CI	1.00 [-0.56, 2.56]

Comparison 16. 3 x 500 impulses ESWT versus 3 x 100 impulses ESWT

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Pain on walking: change in VAS at 6 weeks	1	50	Weighted Mean Difference (Fixed) 95% CI	-0.90 [-2.54, 0.74]

Comparison 17. Custom made orthoses versus stretching

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Heel pain better/ heel pain not better	1	73	Odds Ratio (Fixed) 95% CI	0.82 [0.30, 2.24]

Comparison 18. Prefabricated shoe inserts versus stretching

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Heel pain better/ heel pain not better	1	166	Odds Ratio (Fixed) 95% CI	2.93 [1.22, 7.08]

Comparison 19. Night splints with oral anti inflammatory drugs, stretching exercises and shoe recommendations

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Frequency of heel pain improvement	1	113	Odds Ratio (Fixed) 95% CI	1.12 [0.51, 2.45]

Comparison 20. tibial nerve block prior to steroid injection versus no tibial nerve block prior to steroid injection

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 100 mm VAS for pain at time of heel pain injection	1	102	Weighted Mean Difference (Fixed) 95% CI	0.25 [-0.67, 1.17]

Comparison 21. Ultrasound guided ESWT 2000 or 2500 shock waves versus placebo ESWT 100 shock waves once weekly times 3

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Over all pain change in VAS at 6 weeks	1	161	Weighted Mean Difference (Fixed) 95% CI	-1.90 [-11.83, 8.03]
02 Over all pain change in VAS at 12 weeks	1	160	Weighted Mean Difference (Fixed) 95% CI	0.60 [-10.20, 11.40]
03 Morning pain change in VAS at 6 weeks	1	161	Weighted Mean Difference (Fixed) 95% CI	-0.60 [-12.07, 10.87]

04 Morning pain change in VAS at 12 weeks	1	160	Weighted Mean Difference (Fixed) 95% CI	0.20 [-12.65, 13.05]
05 Activity pain change in VAS at 6 weeks	1	161	Weighted Mean Difference (Fixed) 95% CI	-5.70 [-15.87, 4.47]
06 Activity pain change in VAS at 12 weeks	1	160	Weighted Mean Difference (Fixed) 95% CI	-1.50 [-12.85, 9.85]

INDEX TERMS

Medical Subject Headings (MeSH)

Adrenal Cortex Hormones [therapeutic use]; Electromagnetics; Foot Diseases [*therapy]; Lasers [therapeutic use]; Orthotic Devices; Pain [*therapy]; Pain Measurement; Randomized Controlled Trials; Ultrasonic Therapy

MeSH check words

Adult; Humans

COVER SHEET

Title	Interventions for treating plantar heel pain
Authors	Crawford F, Thomson C
Contribution of author(s)	<p>Fay Crawford initiated the review, developed the protocol, produced the data extraction tool, ran the electronic searches, searched the reference lists and located the papers. She was one of two reviewers who extracted data from the RCTs included in the review and entered it into RevMan. Dr Crawford corresponded with authors of the included RCTs where necessary and wrote all drafts of the review.</p> <p>Colin Thomson acted as the second reviewer. He applied the inclusion/exclusion criteria to the identified trials and data extracted from the included RCTs. He wrote all drafts of the review. He responded to the peer reviewer's comments. Both authors are guarantors of the review.</p> <p>For the first version of the review, published in Issue 3, 2000, Dr Crawford's co-reviewers were Mr David Atkins and Prof Jo Edwards. Mr Atkins acted as the second reviewer, extracted data from included RCTs and handsearched The Foot. Prof Edwards contributed to the interpretation of the data and the write-up of the review.</p>
Issue protocol first published	1997/2
Review first published	2000/3
Date of most recent amendment	23 July 2003
Date of most recent SUBSTANTIVE amendment	08 May 2003
What's New	<p>The main changes for the first update of this review, published Issue 3, 2003, were:</p> <ol style="list-style-type: none"> 1. Date of search for trials was extended to September 2002. 2. Eight new studies (Buchbinder 2002; Crawford 1999; Krischek 1998; Lynch 1998; Martin 2001; Ogden 2001; Pfeffer 1999; Probe 1999) were included. 3. There was no substantive change to the conclusions of the review.
Date new studies sought but none found	Information not supplied by author
Date new studies found but not yet included/excluded	Information not supplied by author

Date new studies found and included/excluded Information not supplied by author

Date authors' conclusions section amended Information not supplied by author

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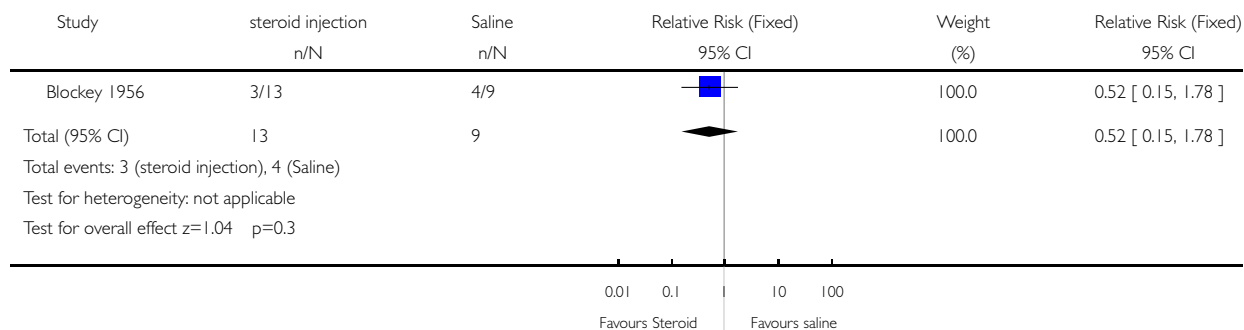
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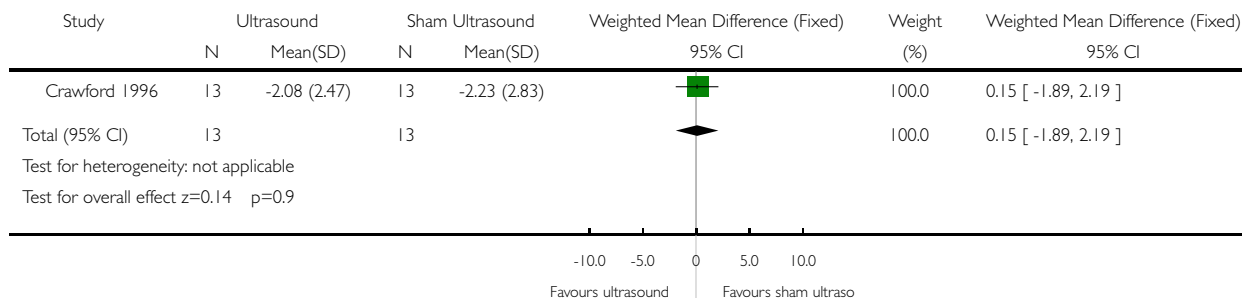
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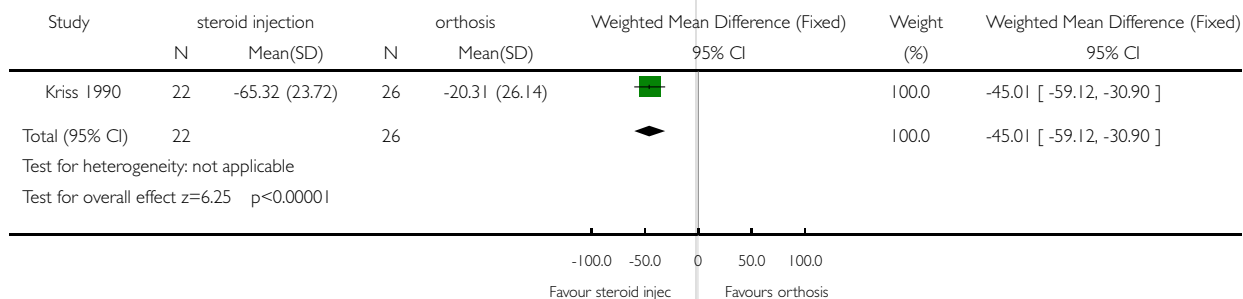
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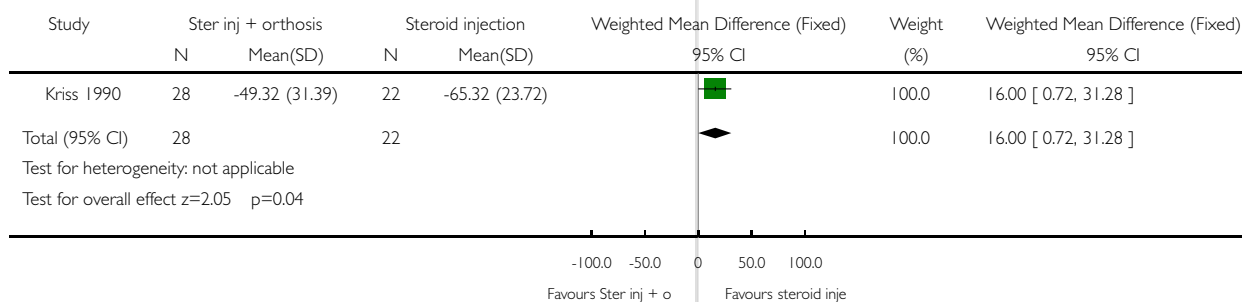
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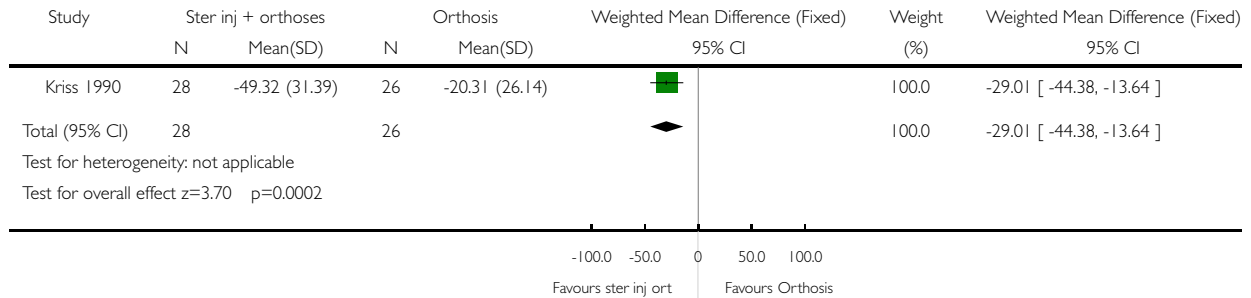
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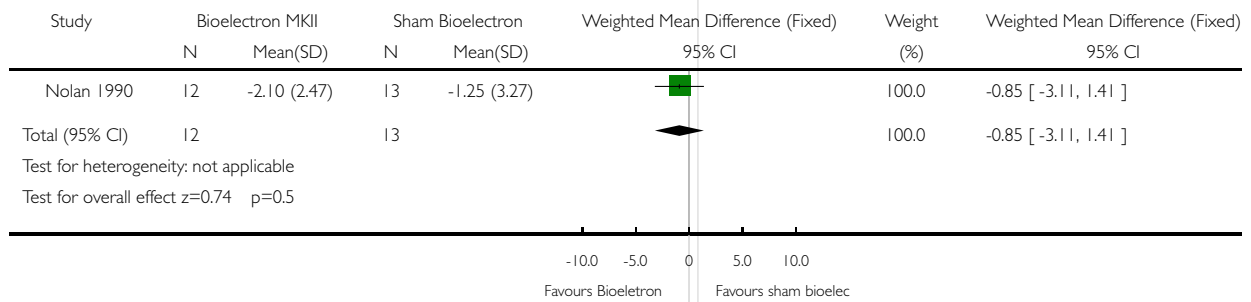
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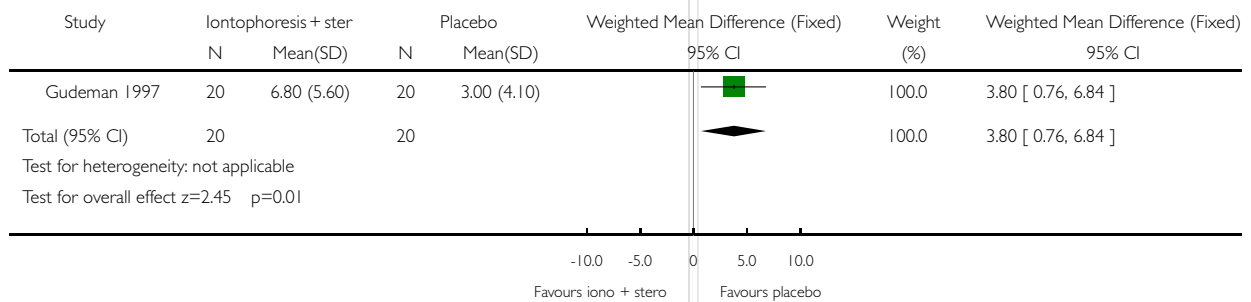
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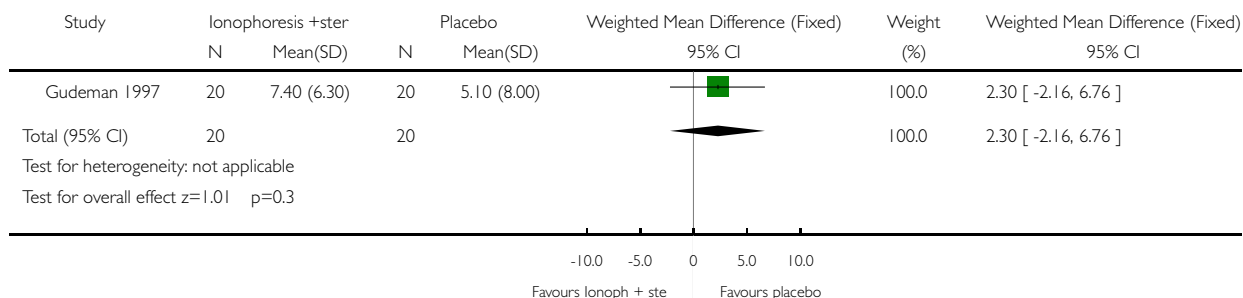
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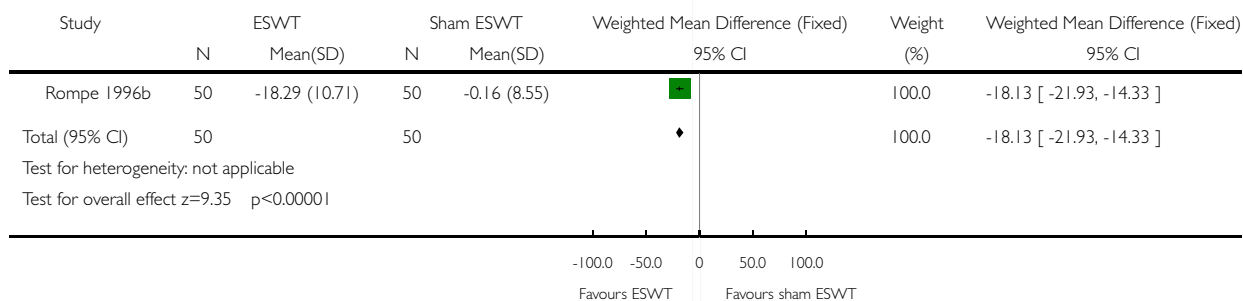
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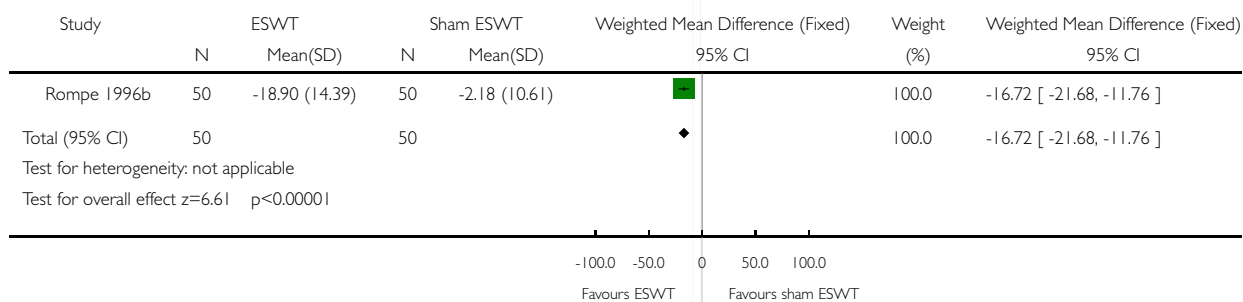
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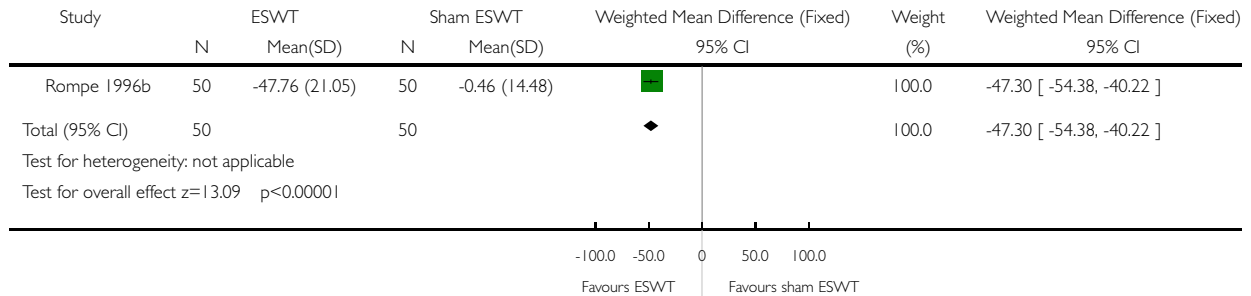
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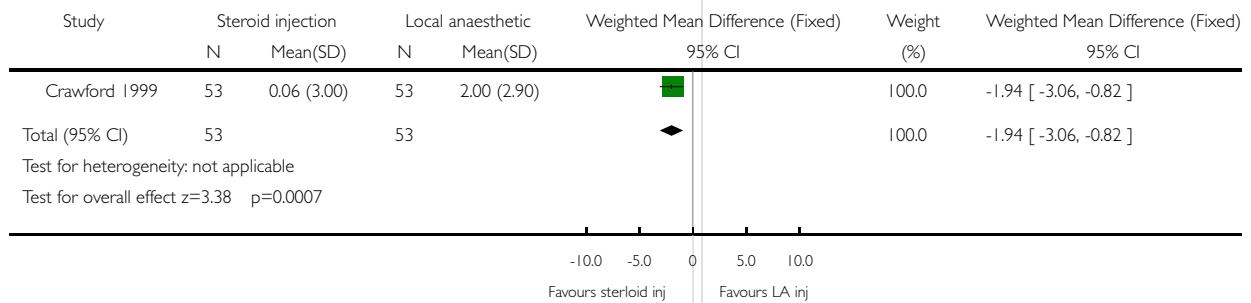
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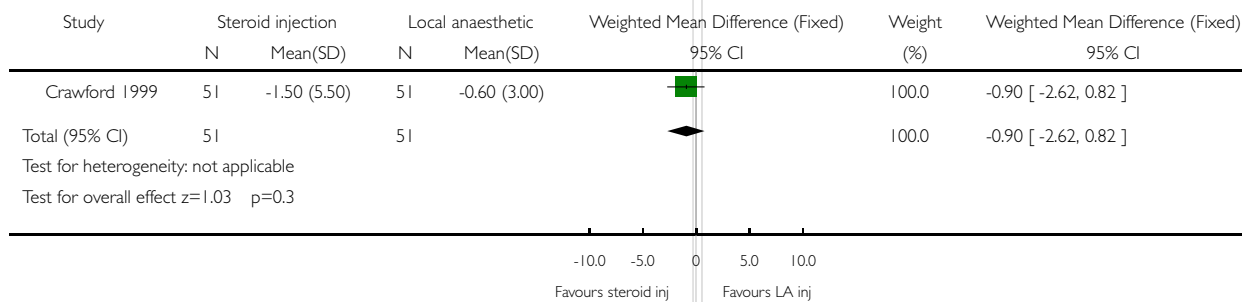
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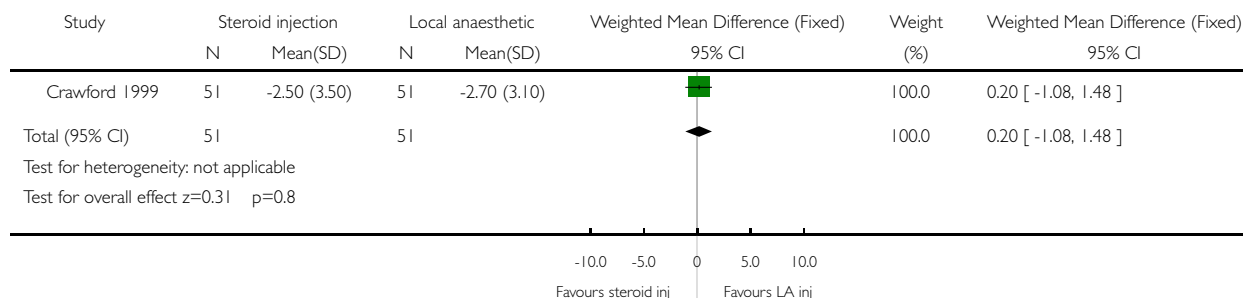


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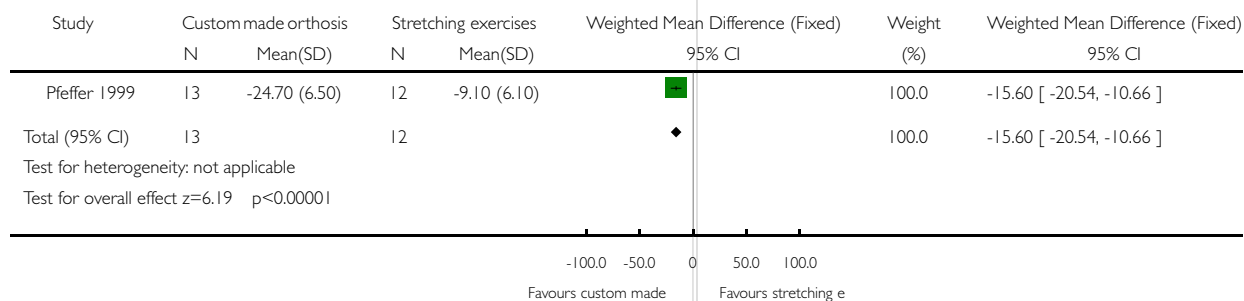


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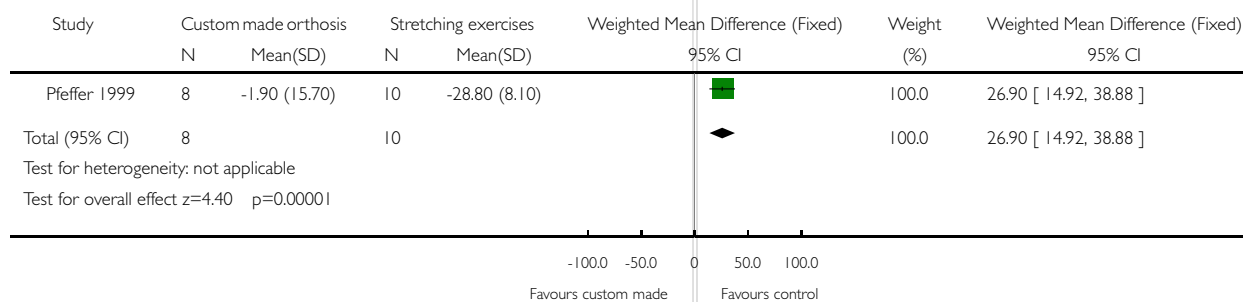


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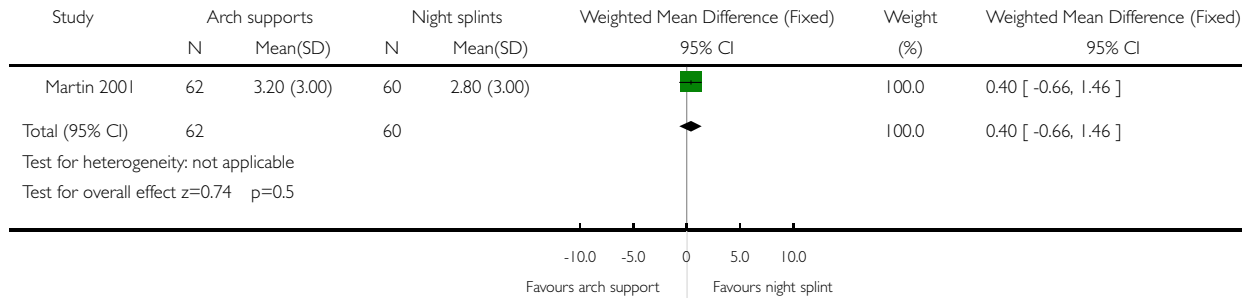
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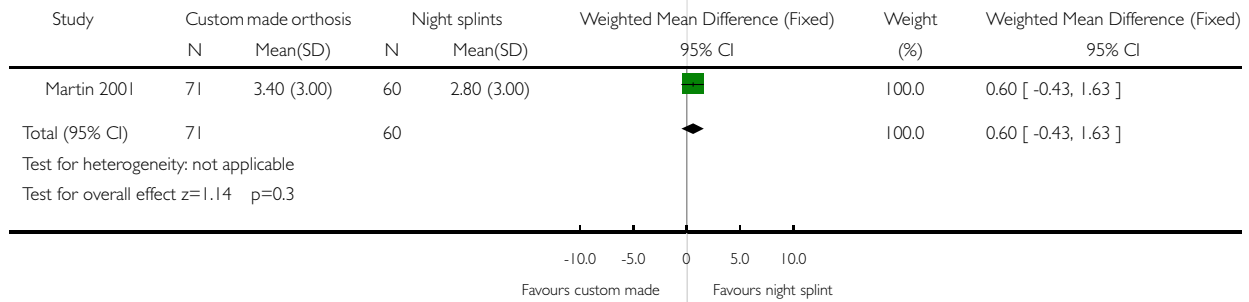
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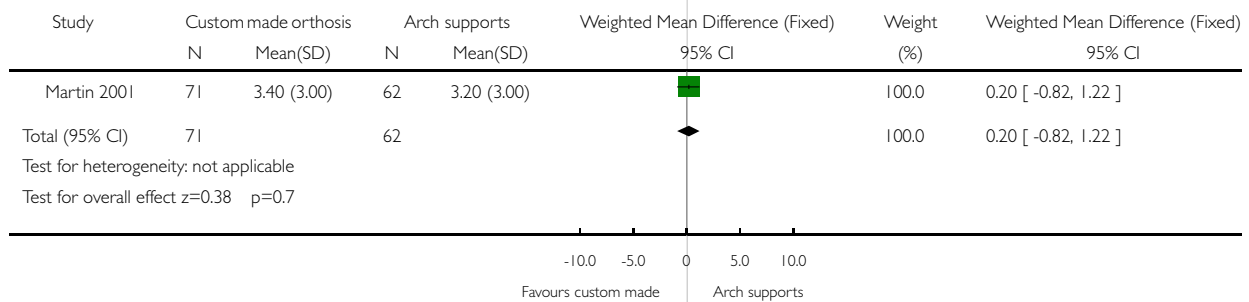
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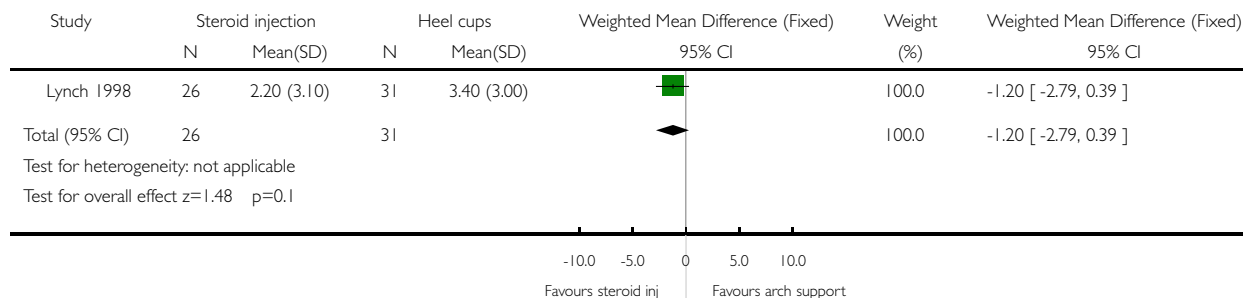
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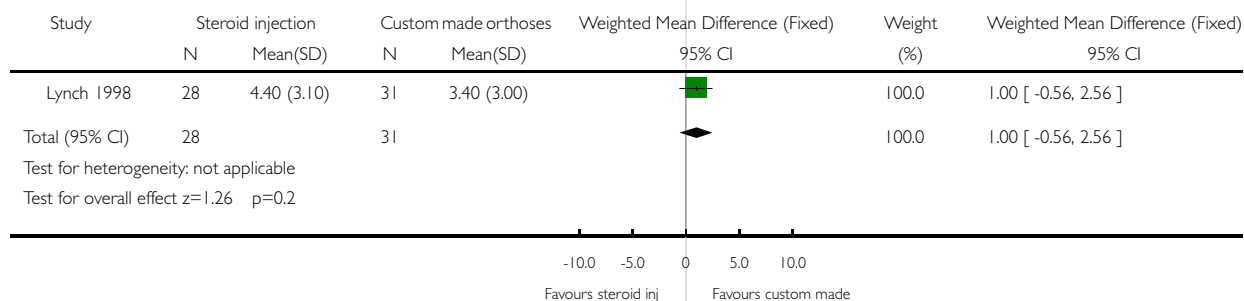
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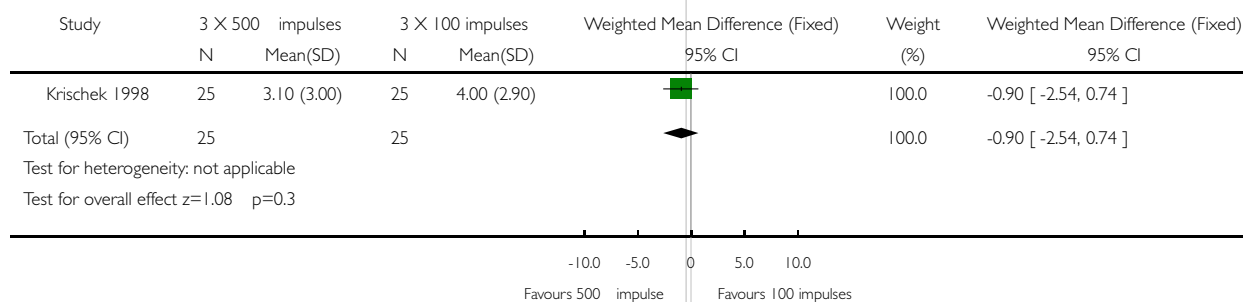
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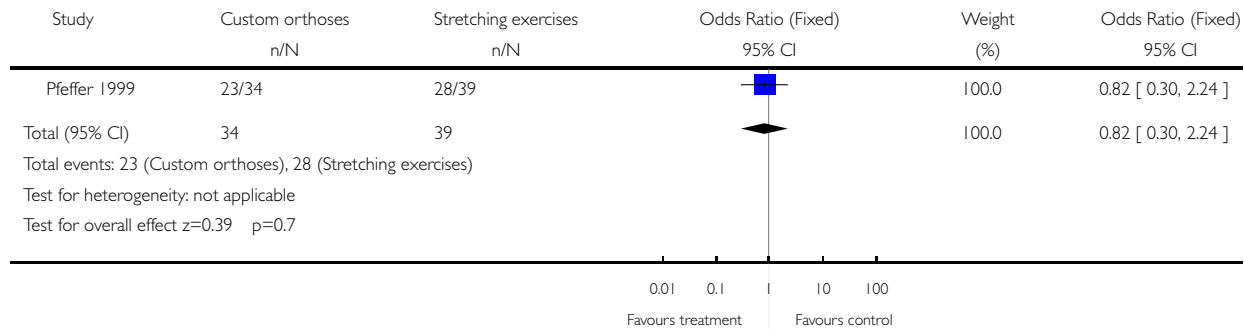
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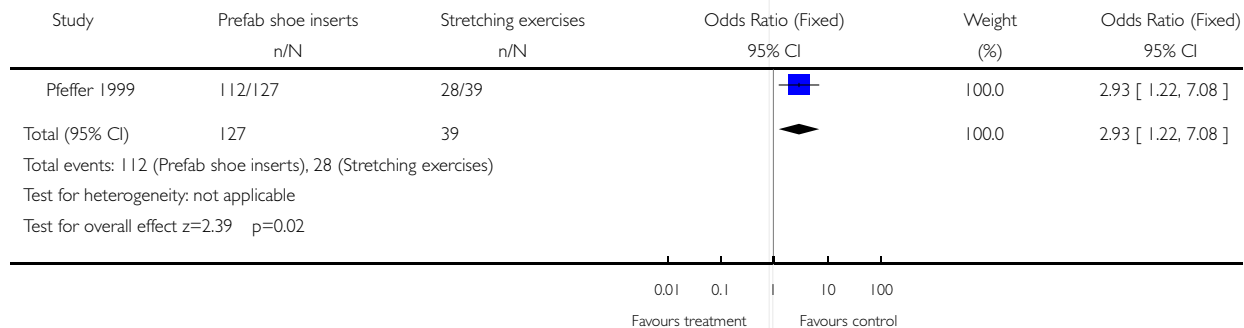
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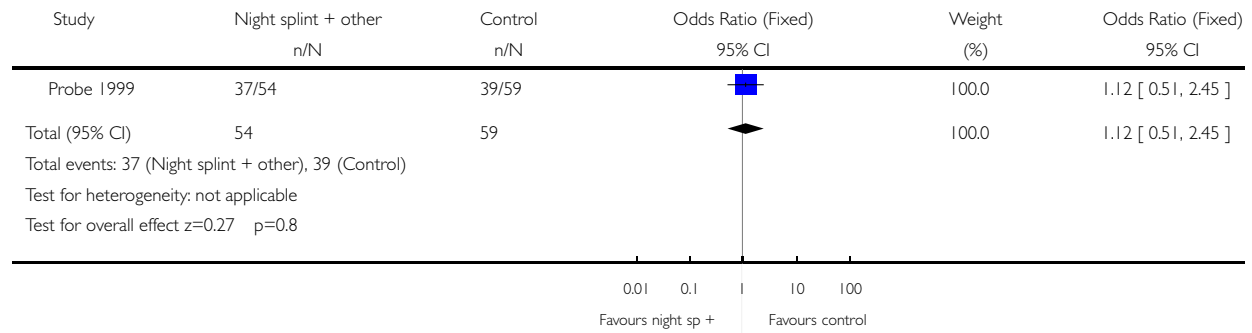


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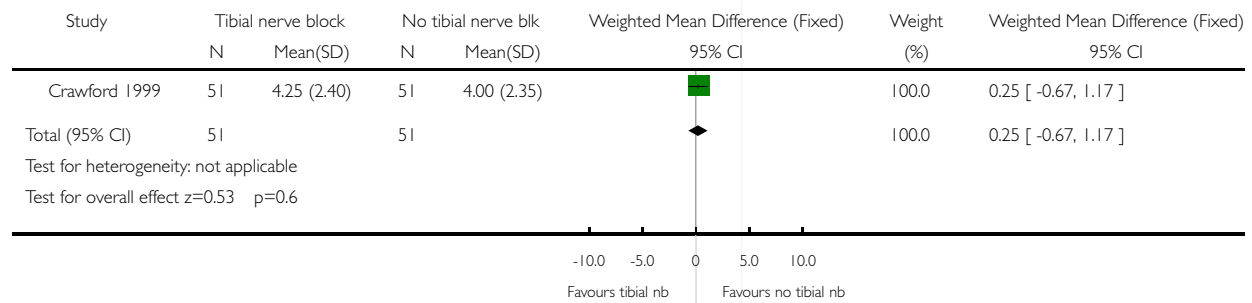


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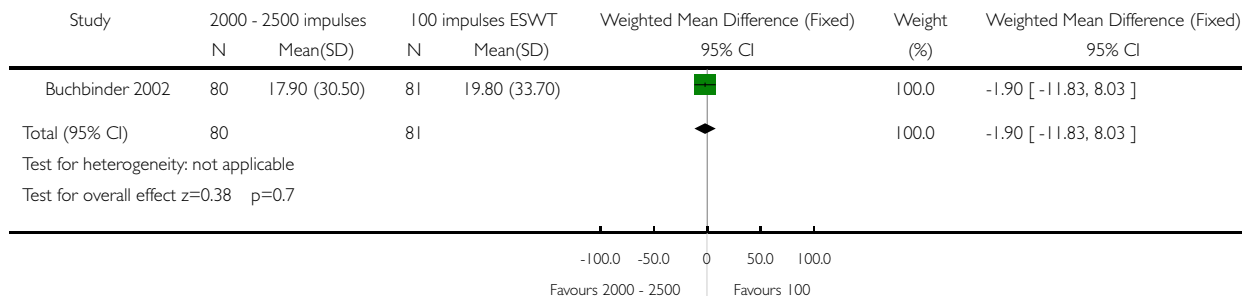


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Outcome: 01 Over all pain change in VAS at 6 weeks

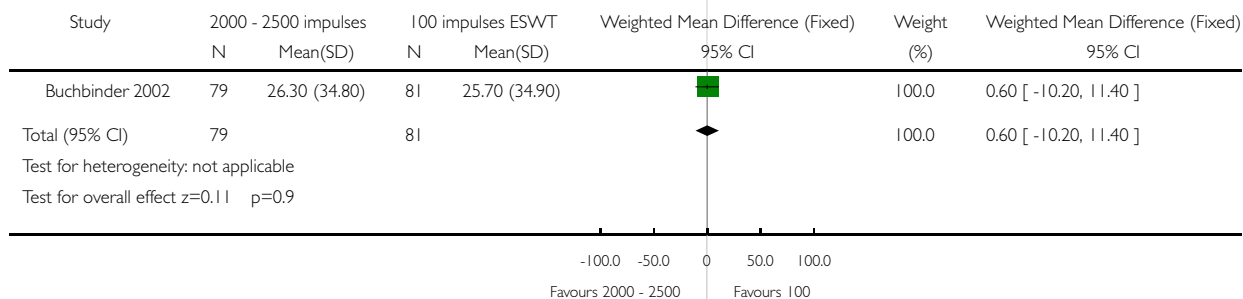


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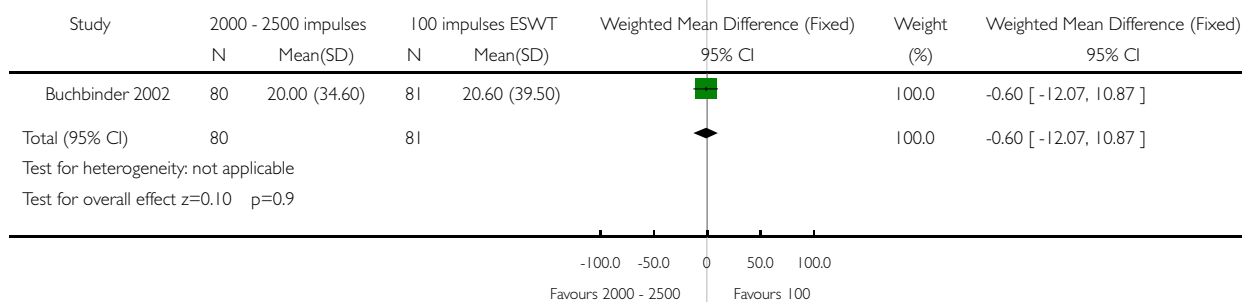


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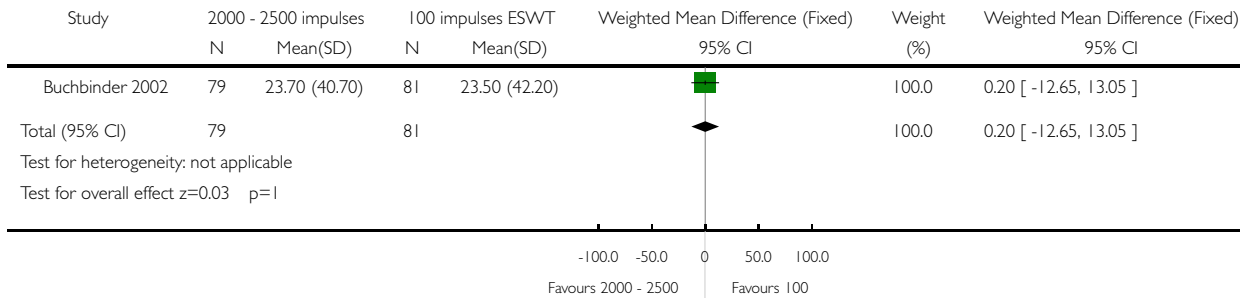


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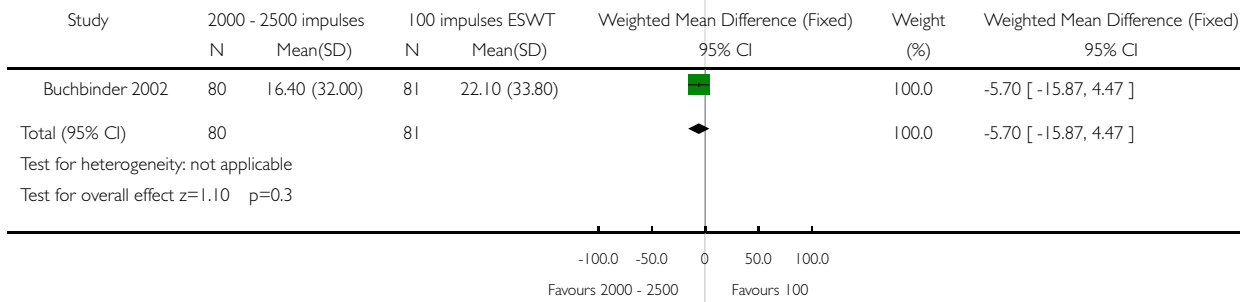


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