This is the full-text of the pre-print version.

Title Page

1. Title of the article.
The Effectiveness of Acupuncture for Plantar Heel Pain: a systematic review.

2. Full name, postal address, e-mail, telephone and fax numbers of the corresponding author.
Richard J Clark  BSc, MBBS, LicAc, DipMedAc
Peninsula College of Medicine and Dentistry, C206 Portland Square, Drake Circus, PLYMOUTH, PL4 8AA, UK
Richard@IntegrativeHealthcare.co.uk
Tel: 01752 691415
Fax: 01752 691415

3. Full names, departments, institutions, city and country of all co-authors.
Maria Tighe  PhD, SCHPN(HV), RGN
School of Nursing and Midwifery, Faculty of Health, Education and Society, Plymouth University, 7 Portland Villas, PL4 8AA, UK

4. Up to five keywords or phrases suitable for use in an index (MeSH terms).
Acupuncture Therapy
Fasciitis, Plantar
Trigger Points
Electroacupuncture
Laser Therapy, Low-Level

5. Word count - excluding title page, abstract, references, figures and tables.
3002
ABSTRACT

Introduction: Plantar heel pain (PHP) is a common complaint, yet there are no definitive guidelines for its treatment. Acupuncture is increasingly used by podiatrists, and there is a need for evidence to validate this practice. It is acknowledged that both PHP and acupuncture are complex phenomena.

Method: A systematic review (PROSPERO no. CRD42012001881) of the effectiveness of acupuncture for PHP is presented. Quality of the studies was assessed by independent assessors with reference to Quality Index (QI), STRICTA and CONSORT criteria. Pooling of data, or even close comparison of studies, was not done.

Results: Five RCTs and 3 non-randomised comparative studies were included. High quality studies report significant benefits. In one, acupuncture was associated with significant improvement in pain and function, when combined with standard treatment (including NSAIDs). In another, acupoint PC7 improved pain and pressure pain threshold significantly more than LI4. Other papers were of lower quality but suggest benefits from other acupuncture approaches.

Conclusion: There is evidence supporting the effectiveness of acupuncture for PHP. This is comparable to the evidence available for conventionally used interventions, such as stretching, night splints or dexamethasone. Therefore acupuncture should be considered in recommendations for the management of patients with PHP. Future research should recognise the complexity of PHP, of acupuncture and of the relationship between them, to explore the optimum use and integration of this approach. There is a need for more uniformity in carrying out and reporting such work and the use of STRICTA is recommended.
Introduction

Plantar heel pain (PHP) is one of the most common foot problems and is responsible for substantial morbidity and financial burden. An array of pathologies can give rise to pain beneath the heel, including vascular, neurologic, arthritic and malignant aetiologies; once such conditions are excluded, what remains is PHP. Typical findings include pain on taking the first few steps in the morning, pain that increases with weight bearing, and pain and tenderness upon palpation of the medial calcaneal tubercle. Historically, PHP has been referred to as ‘plantar fasciitis’ (PF) and some authors also use the term ‘calcaneal spur’. The accuracy of such terms has been contested and they are beginning to be replaced by others, such as ‘plantar fasciosis’. However, even this term is inappropriate here, as it embodies the assumption that the plantar fascia is the seat of the problem. The aetiology of PHP is complex, involving the interplay of tissue, biomechanical, psychological and other factors. These are modelled in different ways by acupuncturists (e.g. myofascial trigger points, or disturbances of ‘Qi’) and, as Sackett et al point out, the practitioner perspective is an important aspect of the Evidence Based Practice (EBP) triad. Therefore an inclusive approach was adopted for this paper (see methods and discussion sections).

Conventionally many different interventions are used, yet the evidence for their use is inconclusive. Compliance is often poor and interventions such as non-steroidal anti-inflammatory drugs (NSAIDs) and steroid injections carry significant risks.

Recently, increasing numbers of podiatrists are incorporating acupuncture into their practices and initial results seem favourable. Anecdotally, alumni of a training programme validated by the Society of Chiropodists and Podiatrists report good results from incorporating acupuncture into their approaches. Meanwhile the body of published work in this area is increasing. Thus it is now appropriate to conduct a rigorous assessment of the role acupuncture might play in the management of PHP.

An earlier systematic review addressed a related question, considering dry needling and injections of myofascial trigger points (MTPs) associated with plantar heel pain. Recognising (from clinical experience) that many patients suffer from PHP in the absence of MTPs, the current authors chose to review studies drawing on a wider range of types of acupuncture practice.

Thus, the research question was: “what is the evidence regarding the effectiveness of acupuncture for PHP?” This paper presents a systematic review of publications relating to this question, discusses the implications, and makes suggestions for future development. Safety was not considered in this review; this aspect has been studied more appropriately elsewhere.
METHODS

The protocol was registered with PROSPERO (no. CRD42012001881).[23] Recognising the heterogeneity in the reporting of this phenomenon, a broadly inclusive search strategy was chosen to identify relevant work.

A comprehensive literature search was carried out as follows. The databases searched were: PubMed, AMED (EBSCO), British Nursing Index, CINAHL plus (EBSCO), EMBase, MEDLINE (EBSCO), MEDLINE (Ovid), Oxford Journals, PsychARTICLES, ScienceDirect, SocINDEX (EBSCO), SwetsWise, Taylor & Francis Online, Wiley Online Library.

The search parameters included All Dates (from inception to the end of 2011), All Types of publication, All Languages, and All Fields. The precise wording of the searches varied in different databases, using different thesauri. The general principle was to include ‘Acupuncture’ OR ‘dry needl*’ OR ‘Trigger Points’ OR ‘moxibustion’ OR ‘TENS’ OR ‘laser therapy’ AND ‘heel pain’ OR ‘plantar fasci*’ OR ‘heel spur’ OR ‘calcan*’.

The search was extended by following all relevant leads in sources read. Reference lists of papers obtained were scanned for further relevant papers. Journals identified were searched electronically where possible, or by scanning tables of contents. Leads were also obtained from available textbooks, online forums and the internet and personal communications.

Titles and abstracts were scanned to identify papers for inclusion. Papers relating to PHP and related diagnoses were included; those relating to pain secondary to other pathologies,[24,25] or to experimental pain in animal subjects[26] were excluded.

Papers were included if they described the use of acupuncture, acupuncture points, TCM or moxibustion. Papers describing the use of MTPs were included if the treatment was (dry) needling, whether or not an acupuncture-related rationale was used. Papers describing the use of laser therapy or transcutaneous electrical nerve stimulation (TENS) were included only if the therapy was applied specifically to acupuncture points, or if an acupuncture-related rationale was used.[27]

Randomised Controlled Trials (RCTs) and non-randomised comparative studies were included. Case series, single case studies and secondary reports were excluded from this review but will be considered in detail elsewhere (Clark & Tighe, in preparation).

Two papers were translated.[27,28] Data were extracted into a spreadsheet, as summarised in Tables 1a-1c.

Assessment of the standards of reporting was carried out using CONSORT[29] (for RCTs) and STRICTA[30] and quality of the studies was assessed using the Quality Index[31]. To enable comparison, the QI scale was modified as recommended by Cotchett[18] (however, only one paper appeared in both studies, so meaningful comparison was impossible). The two authors rated each paper independently; scores were discussed to identify and resolve differences, and so achieve consensus. Percentage scores were calculated in relation to the number of relevant items, to enable comparison across the scales. Further quality data were extracted, as summarised in Table 2.

Narrative summarisation was performed; neither data synthesis nor meta-analysis was possible.
RESULTS AND DISCUSSION OF STUDIES

Papers

The search identified 342 potentially relevant articles (see Fig. 1), of which 8 met the inclusion criteria: 5 RCTs,[27-28,32-34] 2 non-randomised comparative studies[35-36] and 1 cohort study using “patients as their own controls”.[37]

Fig. 1: Flow chart for selection of papers

A summary of the papers is provided in Tables 1a to 1c:
Table 1a – Higher quality trials*  

<table>
<thead>
<tr>
<th>Study Type (N)</th>
<th>Participant characteristics</th>
<th>Acupuncture intervention**</th>
<th>Comparison intervention(s)</th>
<th>Outcome measures</th>
<th>Results / Conclusions</th>
</tr>
</thead>
</table>
| Karagounis et al, 2011 DBRCT (38) | Plantar Fasciitis  
*Duration >2wk (mean 16.1d)*  
100% male.  
*Mean age 37.1*  
No prior treatments received. | (Gp 2) Up to 12 painful and other points chosen from a list of 18 classical acupoints.  
Slight rotation and thrusting to elicit deqi (dull, numb or heavy)  
Retained 20-30 min, with "periodic manual stimulation".  
16 sessions, 2/wk.  
Plus standard treatment as Gp1. | (Gp 1) standard tmt including: ice, extensive stretching program and NSAID drug | PFPS (Plantar fasciitis pain scale – Willis et al) | Both groups improved significantly, Gp2 more so.  
At wk 8 improvement =  
Gp1 26%, Gp2 47%; P<0.05  
Minor adverse effects noted |
| Zhang et al, 2009 DBRCT (53) | Plantar fasciitis (diagnosed as ‘pain localized to the medial tubercle of the calcaneum’)  
*Duration > 3mo (3-216 mo)*  
26.4% male.  
*Age >18 (mean 48.5)*  
Various prior treatments | (Gp 1) PC7, contralateral to pain.  
Depth 10 mm.  
Deqi elicited each 5 min; Retained 30 min.  
Daily x10 | (Gp 2) LI4, contralateral to pain.  
Depth 10 mm.  
Deqi elicited each 5 min; Retained 30 min.  
Daily x10 | VAS for Morning pain (MP),  
Activity pain (AP),  
Overall pain (OP) also  
Pressure algometry (PP)  
At each daily session and follow-up at 1, 3 & 6 mo | Significantly greater improvement in Gp1 than Gp2 at 4 data points.  
Significant decrease in MP (from baseline) seen in Gp1 at 1, 3 and 6mo f-u (P<0.001).  
Both groups showed significant decreases in AP and OP.  
Gp2 non-significant improvement in MP.  
Negative correlation found between prior duration of complaint and improvement.  
One drop-out due to needling pain at LI4. |

* These two trials scored higher than all the others in terms of quality of trial and of reporting, as indicated by QI, STRICTA & CONSORT scores (see Table 2).  
** In original papers, acupoints were named according to different conventions; where necessary, these have been translated to the WHO recommended format (eg. the point Xiaguan is rendered as ST7).  
Abbreviations used: DBRCT, double blind randomised controlled trial; deqi, the characteristic feeling produced by the needle; f-u, follow-up; Gp, group; NSAID, non-steroidal anti-inflammatory drug; P, probability value; pt, point; tmt, treatment.
### Table 1b – Other randomised controlled trials

<table>
<thead>
<tr>
<th>Study Type (N)</th>
<th>Participant characteristics</th>
<th>Acupuncture intervention*</th>
<th>Comparison intervention(s)</th>
<th>Outcome measures</th>
<th>Results / Conclusions</th>
</tr>
</thead>
</table>
| **Liu et al, 2010**  
[Chinese]  
RCT (66) | ‘Calcaneus spur’ (on XR)  
*Duration 4-38mo*  
*37.9% male.*  
*Age 31-64*  
*Prior treatments not stated.* | (Gp 1) GB39  
Even method, deqi to heel,  
Retained 20 min.  
Daily, 30 sessions during 3 courses of 10.  
Plus pyrogenic herbal dressing & heat application. | (Gp 2) "common acupuncture" -  
GB34, BL60, BL57, KI3.  
Ipsilateral | PRR (points reduction rate) based on:  
walking pain, walking function, swelling, burning sensation, each on 5-pt scale | Both gps PRR >50%.  
PRR of over 60% for  
64.7% Gp1, 37.5% Gp2  
P<0.05.  
Asserts safe, but without giving data. |
| **Orellana Molina et al, 1996**  
[Spanish]  
RCT (52) | Heel spur (but diag clinically)  
*Duration not stated*  
*30.8% male.*  
*Age <40 to >60*  
*Prior treatments not stated.* | (Gp 2) Acupuncture to ahshi, BL40, BL60, KI3, Ki6.  
Rotate at start & at 10min.  
Retain 20 min.  
Daily x10, repeat if necessary. | (Gp 1) Point application of infra-red laser (904 nm) to ahshi, BL40, BL60  
16J/cm² to ahshi, 7J/cm² to other points.  
Daily x10, repeat if necessary. | VAS pain scores at sessions 3, 6,  
10 combined into 3 categories:  
Cured = VAS < 2  
Improved = VAS 3-5  
Not improved = >5 | Gp1: Cure 11/26; Improved 15/26  
Gp2: Cure 16/26, Improved 10/26  
Also Gp2: Onset of benefit sooner; fewer pts required 2nd course. |
| **Vrchota et al, 1991**  
DBRCT (40) | Plantar fasciitis  
*Duration not stated*  
*Gender not stated*  
*Age not stated*  
*Prior treatments not stated.* | Gp 1 - ‘true acupuncture’:  
Electroacupuncture to KI1, KI3, Ahshi;  
5/80 Hz, to tolerance.  
Retained 20 min.  
Plus calf stretches, footwear advice, insoles. | Gp 2 - ‘Sham acupuncture’:  
sham points on sole, minimal depth, subthreshold electrostimulation.  
Plus calf stretches, footwear advice, insoles;  
Gp 3 - ‘sports medicine therapy’, including reduced training, stretches, ice and NSAID.  
Plus footwear advice, insoles. | Pain score, tenderness score, decided by doctor with patient, each on 4-point scale.  
Pain log, daily until 3w after last treatment.  
Activity log (data not used). | Mean pain score >50% less. Sig diff.  
True > sham > sports medicine (including NSAID drug)  
Pain log showed more relief in Gp1 than Gp3 at wk 4 (P=0.010) and follow-up (P=0.016).  
Pain score showed more relief in Gp1 than Gp3 at wk 4 (P=0.014).  
Tenderness scores changed little. |

Abbreviations used: ahshi, the point of maximum tenderness; DBRCT, double blind randomised controlled trial; deqi, the characteristic feeling produced by the needle; Gp, group; NSAID, non-steroidal anti-inflammatory drug; P, probability value; pt, point; RCT, randomised controlled trial; sig diff, significant difference.
## Table 1c – Non-randomised studies

<table>
<thead>
<tr>
<th>Study Type (N)</th>
<th>Participant characteristics</th>
<th>Acupuncture intervention*</th>
<th>Comparison intervention(s)</th>
<th>Outcome measures</th>
<th>Results / Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chen &amp; Zhao, 1985 Non-randomised comparative case series (900)</td>
<td>Heel pain, mostly non-specific +/- calcaneal spurs. Duration 3 mo - 30 yr 33.3% male. Aged &lt;30 to &gt;70 Prior treatments not stated.</td>
<td>(Gp 3) BL61 Depth 0.3-0.5 cun Retained 5 min. 10 sessions, daily, during two weeks plus herbs as in Gp 2</td>
<td>(Gp 1) Steroid + LA local pt, x5-6 in 3wk;</td>
<td>Excellent = complete resolution Good = remarkable improvement Poor = no response</td>
<td>3 groups comparable - no sig diff. Acupuncture group: Excellent 15/50, Good 20/50, Poor 15/50 [allowing for typo] Follow-up 1-8yr (mean 3.5)</td>
</tr>
<tr>
<td>Ouyang &amp; Yu, 1996 Non-randomised comparative clinical trial (73)</td>
<td>‘Pain in the sole’ (including heel). Duration 1-6mo (N=14); &gt;1yr (N=29); 3yr (N=1); rest not stated. 43.8% male Age 30-78 Prior treatments not stated.</td>
<td>Gp 1: ST7, Ipsilateral. Depth 1.5 cun; Rotation 1 min counter-clockwise; Retain 20-30 min. Daily x5 per course</td>
<td>Gp 2: ‘corresponding’ palmar pt, Ipsilateral. Depth 0.5 cun; Rotation 1 min counter-clockwise; Retain 20-30 min. Daily x5 per course Gp 3: both ST7 and palmar point</td>
<td>CR = complete relief MR = marked relief PR = partial relief NR = no relief CR+MR+PR = response rate (RR).</td>
<td>RR% = 97.1 (Gp1); 92.6 (Gp2); 100 (Gp3) Concludes combination is more effective, but palmar points often painful, so use latter only if ST7 fails.</td>
</tr>
<tr>
<td>Tillu &amp; Gupta, 1998 Prospective case series with ‘self-controls’ (18)</td>
<td>Plantar fasciitis Duration 12-30mo 27.8% male Mean age 49.17 (SD 10.66). Previously unsuccessful conservative treatment (physiotherapy, shoe support, steroid injection) ‘Classical acupoints’ KI3, BL60, SP6; Ipsilateral; Deqi sought (tingling) each 5 min; Retained 15 min. Weekly x 4</td>
<td>Trigger points (calf and plantar) added if needed for sessions 5-6.</td>
<td>VAS pain score; VAS % change; verbal rating score</td>
<td>Significant reduction from baseline in VAS scores at wk 4 [40.3%] (P&lt;0.0009) and wk 6 [69%] (P&lt;0.0001). Significant reduction between w4 and wk6 (P&lt;0.047). Concludes classical acupoints effective, enhanced by addition of trigger points in failed cases. Recommends use of MTP from the start.</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations used: b.d., twice a day; cun, a standard measurement used in acupuncture practice; deqi, the characteristic feeling produced by the needle; Gp, group; LA, local anaesthetic; MTP, myofascial trigger points; P, probability value; pt, point; sig diff, significant difference.
and quality assessment is summarised in Table 2

Table 2: Evaluation of trial reporting and trial quality

<table>
<thead>
<tr>
<th>Authors, date, place</th>
<th>QI % (Quality Index)</th>
<th>STRICTA %</th>
<th>CONSORT %</th>
<th>Ethical governance</th>
<th>Notes re publication bias</th>
<th>Randomised</th>
<th>Blinding</th>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Karagounis et al, 2011 [Greece]</td>
<td>85.2</td>
<td>78.1</td>
<td>44.6</td>
<td>Informed written consent</td>
<td>‘No sources of funding’</td>
<td>Computer generated</td>
<td>Patients and assessor</td>
<td>University Laboratory of Functional Anatomy and Sports Medicine</td>
</tr>
<tr>
<td>Zhang et al, 2009 [China]</td>
<td>72.2</td>
<td>94.1</td>
<td>75.0</td>
<td>Ethical committee approval</td>
<td>Partially supported by Faculty research grant</td>
<td>Computer generated</td>
<td>Patients and assessor. Credibility rated</td>
<td>School of Chinese Medicine, &amp; Dept TCM</td>
</tr>
<tr>
<td>Tillu &amp; Gupta, 1998 [UK]</td>
<td>66.7</td>
<td>55.9</td>
<td>-</td>
<td>‘Patients … willing to participate’</td>
<td>Acupuncture journal</td>
<td>No</td>
<td>No</td>
<td>Depts of Orthopaedics &amp; Anaesthetics</td>
</tr>
<tr>
<td>Orelliana Molina et al, 1996 [Cuba]</td>
<td>61.1</td>
<td>52.9</td>
<td>41.7</td>
<td>Informed consent</td>
<td>States ‘no conflicts of interest’</td>
<td>Yes, method not stated</td>
<td>No</td>
<td>Center for Technological Applications and Nuclear Development &amp; National Rheumatology Service</td>
</tr>
<tr>
<td>Vrchota et al, 1991 [US]</td>
<td>51.9</td>
<td>46.9</td>
<td>40.3</td>
<td>Patients recruited via newspaper advert</td>
<td>Acupuncture journal</td>
<td>Yes, method not stated</td>
<td>Implied, patients and assessor</td>
<td>Pain clinic and research centre, Dept Neurology and Family Practice</td>
</tr>
<tr>
<td>Liu et al, 2010 [China]</td>
<td>50.0</td>
<td>64.7</td>
<td>41.4</td>
<td>Written consent</td>
<td>Acupuncture journal</td>
<td>Yes, method not stated</td>
<td>Patients</td>
<td>TCM College Hospital &amp; University Hospital</td>
</tr>
<tr>
<td>Ouyang &amp; Yu, 1996 [China]</td>
<td>20.4</td>
<td>61.8</td>
<td>-</td>
<td>Avoidance of painful point</td>
<td>Acupuncture journal ‘wish to present the satisfactory results’</td>
<td>No</td>
<td>No</td>
<td>Military Medical University</td>
</tr>
<tr>
<td>Chen &amp; Zhao, 1985 [China]</td>
<td>11.1</td>
<td>55.9</td>
<td>-</td>
<td>-</td>
<td>Acupuncture journal</td>
<td>No</td>
<td>No</td>
<td>Academy of TCM &amp; County Hospital</td>
</tr>
</tbody>
</table>

Quality

The parallel use of STRICTA, QI and CONSORT gave a multifaceted appreciation of the overall quality of the studies and their reporting. There was reasonable agreement between the rankings by the three instruments. Table 2 illustrates the wider quality issues of clinical and research ethics governance, revealing weak methodology in most of the papers. No papers declared their commissioning or peer review status (although three appeared in peer-reviewed journals). Only two declared funding received. Five papers appeared in acupuncture-focused journals; three studies took place in colleges of TCM. The relationship between clinical practice and research was often blurred (indicating potential for Hawthorne effect and social desirability bias) and there was a lack of transparency regarding ethical governance. However two papers[32,34] achieved high standards by most of these criteria and this is reflected in their high QI ratings.
Individual papers

Karagounis et al[32] assessed the value of adding acupuncture treatment to a standard clinical approach, for men with acute PF. While the ‘standard’ group showed improvement (pain score reduced 26%), the acupuncture group improved almost twice as much (47%, P<0.05). This is a high quality study with good internal and external validity, and well reported. The treatment used was semi-individualised and the detail provided for the acupuncture given is not enough for precise duplication of the process.

Zhang et al[34] assessed the specific efficacy of acupoint PC7 (compared to LI4) for PF of over 3 months duration. They concluded that PC7 gives a significantly greater benefit, at 1mo and 6mo follow-up. This trial scores well on internal validity, less so on external validity.

One might criticise the choice of LI4 as a comparator, in that it is widely used to treat pain, including heel pain (e.g.[38]). Conversely, this makes it ideal as a ‘control’ treatment; if LI4’s reputation is undeserved and it is, in fact, an inert intervention, then it serves as a demonstrably credible placebo; conversely, if it is an effective point, then PC7 has been shown to be even more so.

Tillu & Gupta[37] studied a series of 18 consecutive patients with PF of over a year duration. All had failed to benefit from prior conservative treatments, including steroid injection in 12 cases. Patients received acupuncture to ‘classical points’ (KI3, BL60, SP6), weekly for 4 weeks which resulted in significant improvement of mean VAS (Visual Analog Scale) pain scores (P<0.0009). Two patients needed no further treatment; the remaining 16 were then given the same treatment twice more, with the addition of needling ‘trigger points in the gastro-soleus and plantar fascia’. This resulted in a significant further improvement (P<0.047). This was an uncontrolled and non-blinded study and so has low scores on internal validity; also the quality of reporting is moderate by modern standards. However the approach used is very relevant to clinical practice. The authors argue that each patient served as their own comparator in view of the long duration of complaint, with failure of prior treatments. Comparison is also possible between the two phases of the study, however without concurrent control groups one can not eliminate change due to non-specific factors.

Orellana Molina et al[27] studied pain related to heel spurs, comparing the effectiveness of laser treatment at acupoints with needling a similar group of points, chosen according to the traditional ‘eight principles’ approach. While both groups showed benefit, the laser group reported improvement sooner and to a greater degree. Significance is claimed for this result but (even after professional translation) the statistical method used is unclear.

Vrchota et al[33] studied the efficacy of ‘True Acupuncture’ (TA) compared to ‘Sham Acupuncture’ (SA) and to ‘Sports Medicine Therapy’ (SMT) for PF in a Sports Medicine Clinic. TA included the use of ahshi, local trigger points and classical acupoints, to which electroacupuncture was applied at the level of tolerance. SA consisted of shallow needling at two unrelated points on the sole, with minimal electroacupuncture (below threshold of perception). The SMT group received advice to reduce training, apply ice, stretching exercises and NSAID medication. Pain reduction was significantly greater in the TA group than the SMT group after 4 treatments and 3 weeks later. The results in the SA group were intermediate between the other two groups, but differences did not reach significance. This paper lacks many details including: demographic characteristics, duration of complaint, prior treatments and blinding. Thus TA appears more effective than SMT but questions remain as to which aspects are important, and the possible confounding effect of other variables.
Liu et al\cite{28} studied the effectiveness of needling a single point (GB39) in conjunction with local heat application via a herbal dressing, in comparison to ‘common acupuncture’ needling 4 other points, for patients with chronic pain related to heel spurs. Using a combined ‘Points Reduction Rating’ they found significantly greater improvement in the ‘GB39 plus heat’ group (“marked improvement” in 64.7% compared to 37.5%; P<0.05). This is described as a single blind study, with patients uninformed. No concealment of treatment is described; it is assumed that patients were simply not informed that their treatment was different from the ‘common’ treatment. The ethics of this is not discussed. The outcome measure used is a points score derived from subjective reporting. Variants of this approach are common in Chinese clinical studies over the past few decades but no validation is mentioned.

Ouyang & Yu\cite{36} studied patients with pain in the sole (including an unstated number in the heel), comparing the use of ST7 with a ‘corresponding point’ on the palm, or both of these combined. (Corresponding point is assumed to mean a location on the palm analogous to the pain location on the foot but this is not made explicit.) They conclude that the combination is more effective, however the differences are small and unlikely to be of statistical significance. This paper reports outcomes as clinical judgements of relief obtained (complete, marked, partial, none) and, unlike comparable papers, combine the first 3 into a global Response Rate. When ‘partial’ is excluded (by the current authors, to reflect more common practice) ST7 emerged as more effective than the Palmar point (76.5 cf 59.3%). Furthermore, needling the palm was found to be too painful for some patients, so the recommendation was to use ST7 as first choice and reserve palmar needling for unresponsive cases. This approach is not widely known in the West, and challenges the professional boundaries of some practitioners (eg. podiatrists, who would not normally needle the face) yet the response rates reported here seem promising.

Chen & Zhao\cite{35} retrospectively reported an extensive series of patients with heel pain. They compared the results of 50 receiving acupuncture to BL61 (plus an individualised herbal decoction), with 102 receiving steroid injection into tender point (plus herbal decoction), and with 748 receiving steroid alone (5-6 injections during 3 weeks). They stated that there was no significant difference between the ‘effective rate’, which averaged 73.5% in the three groups. The statistical method used is not stated and, on close inspection of their data, the numbers in the table do not add up to the totals given, so it is impossible to draw a conclusion from this.
DISCUSSION

A systematic search identified 8 papers providing evidence regarding the effectiveness of acupuncture for PHP. Two studies provide good reporting of high quality studies; 6 are of lesser quality. All report positive outcomes however they are heterogeneous in several ways, making it difficult for simple conclusions to be drawn.

Heterogeneity

The STRICTA scores achieved by these papers range from 46.9 to 94.1%. This is unsurprising because 5 of them were published before the STRICTA guidelines were available. The highest scores were obtained by the three most recent papers. Future studies should be more rigorous in adhering to these guidelines.

The indication for treatment is variously stated as heel pain (although one paper is less precise), plantar fasciitis (but the definitions differ) or heel spur (with or without XR confirmation). The problem of diagnostic labelling for heel pain was discussed above. Authors of the papers reviewed showed variable awareness of the shortcomings of these terms. The assumptions underlying such labels are now seen to be incorrect, yet it is likely that they influence the design of treatments. For example, if the focus is on ‘inflammation’, then acupoints thought to influence inflammation may be chosen; meanwhile a potentially more useful approach (e.g. treating MTPs) may be overlooked.

An earlier systematic review[18] focused exclusively on MTPs. While this has the merit of simplicity, it may not reflect a reality which is complex. This review has shown that MTPs may give additional benefit when added to classical acupuncture[37] but also that acupuncture unrelated to MTPs confers significant benefits.[34] Clinical experience (RJC) shows that some patients have MTPs related to their heel pain and others do not; there is a need to explore the possibility that these are two pathologically distinct groups, requiring different treatment approaches.

Prior duration of the complaint, where stated, varied between 2 days and 30 years. This is perhaps of particular significance in that one paper[34] noted an inverse correlation between duration and benefit obtained, which suggests that it would be prudent to control for duration in future studies.

The gender ratio also varied. In most papers it was between 26.4 and 43.8% male, which is comparable to the distribution of heel pain in the general population. However one study[32] included only male patients, which may be a significant confounding factor; recent papers highlight effects of patient or practitioner gender on perceptions of pain and acupuncture.[39-41]

The outcome measures vary from precise, prospective use of relevant pain scales (VAS, PFPS (Plantar fasciitis pain scale)[42]) to retrospective clinical judgements. All assessed subjective pain, some assessed function and one assessed tenderness objectively. Perhaps the greatest difference between these papers is the treatment approach used – although all studies involve acupuncture, none of them use the same approach. This should remind us that acupuncture is not a unitary intervention, indeed it is very complex.[43]
Limitations of this paper

Bias
As a practising acupuncturist, the present author (RJC) might be biased in favour of a positive outcome. Any such bias should be apparent, if not neutralised, by the transparency and systematic nature of this review.

Publication bias

Positive outcomes
Five of the papers reviewed were published in acupuncture journals, with unknown peer-review standards, so it seems likely that there is a bias in favour of positive findings, particularly as they date back as far as 1985. However the two higher quality papers were published in peer-reviewed non-acupuncture journals, so we place more confidence in them. It is impossible to know if there were similar studies with negative outcomes that remain unpublished.

Positivist methodology
Including RCTs but excluding case studies, imposes a bias towards formulaic (rather than individualised) approaches. This fails to reflect the reality of practice. Sackett notes the importance of this: “Evidence based medicine … requires a bottom up approach that integrates the best external evidence with individual clinical expertise and patients’ choice”.[8]
At this point it is worth comparing the two high-scoring papers: Zhang et al[34] is a rigorous and well-reported DBRCT, high on internal validity. However the interventions compared bear little relation to common practice, and the effect size is small. In contrast, Karagounis et al[32] demonstrated a worthwhile level of effect, using a treatment approach which is much closer to real-world practice, and it scored well on external validity.

Conclusions
In view of the heterogeneity of these papers, it is not possible to give a simple conclusion, in the form: X is shown (or not) to be efficacious for Y. A number of different approaches were identified, which indicate potential uses of acupuncture for treating heel pain, as summarised in Table 3:
Table 3: Summary of findings

- High quality studies have shown:
  - a part-individualised approach using up to 12 classical points gave significant improvements in pain and function, when added to standard treatment (including NSAIDs)
  - PC7 is significantly more effective than LI4 for medial heel pain and tenderness

- Less rigorous studies suggest that:
  - Electroacupuncture to local points (classical, ahshi and MTPs) gives significantly more benefit than Sports Medicine Treatment (including NSAIDs)
  - Infrared laser stimulation of BL40 + BL60 + Ahshi seems more effective than needling BL40 + BL60 + KI3 + KI6
  - Needling GB39 plus local heated herbal dressing gives significantly more benefit than needling GB34 + BL57 + BL60 + KI3
  - Needling BL61 + individualised herbal decoction, is as effective as multiple steroid injections into Ahshi point (with or without the herbs)
  - Needling ST7 is as effective as (and more comfortable than) palmar points
  - In patients unhelped by prior treatments (including steroid injection) for 12 months, significant benefit was obtained by needling KI3 + BL60 + SP6, and this was enhanced by the addition of MTPs

Thus there is evidence at level I and II supporting the effectiveness of acupuncture for heel pain, leading to a recommendation at Grade B.[44] This is comparable to the evidence available for conventionally used interventions, such as stretching, night splints or dexamethasone.[10] Therefore acupuncture should be included in recommendations for the treatment of PHP.

Future research should avoid the simplistic question ‘Is acupuncture efficacious for heel pain?’ and instead focus on exploring the optimum use of acupuncture for heel pain. The field is not yet ripe for RCT studies. We are currently at the ‘Development’ stage as defined by the MRC[45] – this paper is ‘identifying the evidence base’ and the next two phases (2 Identifying/developing theory and 3 Modelling process and outcomes) are being addressed in a separate study.
CONTRIBUTORS
RJC carried out the searches, screened the papers, assessed quality, drafted and finalised the paper.
MT collaborated in the design of the literature search strategy, provided independent assessment of bias and quality, discussed the findings, contributed to writing of the paper and agreed its final draft.

ACKNOWLEDGEMENTS
We are grateful for the generous support of various people: the librarians at the University of Westminster, Plymouth University and the Open University. Translations were carried out by Ding Renxiang and by RJC with the help of Arantxa and Ismael Arinas Pellon. Help in obtaining some papers was received from Anthony O'Reilly (Department of Foot Health, Derbyshire County PCT) and from Laura Gearing (Department of Foot Health, Southwark PCT). Critical commentary on a draft of the paper was received from: Emma Cowley and Mark Price.

DECLARATION OF INTEREST
RJC offers training courses on the use of acupuncture for podiatrists and other health professionals.

FUNDING
This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.
REFERENCES


