Author's response to reviews

Title: Effectiveness of dry needling and injections of myofascial trigger points associated with plantar heel pain: a systematic review

Authors:

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Author's response to reviews: see over
RESPONSES BY THE AUTHORS TO THE REVIEWERS’ COMMENTS

Reviewer 1: Peter Huijbregts

Major Compulsory Revisions

Comment 1.
Background. Paragraph 3. Line 2. Physical therapy is not an intervention, it is a profession. Please clarify which PT interventions were used in the referenced studies and if no such data is available include a comment indicating the lack of specific description and how this affects external validity of studies.

Action by the authors
In response to the reviewer’s comment we have modified the manuscript. This section now reads:
“Numerous interventions are used to treat plantar heel pain including calf stretching, foot taping, manual therapy (joint mobilisation and manipulation; mobilisation of soft tissue near sites of nerve entrapment and passive neural mobilisation techniques) foot orthoses, oral and injectable anti-inflammatories and night splints [1].”

Comment 2
Methods, search methods for identification of studies. Paragraph 1. Why not include MANTIS database. Please justify the choice of databases to allow the reader to establish level of comprehensiveness of the review.

Action by the authors
As we specifically targeted RCT's and/or quasi-experimental trials we were confident that the databases we searched would yield appropriate trials, including those that might be found in other databases like MANTIS. To check, following the reviewer’s comment, we entered the original search strategy into the MANTIS database. As a result, no further studies were identified. We do not intend on including this search in our manuscript though as it is retrospective and not in the spirit of our original systematic review.

<table>
<thead>
<tr>
<th>Comment 3</th>
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<tr>
<td>Methods, search methods for identification of studies. More information on specific search terms used is required.</td>
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</table>

**Action by the authors**

In response to the reviewer’s comment we have modified the manuscript. A table (Table 1) has been included in text which outlines a full electronic search strategy from the EMBASE database

**Table 1. A full electronic search strategy from the EMBASE database, April, 2010**

<table>
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<tr>
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<tbody>
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<td>exp Lower Extremity/</td>
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<td>2</td>
<td>exp Therapeutics/</td>
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<tr>
<td>3</td>
<td>exp Myofascial Pain Syndromes/</td>
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<tr>
<td>4</td>
<td>exp &quot;Outcome and Process Assessment (Health Care)&quot;/ or exp &quot;Quality of Life&quot;/ or exp &quot;Outcome Assessment (Health Care)&quot;/ or exp Questionnaires/ or exp Treatment Outcome</td>
</tr>
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<td>5</td>
<td>exp Heel Pain/ or exp Pain Assessment/ or exp Foot Pain/ or exp Musculoskeletal Pain/</td>
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<tr>
<td>6</td>
<td>exp fasciitis/</td>
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<td>7</td>
<td>exp methodology/</td>
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<tr>
<td>8</td>
<td>(leg* or calf or calves or foot or feet or ankle* or toe* or plantar fascia or plantar aponeurosis or plantar ligament or area).mp.</td>
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<td>9</td>
<td>(needle* or acupuncture or inject*)</td>
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<tr>
<td>10</td>
<td>(trigger area* or trigger point* or &quot;myofascial trigger point pain&quot; or &quot;myofascial pain components&quot; or taut band).</td>
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<tr>
<td>11</td>
<td>(systematic review or &quot;randomised controlled trial&quot; or RCT or quasi experimental or &quot;single subject design&quot; or comparative study)</td>
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<td>12</td>
<td>VAS or &quot;visual analogue scale&quot; or &quot;visual analysis scale&quot; or &quot;activities of daily living&quot; or &quot;quality of life&quot; or &quot;pressure pain threshold&quot; or algometry</td>
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**Comment 4**
Methods, Assessment of Methodological quality: Paragraph 1. Line 7. Clarify in the text why items were removed and modified.

Action by the authors

In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“However, for this systematic review, three items were modified. First, for Item 10, two points were allocated to trials that utilised confidence intervals as well as p values for the main outcomes as confidence intervals provide more information regarding the magnitude and precision of a treatment effect [2]. Second, Item 25 was removed as it has been shown that case mix adjustment cannot reduce the extent of bias in non-randomised trials [3]. Finally, Item 27 was removed as a minimally important difference using the visual analogue scale has not been calculated for trigger point interventions in participants with plantar heel pain.”

Comment 5

Results, Trial characteristics. Paragraph 1. Lines 3-4. Provide operational definitions of physical therapy and standard therapy.

Action by the authors

In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“All trials had a quasi-experimental design with pre-test and post-test measures. Imamura et al.[4] conducted a quasi-experimental trial with a non-randomised control group to evaluate the effectiveness of 1% lidocaine injections of MTrPs in combination with physical therapy or conventional therapy alone within the foot and leg (Table 4). The physical therapy component included heat application for 20 minutes and faradic stimulation over the area treated for another 20 minutes. Stretching exercises were prescribed (3 times per day for 15 seconds) after heat application. In addition, relaxation exercises were issued to some participants if required. In contrast,
the control group received conventional therapy, although the details were not included.”

**Comment 6**

Discussion. Paragraph 4. Indicate that no study has been done to assess interrater reliability of trigger point palpation in LE/foot.

**Action by the authors**

In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“As there is considerable variability in the criteria used to identify MTrPs [5] and the reliability of trigger point palpation has not been reported in the lower extremity and foot, it is imperative that researchers outline detailed diagnostic criteria used to identify MTrPs [5]. This would ensure that the methods used to diagnose MTrPs is transparent and can be reproduced.”

**Minor Essential Revisions**

**Comment 1**

Background. Paragraph 3. Line 8. Two other systematic reviews? Clinical Practice Guidelines are generally based on multiple systematic reviews; therefore, reference to the CPG as a systematic review seems incorrect.

**Action by the authors**

In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“Clearly there are many interventions used to treat plantar heel pain, although the Clinical Practice Guidelines for plantar heel pain proposed by the Orthopaedic Section of the American Physical Therapy Association [6] do not recommend one treatment over another. Furthermore, two systematic reviews [7, 8] have found few interventions that are supported by good evidence.”
Comment 2
Methods, types of studies: Please justify why also quasi-experimental studies were included in this review.

Action by the authors
In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“The decision to include quasi-experimental trials was based on the lack of randomised controlled trials to draw evidence from; hence we attempted to obtain an overview of what was known to date. Including non-randomised trials in systematic reviews can be appropriate when there are a limited number of randomised trials available [9]. Further, Linde et al.[10] conducted a systematic review of randomised and non-randomised trials that evaluated the effectiveness of acupuncture for chronic headache and found that non-randomised trials of good quality yielded positive responses to treatment that were similar to randomised-controlled trials. The authors concluded the inclusion of high quality non-randomised controlled trials into a systematic review might add to the generalisability of the findings.”

Comment 3
Methods, types of outcome measures; lines 2-3. It seems strange that the authors come up with such specific outcome measures. Were they established a priori by a preliminary literature review or a posteriori after the review at hand? If only VAS and health-related quality of life measures without going into specifics were considered please revise to reflect this and not even minimally “mislead” [too strong of a term] the reader?

Action by the authors
The decision to include the FHSQ and FFI was established a priori. This was not based on a preliminary literature review, rather both questionnaires represent two of the most commonly used and rigorously validated measures of foot-specific health outcome assessment [11].
Comment 4
Methods, search methods for identification of studies. Paragraph 2. Elaborate on the method with which the grey literature was searched.

Action by the authors
In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“Finally, Google Scholar and SUMsearch were searched for grey literature (information that has not been published, or if published is not readily accessible). No language restrictions were applied.”

Comment 5
Methods, Assessment of Methodological quality: Paragraph 1. Line 8. Please indicate if [or if not] the literature has established cut-off values for the interpretation of the of the Quality Index methodological quality assessment tool.

Action by the authors
In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“The literature has not established cut off values for the Quality Index methodological quality assessment tool. Downs and Black [12] (p. 381) stated that “the value of a single global score needs to be tested by reviewers making such an assessment before rather than after using the 27 item checklist”. The use of a single summary score or global score has been criticised in the literature as it might eliminate sources of heterogeneity among the results [3].”
Results, Quality of Evidence. Paragraph 1. Line 1. Should “individual” be replaced by “overall” or “total”, especially since in line 3 reliability per item seems to be discussed?

**Action by the authors**

In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“The inter-rater reliability of total Quality Index scores was not calculated due to the small number of trials included. Perfect agreement was recorded on all items except question 4 where there was 67% agreement between the assessors.”

Comment 7

Results, Trial characteristics. Clarify here in text that Imamura et al used a non-randomized control group?

**Action by the authors**

In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“All trials had a design with pre-test and post-test measures (Table 3). Imamura et al. [4] conducted a quasi-experimental trial with a non-randomised control group to evaluate the effectiveness of 1% lidocaine injections of MTrPs in combination with physical therapy or standard therapy alone within the foot and leg.”

Comment 8

Results, evidence for the effectiveness…paragraph 3, Line 3. Indicate if indeed the Tillu and Gupta study was a crossover design?

**Action by the authors**
In response to the reviewer’s comment we have modified the manuscript. However, rather than modify the text in this paragraph we have amended the manuscript by addressing the reviewer’s comment in the Results section under “Trial characteristics.” This section now reads:

“Tillu and Gupta [13] investigated the effectiveness of a four-week course of traditional acupuncture followed by a two-week course of trigger point dry needling combined with acupuncture. This trial was not a cross-over design in the strict sense, rather all participants received the course of treatment in the same order.”

Comment 9
Data file 3: do the changes to the quality index not make it a 26-point maximum scale?

**Action by the authors**

The changes to the Quality Index tool do not make it a 26-point maximum scale. Table 3 in the original text provided an outline of the points allocated to each item. One point was allocated for 23 items and two points were allocated for 2 items (items 5 and 10), which gives a total maximum of 27 points.
Discretionary revisions

Comment 1
Background. Paragraph 3. Line 5. Replace “although” with “but”

Action by the authors
In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“Clearly there are many interventions used to treat plantar heel pain, but the Clinical Practice Guidelines for plantar heel pain proposed by the Orthopaedic Section of the American Physical Therapy Association [6] do not recommend one treatment over another.”

Comment 2
Methods, types of participants: Line 4. Although likely obvious to clinicians that treat trigger points, can I suggest that the authors justify why only trigger points in LE/foot?

Action by the authors
In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“A trial was only included if the participant’s plantar heel pain was managed by treatment of MTrPs in the lower extremity and/or foot. The rationale for this decision was based on the assumption that some forms of plantar heel pain might occur secondary to MTrPs in plantar heel muscles (i.e. abductor hallucis and quadratus plantae) and/or referred pain from the soleus muscle [14].”

Comment 3
Methods, types of interventions: Line 7. Can I suggest that the authors specify similarity between trigger point dry needling and specifically Ashi or pain point but not meridian-based acupuncture?

**Action by the authors**

In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“Trials were excluded if they involved needling of traditional acupuncture points as the sole treatment because the relationship between traditional acupuncture points and MTrPs is unclear [15]. However, it has been suggested that there might be a correlation between MTrPs and a class of acupuncture points referred to as Ah Shi points (pain points). Ah Shi points are a class of acupuncture points positioned outside the traditional Chinese meridians and are commonly treated by traditional acupuncturists for painful conditions including muscle spasm [16]. Given the uncertainty of this relationship, we included trials that utilised acupuncture only if it was combined with dry needling or injection of MTrPs.”

**Comment 4**

Discussion. Paragraph 1. Line 7. Replace “While” with “…, whereas…”

**Action by the authors**

In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“A second trial evaluated the effectiveness of trigger point dry needling combined with electro-acupuncture, whereas a third trial evaluated the effectiveness of acupuncture followed by a period of acupuncture combined with trigger point dry needling.”

**Minor issues not for publication**
Action by the authors
In response to the reviewer’s comment we have modified the manuscript. This section now reads:
“It is estimated to affect 10% of the population at some time in their life [8], although there are few high quality epidemiological studies available.”

Action by the authors
In response to the reviewer’s comment we have modified the manuscript. This section now reads:
“It is estimated to affect 10% of the population at some time in their life [8], although there are few high-quality epidemiological studies available.”

Action by the authors
In response to the reviewer’s comment we have modified the manuscript. This section now reads:
“In a study of 784 North American community-dwelling residents aged 65 years or greater, 7% reported pain and tenderness beneath the heel [17].”

Comment 4
Results, evidence for the effectiveness... Paragraph 2. Line 7. Precede
“however” with semicolon?

**Action by the authors**
In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“Similarly, a statistically significant decrease in pain was found for the control group at discharge (54.9% improvement, $p<0.05$, the exact $p$ value was not reported); however there was no follow-up at six months or two years for this group.”

**Comment 5**
Results, evidence for the effectiveness... Paragraph 2. Line 10. Replace “between group” with “between-group”

**Action by the authors**
In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“Importantly the only between-group comparison made in this trial was for the total duration of treatment.”

**Comment 6**
Discussion. Paragraph 2. Line 17. Insert comma before “as”

**Action by the authors**
In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“Further threats to internal validity might have occurred in all three trials, as no attempt was made to blind those responsible for measuring the outcomes.”

**Comment 7**

**Action by the authors**
In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“Imamura et al. [4] did provide details of the muscles that were injected, however there was insufficient information to determine which muscles were treated during each session, the number of injections (total and per muscle) and the depth of needle insertion.”

Comment 8

**Action by the authors**
In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“In addition, Tillu and Gupta [13] and Perez-Millan and Foster [18] did not report which muscles were dry needled in the foot, the number of needles inserted into a MTrP, the depth of needle insertion, or the needle response elicited during dry needling of a MTrP.”

Comment 9
Discussion. Paragraph 5. Line 5. Replace “criteria that is” with “criteria that are”

**Action by the authors**
In response to the reviewer’s comment we have modified the manuscript. This section now reads:

“In addition, future RCTs should be designed based on criteria that are recognised for the quality assessment of randomised controlled trials [19].”
Reviewer 2: Michele Sterling

Revisions
Nil
References


