Author’s response to reviews

Title: Treatment of Myofascial Trigger Points in Patients with Chronic Shoulder Pain: A Randomized Controlled Trial

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Author’s response to reviews: see over
We would like to submit the revised version of the manuscript “Treatment of Myofascial Trigger Points in Patients with Chronic Shoulder Pain; A Randomized Controlled Trial” for publication in BMC Medicine. We are pleased that all reviewers considered our paper suitable for publication. We would like to thank the reviewers for their thoughtful comments, which we have incorporated into the revised version of the paper. All changes in the manuscript have been highlighted in red. Our responses to the comments have been included below in this cover letter.

Looking forward to your final decision,

Yours sincerely,

Carel Bron, PT, MPT (PhD student)

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Reviewer's report

Title: Treatment of Myofascial Trigger Points in Patients with Chronic Shoulder Pain: A Randomized Controlled Trial.

Version: 1 Date: 25 October 2010. Reviewer: Cesar Fernandez-de-Las-Penas

Reviewer's report:

This is an interesting study, which deserves publication since investigates an extremely necessary and important topic: the effectiveness of TrP treatment for shoulder pain. I have some comments for improving the quality of the manuscript.

1. Abstract. I recommend that the method section would be rewritten with more and clear data about what was done, particularly about groups. One sentence is included to explain the content of the treatment, but unfortunately not much more space is available. In the results section authors should comment the cut-off for considering improvement or non-improvement in the GPE. The cut-off point is explained in the abstract and in the methods section.

2. Methods: Authors can describe the medical diagnosis that patients with shoulder pain included in this study had been referred to the clinic. Most patients were diagnosed with shoulder pain (“working diagnosis” according to the Dutch shoulder guidelines) except for those patients who came directly to the physiotherapy practice without diagnosis. A figure with the referred pain patterns from the TrPs included in this study (or some) would help to some readers. Some extra sentences are included to explain this.
have been included. It is important that authors include which muscles were explored. An extra table (table 1) has been included. Authors should include a reference for the sample size calculation. We have done this now. A better and complete description of TrP treatment is recommended. The description of MTrPs is rewritten and completed. Also a figure with some techniques would help to readers not familiar with these interventions. Pictures (figures 5a,b,c) are included. Which is the cut-off for consider a recovery in the GPE? In the statistical section they classified patients in improved and not improved, a cut-off in the GPE is necessary. The cut off is expressed as improved (from slightly improved to completely recovered) versus not improved (from unchanged to much worse).

3. Results: A short phrase clarifying that no differences between groups before start the treatment is necessary to see the comparative situation between groups. Is included at the beginning of the results section. In the results section references are not properly included [95]. The references are deleted. Although not significant, PROM part should be included in the text (F and P values). The t statistic and p-values for 6 weeks and 12 weeks are included. The values for the baseline are presented in table 2. So the reader can compare these figures and conclude that there is no difference between baseline, 6 weeks and 12 weeks.

4. Discussion. Very good. I would like to see some hypothesis why TrP treatment is effective for shoulder pain (changes in sensitization, improvement of motor control, improvement of shoulder girdle biomechanics, etc. One paragraph about this topic is included in the discussion section and a statement about the therapeutics effects is made. Authors should also comment that the control group also improved (figure 3). This point is now commented in the discussion section.

5. Tables: I believe that authors should include in the discussion that the control group have a greater number of latent TrPs (5.) than the intervention group (4.2), which was statistically significant (table 2). Can this finding related to the results of the study? This point is commented in the discussion section.

Quality of written English: Acceptable. Statistical review: Yes, and I have assessed the statistics in my report. Declaration of competing interests: I declare that I have no competing interests.

Reviewer: Chang-Zern (John) Hong
Reviewer's report:
This is a single blinded randomized controlled trial to evaluate the effectiveness of a 12-week comprehensive physical therapy program for myofascial trigger points (MTrPs) in patients with chronic non-traumatic unilateral shoulder pain, compared to a control group with "wait-and-see" strategy. After 12 weeks of therapy, the intervention group showed significant improvement in all outcome measures compared to the control group. This study is well designed and conducted. It is important and valuable in the field of myofascial pain. Authors should emphasize that their findings can further support the importance of MTrPs as a major cause of soft tissue pain. One concern in this article is the definition of active MTrP and latent MTrP. Simons defined an active MTrP as the one with spontaneous pain (or + referred pain) or pain in response to movement, while a latent MTrP is the one without spontaneous pain but pain in response to compression (tenderness). In the "Introduction" of this paper, active MTrP was defined as "a symptom-producing MTrP and can trigger local or referred pain or paraesthesia". According to this definition, an MTrP without spontaneous pain may also trigger clinical symptom (trigger local or referred pain similar to patient's usual clinic discomfort [pain recognition]) by compression of this MTrP, and can also be called active MTrP. This would be quite different from Simons' original definition. Since Simons' "Trigger Point Manual" was quoted in this paper as a reference for definition, it is strongly suggested that "active MTrP" and "latent MTrP" should be defined following Dr. Simons' definition. In this study, the "active MTrP" was confirmed, "when the patient recognized the pain from compression on the tender spot". In such case, some of them might not be active MTrPs at the time of examination, although they might be active MTrPs sometimes after the onset on clinical symptoms. It is suggested to use different term (other than active MTrP) in this study, such as "symptom-producing MTrP (sp MTrP)". The exact definition from Simons et al is cited, which makes it more clearly to the reader. To introduce a new term symptom-producing MTrP instead of activeMTrP may confuse the reader. MTrPs can change from active to latent and vice versa. This is mentioned in the discussion.

It is also suggested to add the following important issue in the "Discussion". Reduced tightness of MTrP and taut band after MTrP therapy can improve focal circulation, and thus to improve the healing of the
underline pathological lesion (such as tendinitis, bursitis, etc. if any) associated with shoulder pain. Especially altered kinematics of the shoulder have (theoretically) influence on the status of tendons and bursae. To my knowledge, there is no evidence that altered blood circulation within the muscle has an effect on the healing process of tendons and bursa. And although it might give us more insight into the mechanisms of recovering from shoulder disorders, I’m not aware of any study confirming this interesting hypothesis at this moment. Reduced pain and tightness can also improve mobility and daily life. The importance in MTrP therapy should be emphasized in this study. We fully agree with you and some text is added to emphasize the importance of MTrP therapy.

There are few other minor points as listed below:

1. The standard for DASH should be spelled out in the text (beside the "Abstract") when it first appeared in the text. DASH is spelled out.
2. It is suggested to list these 17 muscles examined for "active" MTrPs. A Table with all 17 muscles is added.
3. It appears that many references (totally 113) were listed. You may consider cut some unnecessary ones. Some references are skipped, but the remaining references are relevant for the paper.

Quality of written English: Acceptable. Statistical review: Yes, but I do not feel adequately qualified to assess the statistics. Declaration of competing interests: I declare that I have no competing interests.

Reviewer: Martin Descarreaux

General comments:

The manuscript presents results from a RCT designed to compare a global intervention for treating trigger points versus a no intervention strategy. The study seems to be properly designed and complies with most of the Consort statement on reporting randomised trial. The statistical section of the methods however is not clearly presented and it seems like the authors have confused the different analyses performed. The manuscript would also need some English editing. I have provided some comments as a reviewer regarding editing but the author should consult with someone whose first language is English. I am not sure the study is of general interest for the readership of BMC medicine but it would definitely be appropriate for BMC musculoskeletal disorders.

Major Compulsory Revisions

Abstract: The overall treatment strategy should be explained in the abstract. The treatment strategy is explained. Otherwise the potential reader could assume that only ischemic therapy was performed. The treatment strategy should also be reflected upon in the conclusion section of the abstract. Done

Background: A clear hypothesis should be stated in the background section. The introductory lines have been rewritten to explain the hypothesis more accurately (within the limits of the word counts).

Methods: The authors mention that a "set of self-administered questionnaire were used in the evaluation of the participants". However these outcomes are not defined clearly neither their use nor purposes in the current study. Were these questionnaires the ones used to create table 1. Please specify. “ A detailed medical history was taken, that included demographic variables and potential prognostic factors, and a set of self-administered questionnaires for outcome measurement”.

Methods: the randomization section is clear to me. However there is no clear mention of the concealment strategy described in the manuscript. The strategy implemented to conceal the sequence until interventions is assigned needs to be described. Done.

Methods: The precise nature of the prescribe exercises and ergonomic advice needs to be detailed in order to be clinically relevant for the clinician and research communities. Illustration may be helpful if permitted by the journal. This section has been expanded and three photographs have been added.

Methods and results: the authors do not properly address the issue of possible co-interventions. Were they controlled, avoided, taken into account? The authors need to expand on this important issue. Information about co-interventions is added in the text. The allowed and uncontrolled self-management strategy poses
some risks. The authors should clearly justify their choice and its possible impact on the study results and the overall generalization of their data. A comment is added to the limitations of the study section.

Methods: the intention-to-treat strategy (preferred method) should be stated and clearly described. The intention to treat strategy is mentioned in the text.

Discussion: Overall the discussion is well written and comprehensive. I would suggest the author discuss the following points.

- The possible impact of having an underpowered study. This is mentioned in the text.
- Is there a possible bias associated with the high rate of observers' capability to identify the group? An extra sentence is added to the text.

Minor Essential Revisions
- Background: A reference is needed for the last sentence of the second paragraph (definition of myofascial trigger points). Done.
- Background: There is a syntax error in the last sentence of the third paragraph (Although....but the clinical). Done
- Background: There is also a syntax error in the first sentence of the fourth paragraph. ...and may be combined refers to the MTrPs at the beginning of the sentence. The authors should make two sentences out of it. Done
- Background: Even though the study by Hains is a small scale clinically based study, the author should reference the study in the introduction so the reader gets a full perspective of what was previously published on that topic. The Hains study is now mentioned in the introduction and in the discussion section as well.
- The objective should be rewritten to simplify the sentence. The author might consider two sentences again. Which is done.
- Methods: what is the "physical therapy practice for Neck, Shoulder, and Upper Extremity Disorders, Groningen, The Netherlands". Is this the full name of a clinic or the name and the location? Please specify. The use of capital letter seems to be arbitrary in the name. Done
- Methods: Since direct access to physical therapy became available in the Netherlands in November 2006. Not relevant to the study. We have deleted this sentence.
- Methods: The total number of palpated muscle should be stated in the data assessment section. A table of the palpated muscles is added.
- Methods: The PDF transformation seems to have altered the text and mathematical symbols related to the stats, please verify. Done. In this section, it is not clear which variables were normally distributed and which were not and this should be clarified. The statistical analyses for VAS-P, ROM and number of muscle are not clearly described. This lack of description creates confusion in the results section. The author should specify what statistical analyses were performed for each of the variable and organize the results section so the read can identify the results associated with each of the analysis. We have made important corrections according to your recommendations. Statistical methods are better explained and results section and statistical section are revisited.
- I am wondering if the number of muscle variable is normally distributed (probably not). Clarifications are needed. The number of muscles with active and latent MTrPs was in either group at intake, after 6 weeks and after 12 weeks normally distributed. I have double-checked it visually (comparing means and median) as well as with the Kolmogorov Smirnoff test. Even when we analyzed non-parametrically (Mann Whitney U statistic) the results were largely the same (no statistical difference at baseline and after 6 weeks, and statistically significant at 12 weeks (p=0.02). Therefore we chose to present means, difference of means, and t-test results.
-Results: The author should clearly state if the group were comparable for each of the baseline characteristics. Done

-Results: As stated in the introductory comment it looks like a ANCOVA was performed but the author talk about multiple linear regression while comparing results between groups. This is very confusing and clarifications are needed regarding the ANOVA model used, the ANCOVA (with covariables defined). Sentences like "Adding covariates did not change this result" are very confusing. This section is rewritten.

-Again, correlation analyses, not described in the methods section are presented in the results section. Done

-Discussion: relative risks (RR) should be defined and abbreviated the first time. Discretionary Revisions. Done

-Methods - Randomization section: After collection of all patient's data...Done

-Methods: I would change the "intervention/control variable" to the "group variable" Done

-Discussion: I don't believe the expression "were higher educated" is appropriate. I would suggest the participants had a higher level of education. Done

Quality of written English: Needs some language corrections before being published. A native (American) speaker has checked the text thoroughly and has made a number of corrections.

Statistical review: Yes, and I have assessed the statistics in my report. Declaration of competing interests:

I declare that I have no competing interests