Author's response to reviews

Title: The effect of continuous ultrasound on chronic non-specific low back pain: A single blind placebo-controlled randomized trial

Authors:

Safoora Ebadi (s_ebadi@razi.tums.ac.ir)
Noureddin Nakhostin Ansari (nakashin@sina.tums.ac.ir)
Soofia Naghdi (naghdi@sina.tums.ac.ir)
Shohre Jalaei (jalaeish@tums.ac.ir)
Mirmostafa Sadat (sadat1335@gmail.com)
Hosein Bagheri (hbagheri@tums.ac.ir)
Maurits W vanTulder (maurits.van.tulder@falw.vu.nl)
Nicholas Henschke (nhenschke@georgeinstitute.org.au)
Ehsan Fallah (fallah_e@razi.tums.ac.ir)

Version: 4 Date: 28 July 2012

Author's response to reviews: see over
Dear Editor,

We are pleased to resubmit the revised version of MS: 1444387473641758 “The effect of continuous ultrasound on chronic non-specific low back pain: A single blind placebo-controlled randomized trial.”

We appreciated the helpful comments of the reviewers and have addressed them thoroughly as outlined below.

Required changes were mostly minor corrections and some changes in sentence structure. Clarification was made wherever requested and the manuscript has been proof read to ensure correct spacing, punctuation and consistency.

Yours sincerely,
Safoora Ebadi

Reviewer: Gráinne Kelly

Reviewer's report:

Minor Essential Revisions

This manuscript reports on a study investigating ‘the effect of continuous ultrasound on chronic non-specific low back pain’. The authors have addressed many of the original comments and areas for clarification which had been requested. There are still a number of minor issues which require some clarification or correction prior to this manuscript being ready for publication.

General Comments:

1. The authors use many terms to describe the ultrasound administered to the
intervention group i.e. ‘real’, ‘continuous’, ‘true’. Similar comments are made regarding the terminology used for the control group with the authors using varying terms throughout the manuscript i.e. ‘placebo’, ‘sham’. The abstract, manuscript, tables and figures would benefit from consistency in language; one term should be chosen to reflect both the intervention and controls groups and should be used throughout.

Again, the manuscript would benefit enormously from proof-reading as there are quite a considerable number of punctuation and character spacing errors throughout, with too many errors to comment on individually e.g. spacing between words and punctuation marks in particular.

Response:

Thank you for your helpful point.

Continuous and placebo are used throughout the text.

Abstract:

2. Background: In the second sentence, please detail the abbreviation US (ultrasound) in full prior to the abbreviation.

Response:

Ultrasound is written in full.

Background:

3. The authors state in the second paragraph that NSCLBP ‘is not linked to any underlying tissue damage’, however, later in the third paragraph they detail that ‘therapeutic US is among the commonly used physical modalities for treating soft tissue injuries...., there is a dearth of evidence for (its use) in patients with LBP’. These statements are quite conflicting, perhaps the authors could revisit these
statements and detail more explicitly why US may be useful in the management of NSCLBP.

Response:

Thank you for your useful point.

The paragraph was changed to:

“Specific back pain occurs in approximately 2% of all patients with back complaints [5]. For the majority of patients with LBP a specific diagnosis cannot be defined on the basis of anatomical or physiological abnormalities. Non-specific LBP (NSLBP) is assumed to be inflammatory or mechanical in nature [6]. Chronic NSLBP refers to an episode of activity-limiting LBP (with no pain referred into either lower limb) that lasts for 3 months or more [7].”

4. Second paragraph commencing ‘Specific back pain occurs ...’: Referencing is required for the opening sentence of this paragraph.

Response:

Reference was added.

5. Sixth paragraph commencing ‘Acoustic waves...’: Referencing is required or the first, second and third sentences of this paragraph.

Response:

All three sentences mentioned as well as the forth sentence have the same reference [Allen2006] for which the number has come after the forth sentence.

Methods:
6. Interventions (US therapy section, second paragraph): Final sentence, language should be corrected to read: ‘the need to deliver energy to a large area’, rather than ‘an almost large area’.

Response:

With regard to the other reviewer’s point, the phrase “an almost large area” was deleted.

7. Interventions (US therapy section, fifth paragraph): Referencing for the opening sentence requires correction to Hashish et al. [24]. The authors should revisit the ‘tense’ in which this paragraph is written, and correct to ‘past tense’ e.g. ‘the patient was not aware of what she/he ..... real US the patient was unaware ...’.
The final sentence of this paragraph also has some language issues, a suggestion would be that the authors rephrase this sentence to read; ‘... patients were told in both groups that they may feel some heat and should this cause discomfort to notify the therapist in order to safeguard

Response:

Hashish et al. [24] was inserted in place.
The paragraph is changed to:

“Commonly, the patient is not aware of what she/he should expect at the beginning of treatment with US and since even with real US subjects are unaware of any sensation at most therapeutic intensities [22], patients were told in both groups that they may feel some heat and should this cause discomfort, to notify the therapist in order to safeguard patients in the continuous US group from overheating.”

8. Interventions (Exercise therapy section, first paragraph): Referencing in journal style is required for the opening sentence of this paragraph. Referencing is also
required for the third sentence of this paragraph commencing ‘Studies indicate that stretching ...’.

**Response:**

The style of the opening sentence and the subsequent sentence is changed to read “There is strong evidence that exercise is as effective as other conservative treatments in chronic LBP and that functional and pain outcomes significantly improves in groups receiving exercises relative to other interventions [26]”

Third sentence commencing “Studies indicate that stretching ...” and the forth sentence have the same reference which has come after the forth sentence.

9. Interventions (Exercise therapy section, second paragraph): Referencing is required for the first and second sentences of this paragraph. Also correct the abbreviation in the first sentence to ‘CLBP’, not ‘CLBL’.

**Response:**

All three sentences of this paragraph are referred to Vleeming [28] at the end of the third sentence.

CLBL was replaced by CLBP.

10. Interventions (Exercise therapy section, fourth paragraph): Correct second sentence ‘warming-up’ to read ‘warm-up’. Also correct the sequence of wording in the third sentence to read ‘... patients were asked to maintain the daily home exercises for one further month’.

**Response:**

Warming up was corrected to read warm up.

The sequence of wording in the third sentence was corrected according to your helpful comment.
11. Outcome measures (second paragraph): Correct spelling of ‘electromyography’
second sentence.

Response:

The spelling was corrected.

12. Outcome measures (fourth paragraph, commencing ‘The primary outcomes
were’): Please supply a reference for the VAS.

Response:

Reference was added.

Results:

13. All tables and figures in the results section would benefit from the addition of
further detail; this would allow them to be read alone without reference to the
text. A key should be added to all tables explaining abbreviations, set values for
significance i.e. p#0.05 etc.

Response:

Thank you for your practical comment. Further details were provided for each table.

14. Consistency of reporting both within the tables and text is required. In some
areas numbers, are written as .01, whilst in others they are written as 0.01, as
suggestion would be to make all numbers consistent i.e. 0.01 etc. Similarly,
within the text tables are referred to in some areas with a capital ‘T’ and in other
areas with a lower-case ‘t’, this should be corrected for consistency.

Response:

Reporting became consistent throughout the text for numbers to read .01 and tables to table
(unless where it has been the beginning of the sentence).
15. Table 3 could be condensed from a spacing perspective, allowing it to be viewed on one page only. Also with reference to Table 3, the authors detail significance with respect to Time (denoted by an asterisk), however, is it possible to detail at which time point significance was achieved i.e. between pre and post, pre and 1 month follow-up, at all three time points.

**Response:**

Table 3 was rearranged to fit in one page.

Details regarding improvement at each time point had already been provided in the text:

“There was a significant effect of Time (p < .001) on FRI. Bonferroni post-hoc test revealed that FRI scores had improved significantly after 10 treatment sessions (p < .001) and over time after one month follow-up in both groups (p < .001). The improvement of FRI scores was maintained one month after the end of the 10th treatment session (p = .24). Main effect of Group on FRI was significant (p = .004) while the Time × Group interaction was not significant (p = .31).

There was a significant effect of Time on VAS (p < .001). The mixed model ANOVA on VAS did not reveal a statistically significant Group effect (p = .48). Post-hoc analysis showed that VAS scores improved significantly from baseline to after the 10th session (p < .001) and continued to improve until the one-month follow-up measurement (p = .004). The Time × Group interaction was not significant (p = .48).”

16. Second paragraph commencing ‘Mean age of all participants ...’: In the second sentence the authors refer to Table 1 reporting no statistically significant difference in baseline characteristics or baseline outcome measures, however,
Table 1 does not detail any significance values to allow for this statement.

**Response:**

P values were added to table 1 and to table 2 for baseline differences.

17. Third paragraph commencing ‘Mean values for baseline ..’: The authors refer to the detail featured in Table 2. Improvements in FRI and VAS are reported, whilst these improvements do look likely to be significant, no reference is made to whether these improvements were significant and details of this should be included in the text.

**Response:**

We would like to draw your attention to the point that reporting a decrease for FRI and VAS in this part was only stating of what we see in the table for our very sample size. Details on significance are reported next on the text under primary outcome measures.

18. Fourth paragraph commencing ‘The effect of the US..’: This paragraph would benefit from restructuring to state that ‘Table 3 details the results of the mixed model ANOVA showing the effect of continuous US versus sham US on outcome ....’. Otherwise this paragraph reads like it should be incorporated into the Data Analysis section of the Methods.

**Response:**

Sentence was restructured according to the reviewers comment.

**Discussion:**

19. Fourth paragraph commencing ‘Mohensi et al ...’: The authors to a study by Mohensi et al. and detail greater improvements with manipulation and exercise, compared to US and exercise. Could the authors perhaps attempt to explain possible reasons for this difference, perhaps with respect to the outcome
measures used, proposed mechanisms of action (manipulation versus ultrasound). Also correct ‘didn’t’ to ‘did not’, final sentence of paragraph.

Response:

Below mentioned sentence was restructured to address your very particular comment:

“The authors did not report on the details of the exercise program, and US delivery was very inconsistent (continuous 1MHz, 1.5-2.5W/cm² for 5 to 10 minutes, average 6 sessions, one or two times a week) which could both be possible sources of difference with our study.”

20. Sixth paragraph commencing ‘However, the individual ...’: Referencing for the third sentence ‘Continuous moving ..’ is required.

Response:

Reference was added.

21. Seventh paragraph commencing ‘A significant difference ..’: The second and third sentences should be corrected to read ‘Morrisette et al [48] showed that

Response:

The sentence was corrected accordingly.

22. Ninth paragraph commencing ‘Clinical assessment of movement ...’: The first sentence would benefit from rephrasing to read ‘... in low back pain is predominantly done by measuring ...’. Also the third sentence would benefit from rephrasing to read ‘increase of ROM in the real US group may be due to the thermal ...’, no causal link has been verified in this study.
Response:

Sentences were rephrased accordingly.

23. Paragraphs eleven through to the section on limitations would benefit from restructuring into more coherent paragraphs with progression of thought. At present this section reads quite poorly and is quite disjointed. The final paragraph of this section (commencing ‘one of the main …’) requires further reference support for the final two sentences.

Response:

Paragraphs mentioned were restructured according to the useful comment of the reviewer and references were added.

24. Again, the reference section requires attention for character spacing, punctuation and consistency of reporting.

Response:

Reference part was over read and corrected for inconsistencies.

Title: The effect of continuous ultrasound on chronic non-specific low back pain:

A single blind sham-controlled randomized trial

Version: 3 Date: 20 June 2012
Reviewer: Tim Watson

Reviewer's report:

Thank you for submitting this revised paper. I note with interest that following a reworking of the data and analysis, that the results are now quite different from those originally proposed.

Response:

Thank you very much for the time and consideration.

There are some issues remaining, but I would consider them to be generally minor in nature and are listed below for your consideration:

1. Abstract: in the methods section, worth including 'continuous' in the ultrasound parameters, so that there is no doubt in this regard. I appreciate that the detail is included in the text that follows, but for those skimming the abstract, it would be helpful.

Response:

Continuous was already in the sentence as the name of the group:

“50 patients with NSCLBP were randomized into two treatment groups 1) continuous US (1 MHz & 1.5 W/cm2) plus exercise 2) placebo US plus exercise”

2. Page 5: sample size: you do not identify WHICH effect size is assumed to be at 0.8 - clarification would assist

Response:
The description on sample size was restructured to address your very useful comment:

“The primary outcome measure of this study was changes in functional status using FRI. Assuming the effect size of .8 for FRI with alpha set at .05 and a power of .8, and accounting for 10% dropouts, the sample size needed was calculated as being 23 patients in each group.”

3. Page 6: second last paragraph: not sure what an 'almost large area' is?

Response:

The phrase mentioned is omitted from the sentence.

4. Page 7: typo last paragraph: CLBL

Response:

CLBL was changed to CLBP

5. Page 9: end section on outcome measures. Units missing from sample rate and Gain

Response:

Hertz for sample rate and Decibel for Gain were added.

6. Page 10 end data analysis section: your use of p values is inconsistent - sometimes upper case and sometimes lower case. Technically, it should be lower case. Whichever you use, it should be consistent throughout the document

Response:

(p > .05) was omitted and document was checked for consistency.
7. Page 12 : end results section : statistical significance rather than statistical significancy

Response:
Significancy was changed to significance

8. Page 13 : second last paragraph : . . . US deliver was very unspecified . . . - I know what you mean, but might be better use to use 'variable' or 'inconsistent' or some equivalent term

Response:
“Inconsistent” was put in the sentence instead of “unspecified”.

9. End page 13, top P 14 : I would take issue with the placebo ultrasound being consistent between groups. The mechanical application of the ultrasound head was indeed consistent, but this is not the same as the 'placebo' effect. Your argument can stand IF you make it the mechanics of application which is common to both groups.

Response:
Thank you for your valuable point.

Paragraphs 5 & 6 under discussion were changed accordingly.

10. Page 15 : last paragraph : there is considerable evidence that the extensibility of collagen based tissues will change with ultrasound thermal applications so long
as sufficient temperature change is achieved. See Lehmann and several other authors by way of references for this. Draper, who you have included in your citations also discusses this in several of his papers.

**Response:**

Thank you for your useful point.

The related paragraph (9) were changed according to your comment.

11. Page 16, last sentence, : Sung reference is missing - think it is number 55

**Response:**

The reference had been mentioned at the beginning of the paragraph.

12. Page 17 Paragraph starting 'one aim of the present study . . .' the last sentence is very difficult to understand and should be rephrased

**Response:**

Last 3 paragraphs were restructured to address other reviewer’s comments as well as your particular point.

13. Next paragraph : it is possible that continuous ultrasound may have improved . . .

**Response:**

The sentence was changed accordingly.

References :

14. Almost every reference has formatting issues. You need to be consistent with regards journal abbreviations (or not), spacing between names, commas, and text. Some references include 'volume' and 'issue', most do not. Check with the
published journal agreed style
There are typographical errors throughout, mainly with regards the use of commas and spaces - please check all text

Response:
Reference part was over read and corrected for inconsistencies.