Reviewer's report

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

Version: 2 Date: 28 March 2012

Reviewer: Tim Watson

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Major Compulsory Revisions
You make the claim in the abstract and else where in the text (intro and discussion) that ultrasound is commonly applied for CLBP. I am not sure that this is true, and you provide no reference material to support your claim and thus to justify your investigation

If you have carried out statistical analyses, it is normal to include the actual p values rather than < or > then 0.05.

In your Ultrasound application section you have a reference to Robertson with no reference number - needs to be corrected

The concept that 1MHz ultrasound is used to target chronic conditions is not consistent with the literature that you have cited elsewhere in this paper. You have not made a specific reference to it - it needs some kind of justification. I appreciate that you can not change what you did, but it needs to be justified none the less

The concept that the patient was blinded to the group allocation (verum or placebo) is potentially flawed in that at the dose you have applied, a thermal effect would be expected. If the patient did/did not feel heat, This would have influenced their perception of the therapy. You say in your previous paper (ref 14) that you planned to evaluate the patient awareness of group allocation, but in fact did not carry this out. This needs to be addressed in this report

Outcome measures section
The pain measured using a VAS scale is a common method, but you make no indication whether you were assessing the pain at that moment in time, averaged over the last day, or since the last treatment session or . . . whatever was used. This is known to make a difference to the magnitude and the reliability of the VAS as an outcome measure and needs to be clarified

Data Analysis
The statistical analysis needs to have a stronger justification - particularly why you did not use a repeated measures ANOVA with post hoc analysis

Results paragraph 2 : you say that you 'adjusted' for endurance time - but make
Discussion

Your comparison with previous research in this field appears to be inconsistent. At times you say that your results were generally in agreement with paper XX and later you say you were largely different from paper YY, but this appears to be a rather subjective decision.

You say that ultrasound effects were no different between the real and sham groups and therefore the effect was placebo based. It could be that ultrasound has no effect in this clinical condition and therefore the improvements were attributable to the exercise alone - the ultrasound made no contribution to the change over time. This is a distinct possibility and should be mentioned. You could only attribute the effects to a placebo response if you had a third group who received no ultrasound (real or sham) and then identified that the real and sham ultrasound group changes were no different from each other, but both were different to the control.

Secondary outcome section in discussion

Unless ultrasound has a primary effect on the pain experience, it was unlikely to ever have an effect on gross movement (flexion/extension) as it does not have this capability. It can result in changes collagen extensibility and flexibility range, but not in the lumbar spine and not at these doses. There is a 'stretching window' immediately following high dose ultrasound, and if stretching exercise is undertaken in this (short) period, there have been demonstrable chances (previously published work) but this is not the approach that you adopted, and hence it is difficult to imagine how ultrasound could be expected to influence gross spinal mobility.

Similarly ultrasound does not have the capacity to influence muscle endurance, though exercise does. Demonstrating no difference in endurance capacity between groups is therefore not at all surprising. The fact that your exercise programme, common to both groups, also failed to demonstrate any difference (pre-post) is a different issue. Your previous paper (ref 14) indicated that you would use stretching followed by strengthening exercises. You make the same statements in this paper. If that was the intention, then one would question the justification for recording an endurance outcome when the exercise programme appears not to have been designed to influence endurance capacity. This requires some further justification and rationalisation.

Limitations section (in the discussion)

Agree that the therapist was not blinded, but one remain unconvinced that the patient was blinded based on the thermal issues identified previously. This needs to be considered.

You mention that it was 'impossible' to check for compliance with the exercise programme. Whilst it is problematic, it is not impossible, and some kind of diary
compliance monitoring has been reasonably widely used in other studies. Whilst it is too late for this study, it could reasonably be included in your limitations section.

Conclusion: given that ultrasound would not be expected to influence spinal mobility nor endurance, I am not sure that your conclusion is justified. Your work does show that the addition on ultrasound to an exercise programme did not make any difference to the outcome on your primary outcomes, and also that the exercise programme as employed in this study did not make any difference to mobility nor endurance etc.

**Level of interest:** An article of limited interest

**Quality of written English:** Needs some language corrections before being published

**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 with any aspect of this research.