Author's response to reviews

Title: Training in ChiRunning to reduce blood pressure: A randomized controlled pilot study

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Author's response to reviews: see over
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Version: 4
Date: 27 August 2015

Author's response to reviews: see over
Re: Publication of the manuscript “Training in ChiRunning to reduce blood pressure: A randomized controlled pilot study”

Dear Editor,

We have made the changes, described in italics and indicated in the manuscript in red, based on reviewer comments.

1. Please address medication use. Specifically, how many patients were taking an anti-hypertensive? Patients in the hypertensive range would be typically expected to be taking medication. However, medication effects could overwhelm the intervention effects. As this is a feasibility study, that is not a serious flaw, although future larger scale trials might need to exclude antihypertensive use.

   Four participants were on medication and all of them were randomized to one of the two control groups. We conducted a sensitivity analysis to look at whether excluding these participants made a significant difference in the change scores and it did not (although this may be because the numbers are very small to begin with). We included a short description of this sensitivity analysis under “Blood Pressure” in the Results and Discussion section. In a larger scale trial, we would exclude antihypertensive use given the affect on outcomes.

2. Please consider the self-reported injuries in the discussion. Self-reported adverse reactions to running that limit the amount of running in which the patient engages might not really be injuries. For example, shin pains or cramping. Sore muscles can reduce motivation to run, but those are really training effects. Also, the title of the ChiRunning book implies that a desired outcome was fewer injuries, but the trial found a high rate of injuries (50%+). This is not a major flaw, but it merits discussion. Was there any sense in which the ChiRunning conferred any advantage to other forms of running? Why is the study a success in terms of feasibility if 50% of the participants have an “injury” that restricts running? I personally suspect that they were not really injuries of the type that require running to cease while they heal (e.g., for 6 weeks).

   We have included discussion about self-reported injuries and the fact that these may just be normal discomforts associated with training. In addition, we changed the name of the variable of “running-related pain” to “running-related discomfort” to further emphasize that this may not be indicative of injury. This is a critical point that we are trying to make and provided some additional clarification in the text as well. We also hope that this change in the language clarifies that the increased running related discomfort may in fact be an indicator of increased body awareness and should not be taken to suggest that ChiRunning leads to increased injury. There was no difference in the self-reported, running related injury between the two groups.

- Discretionary Revisions
1. Figures 2-4 do not add much to the report. There are no error bars and the groups look the same when printed in black-and-white. If space is a consideration, all of this information could be presented in one table.

*The figures were removed. Table 2 includes change scores between the time points.*

1. Lines 167-168, the two control groups were combined for analysis. Was this a pre-determined strategy? The rationale was not clear and seemed to be after the fact. If this was not the original intention, why not compare the result as originally planned in three separate groups?

   *Combining the control groups was a part of the original intention of the study design in order to look at the specific effect of receiving the ChiRunning training versus not. We also had planned on looking at the three separate groups to see what contribution being in a coach-led group accounted for, however, given the challenges we faced with recruitment the resulting cell sizes were very small. The primary research question around ChiRunning and the small cell sizes are the two reasons that we combined the control groups. We added text to provide a more detailed justification in the Methods section.*

2. Lines 221 -229, even though the presentation was mainly by the two groups, the authors now presented some result in this paragraph in a different grouping which is confusing.

   *We deleted the comparisons across three groups and clarified our reasons for combining the control groups.*

3. Line 273-274, was the ChiRunning group trained to increase awareness? Was there any measure to indicate increased awareness?

   *The intervention description was revised to include more detailed description of the ChiRunning intervention including that the training was also in mindfulness and body awareness. The Five Factor Mindfulness Questionnaire (FFMQ) as subscales for increased awareness and the Multidimensional Assessment of Interoceptive Awareness (MAIA) scale is a validated scale of body awareness that was used to measure changes pre/post. While the MAIA did not show significant changes, we believe that the increased perception of “aches and pains” was a preliminary indicator of increased body awareness. Data from the FFMQ and the MAIA are going to be presented in another paper. This paper was intended to only focus on feasibility and preliminary efficacy.*

4. As the authors stated that the aim of the study was to assess feasibility, acceptability and preliminary outcome data. The authors did not document as to the goals of recruitment, retention and adherence. In addition, the aim of assessing acceptability was not explained clearly as to the tool and measures collected and the evaluation, but the conclusion was made that it was acceptable to participants. Please clarify.

   *The text has been revised to clarify recruitment, retention and adherence criteria and to describe the instruments used for assessing acceptability.*

Minor Essential Revisions

5. Abstract and throughout the manuscript, it’s clearly stated that the primary efficacy outcome that the authors were interested in is blood pressures, it’s implied in the title and the results presented but not clearly stated. Please clarify.
The study title refers to blood pressure and were not sure how to further clarify the title; however, we did add clarification to the results section (line 172-3) about blood pressure and BMI being preliminary efficacy outcomes.

6. Line 127, sentence is not clear about medication for SBP

Sentence has been clarified.

Thank you for your time and consideration

Sincerely,

[Signature]

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