Author’s response to reviews

Title: A Randomised Multicentre Trial of Acupuncture in Patients with Seasonal Allergic Rhinitis - Study Intervention including Physician and Treatment Characteristics

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A Randomised Multicentre Trial of Acupuncture in Patients with Seasonal Allergic Rhinitis – Trial Intervention including Physician and Treatment Characteristics

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Research article

Dear Reviewers

We are very grateful for the comments and considered them carefully for our manuscript. Further we have prepared the following point-by point response letter.

Reviewer 1

Reviewer 1, #1: I think the authors need to go back and think very carefully about what this article tells us that is original and why it’s important. This needs to be clearly outlined in the abstract and then followed through in the other aspects and sections of the paper.

Authors’ response: This article mainly describes the interventions used in the ACUSAR trial, including the characteristics of the physicians and the Chinese Medicine (CM) diagnoses in compliance with STRICTA guidelines. We believe that this information is interesting to researchers (e.g. for trial replication) as well as to practitioners in the field of acupuncture (e.g. for acupuncture practice in SAR) considering the substantial discussion about acupuncture and sham acupuncture techniques.
and their standardisation in trials. We discuss the pros and cons of a semi-standardized acupuncture protocol we performed in our trial (page 11 and 12, paragraph 1).

Reviewer 1, #2: The abstract really needs tightening and editing.
Authors’ response: We revised the abstract following your suggestions (page 2).

Reviewer 1, #3: Don’t introduce ACUSAR as an acronym without explaining what it stands for.
Authors’ response: We added the full name of the trial in the abstract (page 2, paragraph 2).

Reviewer 1, #4: Presumably the aim of the paper would describe the trial physicians and intervention in order to understand if they made a difference to the outcome; that is not clear in the abstract. The specific question that needs to be asked and answered by this paper remains a little vague. Some of the English in the method section needs attention; I don’t understand what a facultative acupuncture point is? I’ve never seen it referred to in any of the acupuncture literature I’ve read.
Authors’ response: This paper tries to describe the characteristics of the physicians and the interventions in detail since this was not published in the main paper that way. In this paper, we do not report the possible influence of the qualification of the acupuncturists or of treatments on the outcome, because we did not analyse the results of each physician in this trial yet. However, the trial was not powered to detect any differences between the trial centers in regard to the efficacy of the trial intervention.
A “facultative” acupuncture point was meant to be a point which could be chosen from several given points. We replaced “facultative” by “optional“ which is clearer.

Reviewer 1, #5: The results report Chinese Medicine diagnosis: the abstract in its background does not suggest that we will be looking for a diagnosis but rather will be looking at the trial physicians and intervention (are the diagnosis and intervention synonymous? If so, that needs to be made clear).
Authors’ response: We added the CM diagnosis in the abstract (page 2, paragraph 2). Each patient was diagnosed by the CM diagnosis procedures and categorized by one or more CM syndrome diagnose(s). This CM syndrome diagnose(s) should have an influence on the selection of acupuncture points in the acupuncture group, but not in the sham acupuncture group. We clarified this in the manuscript (page 13, paragraph 2).

Reviewer 1, #6: The conclusions are rather weak, if one recruited well educated and experienced acupuncturists, which this trial did, then it´s rather facile to come to the conclusion that the acupuncture was provided by well educated and experienced acupuncturists. The use of more needles in the acupuncture group may result in a better outcome. The abstract seems a little cloudy.
and needs tightening up; the authors should be aware that very often the abstract is the only information that’s read by people.
The introduction and methods are largely drawn from the primary paper and again the question posed in the last sentence of the introductory section (the aim of this paper is to provide details on the characteristics of the intervention and the acupuncturists who participated) is a little and one wonders why one would want to know that.

Authors` response: Thank you for the advice on our conclusion. We reviewed it and modified it, following your suggestions (page 2, paragraph 4, page 3, paragraph 1 and page 13, paragraph 3).

Regarding the redundancy, we added information from the main paper to the methods section after the first submission because this was required by CONSORT standards as suggested by the BMC CAM editors. This includes the inclusion and exclusion criteria, details about informed consent, the randomisation process and sample size calculation, the ethics approval, and the trial practice following the Declaration of Helsinki Good Clinical guidelines (page 5).

Reviewer 1, #7: I suspect the method section is rather repetitive of the main paper; do we really need to know that? There appears to be no statistical methodology for the proposed analysis in the method section and it seems from the method section that it’s rather unclear as to exactly what scientific questions this paper will be answering, as opposed to the initial protocol and subsequent Annals paper.

Author`s response:
This paper is a description of the mode of intervention according to the STRICTA guidelines and related checklist regarding the reporting of the details of acupuncture intervention in research. As recommended in the checklist, the paper provides the acupuncture rationale, details of needling, treatment regimen, other components of treatment, practitioners’ backgrounds and a description of the control intervention – so we have primarily a report one can use as basis for discussion or to develop further ideas on research topics.

Reviewer 1, #8: There are a large number of tables and I´m sure some of these could be thoughtfully combined.

Author`s response: The new table 3 combines now the main information of the former tables 3 and 4.

Reviewer 1, #9 - #11: I would imagine that an acupuncturist might wish to know some of the following questions:

- Are there particular CM diagnostic categories which respond to acupuncture and others that do not?
- Does the quality of de qi (however that was measured) influence outcome?
- We were not told in the methods section how de qi was measured.
Author’s response:

These questions are really very interesting for CM practitioners but cannot be answered in this manuscript since we did not perform a responder analysis regarding the CM syndromes. De Qi was achieved in nearly all patients from the acupuncture group, so we cannot say if it influences the outcome (see table 3). The patients were asked by the acupuncturist regarding the De Qi sensation in each acupuncture session.

Reviewer 1: #12 Can we ascertain (is the trial adequately powered) to suggest that there are any specific characteristics (number of needles, length of session, etc) which could be predictive of treatment outcome?

Author’s response:

ACUSAR was neither designed nor powered to answer this question.

Reviewer 1, #13:

1. In the discussion section the authors report the conclusion of the large previously published paper. The authors suggest that the consensus-based approach was a very effective way of running this trial but I’m not sure how they arrived at that conclusion; did they have focus groups and did they discuss this with the acupuncturists involved after the trial?

2. The authors make a point that a TCM diagnosis was a great strength of their trial but they don’t really tell us how they used it or how we should handle that in terms of outcome. Should acupuncturists be learning a TCM diagnosis and is it of any real clinical value?

Author’s response:

1. The analyses of the treatment protocols show that most of the trial physicians followed the proposed needling schemes (table 3, page 9, paragraph 4). The common utilization of the needling scheme suggests an implicit consensus among physicians regarding the protocol’s recommended treatment. In addition some of the leaders of the main German acupuncture societies were involved in the Delphi process to develop the acupuncture and sham acupuncture treatment. Since many of the acupuncturists were members of those societies, they had learned to treat seasonal allergic rhinitis in a similar way as suggested in the ACUSAR trial.

2. We discussed the possibility that a previous Chinese Medicine diagnosis may improve results of the treatment by comparing ACUSAR with Choi’s trial (page 11, paragraph 3). From our point of view it would be too early to recommend a CM diagnosis under trial conditions in general.

Reviewer 1, #14: They conclude that the trial represented an acceptable compromise between acupuncture treatment and `the rules` of Chinese medicine. If that’s the conclusion, what evidence is it based on?
**Author’s response:** We concluded that the acupuncture intervention protocol in the ACUSAR trial represented a compromise between acupuncture following the rules of CM (individualized treatment based on a previous syndrome diagnosis) and the need for standardisation in clinical research. For a discussion of treatment standardisation under trial conditions see page 11 and 12.

**Reviewer 2, #1:** I just suggest that there be a review by a native English speaker as there is a bit of awkwardness. However overall this reads well.

**Author’s response:** Thank you for this advice, we now revised the manuscript by a native speaker.

We hope that the manuscript will be found now suitable for *BMC Complementary & Alternative Medicine* and look forward to hearing from you at your earliest convenience.

Thank you for your consideration.

Sincerely,

Dr. Miriam Ortiz, MD