Author's response to reviews

Title: Chinese herbal recipe versus diclofenac in symptomatic treatment of osteoarthritis of the knee: a randomized controlled trial.

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Version: 2 Date: 14 October 2004

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Dear Editor,

We have now submitted the revised version of our manuscript. Below we have provided a point-by-point response to each of the comments raised by the reviewer. We sincerely hope that we have responded thoroughly to the reviewer’s comments. If there are additional issues to be clarified, we are willing to respond accordingly.

Best regards,

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On behalf of all the authors of this manuscript.

Response to reviewer’s comments
Reviewer: Flavia Cicuttini

Main points:
1,3,8. This study was designed as a randomized, double-blind, double dummy, controlled trial. Therefore, the placebo of DJW was also prescribed for the patients in the diclofenac group, and vice versa, the placebo of diclofenac was prescribed for the patients in the DJW group. To make this point clearer, the details concerning placebo component were mentioned in DISCUSSION paragraph 1, Table 1 and have been add to the legend of Figure 1.

2. The data and table 7 relating to post intervention treatment outcomes have been deleted.

4. The cautious use of DJW and diclofenac due to their significant numbers of adverse drug reactions has been emphasized (DISCUSSION paragraph 4).

5,6. We have addressed that the rather high rate of adverse events from DJW should be the limitation of using DJW as an alternative in symptomatic treatment of OA of the knee. (DISCUSSION paragraph 4).

6,7. The delayed onset of action of DJW and its relation to placebo effect and/or natural fluctuation of OA symptoms have been discussed (DISCUSSION paragraph 3). In addition, we have raised some evidence to show that this possibility seems unlikely. Anyway, we agree with the reviewer that the slower onset of action is an important limitation in using DJW as an alternative treatment in OA of the knee.
Specific points:
1. Clinical assessments were evaluated by one physician who had been blinded to the treatment.

2. The data relating to the number of responders has been deleted everywhere.

3. We agree with the reviewer. Therefore, the within group analysis has been only mentioned, but the between group analysis has been emphasized in this new version.

4. Since the reviewer recommended that the number of responders is not an outcome, we therefore deleted the details of sample size calculation, which had been determined by using the percentage of the responders in each group as the efficacy criterion.

5. The DISCUSSION has been revised.

6. The placebo effect, natural fluctuation of the OA symptoms and side effects of the herbal medicine have been discussed (DISCUSSION paragraph 3-4).

7. The CONCLUSION has been revised.