Author's response to reviews

Title: Efficacy of Modified Liujunzi decoction on functional dyspepsia of spleen-deficiency and qi-stagnation syndrome A randomized controlled trial

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Version: 4 Date: 28 October 2012

Author's response to reviews: see over
Efficacy of modified LiuJunZi decoction on functional dyspepsia of spleen-deficiency and qi-stagnation syndrome: A randomized controlled trial

Dear editor,

Thank you for your time and effort in considering our paper. We have incorporated our responses to the Section Editors’ questions into our manuscript. We have also revised the manuscript according to the reviewers’ comments, and have outlined our responses in the point-by-point letter attached. Major changes are also highlighted in the revised manuscript. The paper has been copyedit by Edanz. We hope that you find our revised manuscript acceptable. Please do not hesitate to contact me if there are any outstanding questions.
Reviewer 1

Major Comments

1. Authors showed the significant improvement in scores of total dyspepsia symptom and single dyspepsia compared with patients in the placebo group. But they showed the data only at 4 and 8 weeks. Please show us the details at 0, 1, 2, and 3 weeks because it is important to know when the modified LiuJunZi decoction starts to show its effect.

Response: The scores at week 0 were already shown in Table 3. We have now also added the scores obtained at 1, 2, and 3 weeks to Table 4.

2. The improvement in the change of radiopaque barium markers emptied from the stomach in CHM group was shown. But the details of these data were not shown. Please show it.

Response: In the revised manuscript we report these data in the Results section on page 10.

The relevant section now states: “After CHM treatment, the number of radiopaque barium markers emptied from the stomach from week 0 to 4 was significantly higher in the CHM group (5.16 ± 7.53) compared to the placebo group (1.50 ± 3.21) (P = 0.036).”

Minor Comments

1. In Japan, herbal medicine, for example, Rikkunshito, is also used for functional dyspepsia. Please comment it in Discussion.

Response: We have commented on it in the Discussion.

The relevant section now states: “In Japan, LiuJunZi decoction is used for functional dyspepsia and has been found to improve regulation of gastrointestinal function and
hormone secretion[15-17].”

2. It is better to show some of the results by using a graph.
Response: We have added two figures showing the change in TDS scores over the course of treatment and follow-up (Figures 2 and 3).

Reviewer 2
1. Single dyspepsia symptom scores assessed by patients had some differences to the scores by investigators as shown in table 4. This should be corrected in the results section in page 7.

Response: We have corrected this in the Results section on page 9.
The relevant section now states: “The SDS scores provided by patients were similar to those given by investigators. At week 4, the gastroenterologists’ scores of postprandial fullness and bloating were lower than the patients’ scores, whereas the gastroenterologists gave higher scores for epigastric pain and early satiety than the patients did. At week 8, the scores for early satiety given by the gastroenterologists were higher than those given by patients.”

Reviewer 3
1. It is not appropriate to say that the decoction treats functional dyspepsia in many centuries, sounds not accurate.

Response: We have corrected it in the Background section in page 1.
The relevant section now states: “Chinese herbal medicine (CHM) has been used in China and some other countries for the treatment of patients with functional dyspepsia (FD). However, controlled studies supporting the efficacy of such treatments in patients with FD are lacking.”
2. Need literatures data to support the “spleen-deficiency and qi-stagnation” as one necessary type for gastrointestinal problems, must explain clearly

Response: In Traditional Chinese Medicine (TCM), FD is considered nearly equivalent to the TCM term “stuffiness and fullness” [1], which is divided into different syndromes according to the clinical symptoms and signs. In our previous research, we studied the distribution of the different syndromes in 565 cases of FD and found that “spleen-deficiency and qi-stagnation” is the most common syndrome in FD patients [2]. *The Chinese consensus on diagnosis and treatment of functional dyspepsia* also defines spleen-deficiency and qi-stagnation as a prominent syndrome in FD [3].


In response to this comment, we have added the following text to the manuscript on page 4: “In Traditional Chinese Medicine (TCM), FD is considered nearly equivalent to the TCM term “stuffiness and fullness” [12], which is divided into different syndromes according to the clinical symptoms and signs. In our previous research, we studied the distribution of the different syndromes in 565 cases of FD and found that “spleen-deficiency and qi-stagnation” is the most common syndrome in FD patients..."
The Chinese consensus on diagnosis and treatment of functional dyspepsia also defines spleen-deficiency and qi-stagnation as a prominent syndrome in FD [14]. LiuJunZi decoction is a traditional Chinese compound herbal recipe for invigorating the spleen and regulating qi. We added the related herbal medicines Cortex Mangnoliae officinalis, Common Vladimiria Root, Rhizoma Corydalis, and Villous amomrum fruit to the recipe, and found a modified LiuJunZi decoction with a satisfactory clinical effect. Previous studies had shown that the active ingredients in the modified LiuJunZi decoction can improve gastrointestinal motility, regulate gastrointestinal function and have anti-Helicobacter pylori and anti-inflammatory action [15–21].”

3. The decoction should provide quality control, as the basis of expected curative effect. The dynamic measurement data should be added to the abstract too

Response: The dynamic measurement data have been added to the Abstract.

The relevant section now states: “Herbal or placebo granules were dissolved in 300 ml of boiled water cooled to 70°C. Patients in both groups were administered 150 ml (50°C) twice daily.”

4. Should add some diagnostic criteria for spleen-deficiency and qi-stagnation syndrome, and as far as possible simple explanation. Make a distinction between this pathological type and other types meaningfully.

Response: We have added the diagnostic criteria to Table 1.

The relevant section now states: “The spleen-deficiency and qi-stagnation syndrome is defined as having the main symptoms and at least two of the accompanying symptoms, as well as pale tongue with whitish tongue coating and deep and thready pulse. The main symptoms include epigastric stuffiness and fullness, and asthenia. While the accompanying symptoms include epigastric stuffiness and fullness aggravated after meal, epigastric pain, decreased appetite, belching and acid
regurgitation, fullness and discomfort in chest and hypochondrium, nausea and vomiting, and constipation or loose stool.”

Thank you again for your cooperation.

Sincerely yours,

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