Author’s response to reviews

Title: The efficacy and security of Jianweiqutong pill on the treatment of chronic nonatrophic gastritis (spleen and stomach qi deficiency with damp-heat stasis syndrome): study protocol for a phase II, randomized controlled trial.

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Author’s response to reviewer’s comments:

1. Response to comment: Revise it based on SPIRIT guideline,
Response: we have revised our manuscript based on SPIRIT guideline which can be seen in the modified checklist and figure 2.

2. Response to comment: Provide the detailed information of quality control of herbs and placebos
Response: The test pills are provided by Hunan Anbang pharmaceutical Limited by Share Ltd, China and the prescription consists of eleven herbs which are all approved by the China Food and Drug Administration (CFDA). A quality testing for test pill are performed to compare the solution of test pill and that of herbs for example Rhizoma Coptidis (Batch Number: 120913-200407) and Radix Notoginseng (Batch Number: 120941-200506), and/or that of herbal active ingredients such as berberine hydrochloride (Batch Number: 110713-200208), tetrahydropulmatine (Batch Number: 110726-200409) and magnolol (Batch Number: 110729-200411) by using thin—layer chromatography. All of these standard reference substances are from National Institutes for Food and Drug Control, hence the comparisons can also be regarded as tests for the quality of herbs to ensure quality control of test pill. Placebos are also provided by Hunan Anbang pharmaceutical Limited by Share Ltd, China. Because of the special appearance, smell, color and taste of Chinese medicine, it should add some flavoring agents (bitter agent) and coloring agent (food color) in the manufacturing process of Chinese herbal medicine placebos. All the additive are in compliance with the requirements of Quality Standard for Pharmaceutical Excipients and Hygienic Standards for uses of food additives and overdosage of pigment can not be used to make sure the color of placebos is the same as test
pills'. At present, there is no a guiding scheme on the quality standard and application of Chinese herbal medicine placebos, but placebo in this trial is manufactured similar to test pill in appearance, smell, color and taste as far as possible while concealed in unified, sealed and opaque packages with the same labels.

3. Response to comment: Improve the English writing.

Response: we have made some changes marked in red in the manuscript. Special thanks to you for your good comments.