Reviewer's report

Title: Comparison of conventional medicine, TCM treatment and combination of both conventional medicine and TCM treatment for patients with chronic obstructive pulmonary disease: study protocol of a randomized comparative effectiveness research trial

Version: 2
Date: 7 February 2014

Reviewer: Min Li

Reviewer's report:

In the following I provide some specific comments for the author consideration.

(1) I have to point out that this is not a double blinded clinical trial. It has different sub-groups, which means with different intervention, in one big group, it may result in the evidence not strong enough.

(2) In the statistical part, I suggest to provide more details. For example, it just mentioned that AECOPD will be the primary outcome, but it did not mention whether all the assessment points or only the end of treatment will be the primary outcome. On the other hand, by just using an independent-sampled t test for the analysis may not be enough to show the efficacy. “Change of score” or ANCOVA are much commonly use statistical method in the clinical trial nowadays.

(3) Besides, I have a concern on the grouping and analysis. The TCM treatment can be divided into different sub-group according to their symptom and sign. However, during the analysis, it is highly doubtful that the efficacy of TCM group can be obtained by just adding up the four sub-groups. It is because the efficacy of each TCM formula may not the same, and it can result in a big bias for this clinical study. I suggest that the design of the grouping can be done like a western medicine trial which in different dosage (see reference paper: Weiner WJ et al., Lancet Neurol. 2011 Mar; 10(3):201-3. DOI: 10.1016/ S1474-4422 (11) 70021-7).