Reviewer’s report

Title: Effectiveness of Yi-Zhi-An-Shen Granules on cognition and sleep quality in older adults with amnestic mild cognitive impairment: protocol for a randomized, double-blind, placebo-controlled trial

Version: 1 Date: 07 Apr 2019

Reviewer: Ying Zhang

Reviewer’s report:

The authors have answered all of the questions appropriately, except the previous comment 4:

It mentioned in the feedback, "Because there is no effective treatment strongly recommended in existing clinical practice guidelines of MCI, we choose placebo as the controlled treatment in this study. " and "we expected that the efficacy of this herbal formula could be superior to or at least equivalent to the placebo", so here, surely it doesn't mean that the design ought to be "superior" instead of "non-inferior"?

In addition, either "non-inferior" or "superior" needs a cutoff, meaning minimal clinically improtant difference (MCID), to declare how larger effect size of the herbal than placebo could be regared as large enough from the clinical perspective when choosing superior design, or how smaller is thought as acceptable when using non-inferior design.

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