Reviewer’s report

Title: A randomized controlled trial of acupuncture to treat functional constipation: design and protocol

Version: 2 Date: 3 April 2012

Reviewer: John Norrie

Reviewer’s report:

The authors have responded comprehensively to the reviewers comments and made appropriate changes.

There is one outstanding issue – the sample size description has not been changed and therefore still does not read convincingly. The authors state ‘According to the previous literature[16], an improvement of 2.6 times (standard deviation 2.4) for defecating during one week with functional constipation by prucalopride is reported, and a difference of 1.6 times between groups is considered to be of clinical relevance[16]. So, in this study, we anticipated an improvement of 4.0 times by Shu-Mu points group, 3.8 times by He points group, 5.2 times by Shu-Mu-He points group, 2.6 times by group D. A standard deviation of 6.0 is considered, to allow a relatively high heterogeneous variance in this population. The level of statistical significance is set as 0.05 and power as 90%. Therefore, the sample size in this trial is be estimated to include 700 patients (after assuming a 15% dropout rate), at least 175 patients for each group. The sample size calculation is analyzed using G Power [3.1.2 version#Franz Faul, Universität Kiel, Germany]’. They need to state clearly what statistical test they are using, and what the assumed treatment effect is (for comparisons of how many of the 4 groups) and what the assumed variability is, in an unambiguous way. At the moment they state 4 means:4.0, 3.8, 5.2, and 2.6, with a (common?) assumed standard deviation of 6.0. How then does this calculate to 700 patients to give 90% power at a 5% level of significance, using what statistical test? This needs more carefully explained.