Reviewer’s report

Title: Feeding, stooling and sleeping patterns in infants with colic - description of patterns and the influence of minimal acupuncture in a randomized controlled trial

Version: 3 Date: 1 June 2011

Reviewer: Richard Holubkov

Reviewer’s report:

I have been requested to do a statistical review of this manuscript; therefore, my comments will focus mainly on the statistical aspects of the report.

Major Compulsory Revisions

1. (Abstract) The study is reasonably well described. However, I believe it is standard, in a clinical trial report, to describe whether the two treatment arms differed with respect to the primary outcome (stooling, correct?). I would therefore ask that this comparison be included in the Results section, before you report the within-group p-values as you do now.

2. (Statistical and quantitative analyses) I believe you are correctly using nonparametric tests for the analyses, but I am frankly unclear about when the various different tests (Mann-Whitney, Friedman, and “mean rank” – the last one should be better defined) are used. Could you specify which comparisons use which tests, either here or perhaps in the appropriate Tables or points in the text? If you in fact used Friedman’s test for a repeated measures type of analysis, this should be explicitly explained.

3. (Results) Under “Stooling”, I again believe that the primary between-group analysis should be described first, before you discuss the within-group differences. When reporting the p-values for this comparison, please state explicitly what test was used for the comparison. Also, please state explicitly which test was used to derive the p-values showing significant linear within-control-group declines (p=0.011 is reported) in large bowel movements. Please also do the same when reporting the Table 4 comparison. In the Table 2 analyses, do the analyses for which the p-values are reported (comparing arms at each week of intervention) take each child’s baseline level into account?

Minor essential revisions

1. (Abstract) In conclusions, “out ruled” should be written as “ruled out”.

2. (Limitations) “exact measured” should read “exactly” or “precisely” measured.

Discretionary revisions

1. (Abstract) I would personally again state in the conclusion that this study was
negative, although a minor effect of acupuncture cannot be ruled out.

2. (Design or statistical analyses) Would you be able to state anything about the expected power of your study (when you were designing it) to detect expected, or clinically important, differences in the outcomes being examined in this report?

3. (Overall) I am not a clinician, but I was a bit surprised that you did not include a brief discussion of the other reported results from this study, ref 19, in this current paper. I have not read this other paper in detail, but it showed that acupuncture was helpful in reducing crying and fussing over the first two weeks? What are some reasons this benefit might not have carried over to these secondary outcomes?

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests.