Reviewer's report

Title: Acupuncture for Sequelae of Bell's Palsy: A Randomized Controlled Trial Protocol

Version: 3 Date: 19 November 2010

Reviewer: Charlie Goldsmith

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In general, this protocol needs much more detail before it should be published. The pages were not numbered. This reviewer numbered them from 1 to 18.

1. Page 1, Author emails. There are 2 people with short forms [CJY] and [LSH]. They need to be clarified by making each unique.

2. Paragraph 2, line 2. Drop [ed] from [waitlisted] to read [waitlist]. Also, P 5, p 4, l 5; P 7, p 1, l 2; P 10, p 4, l 2.


4. Page 2, last line. Insert the date of registration as well as the date the first patient has been randomized.

5. Page 3, p 2, l 1. Since [incidence] is time related, there needs to be time listed or the term needs to be changed to [prevalence]. Also, P 9, p 2, l 2.


8. Page 4, p 1, last line. Without a credible literature search, this claim is not justified. This may be the authors’ opinions, however, they have not justified it here.


10. Page 5, outcome measures. Each of the outcome measures should be described, that they are validated in Korean unless the patients all speak English well, and how they are interpreted with relevant measurement properties. The references appear to be all in English.


12. Page 6, p 3, l 3. Provide references to these conditions such as [Ramsay-Hunt Syndrome].

13. Page 7, p 1, l 9. What is the city in Korea for the needles?

14. Page 8, p 4. When will the control group be asked?


16. Page 8, p 6, l 2. This is not the definition of intention to treat. All patients randomized need to be analysed; not subject to a measurable outcome.

17. Page 8, p 6, l 3. Using last observation carried forward is a poor imputation method. One should use a multiple imputation technique and justify the choice of
the method, by providing a reference to one of the standard texts for imputation.

18. P 9, sample size. The sample size is not adequately explained. First of all why choose a 2:1 allocation ratio? The 8 things used to justify a sample size should be argued as to why they were chosen. The Minimum Clinically Important Difference between the groups for the primary outcome measure needs to be included in the sample size, as well as for the other measures. The full size of such a trial and feasibility at the location of the study needs to be added as well.

19. P 10, p 3, l 1. The sample size of 30 has not been justified; nor has its feasibility been shown.

20. P 10, p 4, l 2. It does not make sense to publish the block size choice, because other investigators making inclusion/exclusion patient choices will be able to anticipate the subsequent allocations. This should be concealed from them until time of paper publication, not in the published protocol.

21. P 11, p 1. Subjects need to be told there is a possibility they will be allocated to the control and how long they will be in the study.

22. While the R(eference)s were not checked for accuracy, the following errors were noted.

23. P 13, R 3. There is no volume number.

24. P 13, R 9. Does not have a publication date.

25. P 18, the [N] should be lower case as [n], and the diamond should be a circle for randomization.