Reviewer's report

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

Version: 3 Date: 31 December 2010

Reviewer: Kien Trinh

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This is a generally an easy to follow protocol. I have a few suggestions for improvement

Background:
Is this an efficacy or effectiveness study? Under Background information, the following statement suggests that this is an efficacy study, “our aim is to evaluate the safety and efficacy of acupuncture on the sequelae of Bell’s palsy…” However, under Objective, it suggests that this is an effectiveness study, which is debatable given the small size of the study (The primary objective of this study protocol is to investigate the effectiveness of acupuncture use in patients with sequelae of Bell’s palsy.)

Primary Outcome
The reasons for choosing the Facial Disability Index need to be apparent. Is this tool reliable and valid? The information are important for the readers to know.

Secondary Outcome
Again, what are the reasons for using the “House- Brackmann Grade, lip mobility, and stiffness scales”? Is there information on reliability and validity?

Exclusion criteria
There are many exclusion criteria listed. What are the reasons for the exclusion criteria?

Acupuncture Intervention
How did the researchers come up with this list of points? What are the rationales for their selections?

Statistical Analysis
A description of the variable is required. Is it a discrete or continuous variable? The statistical test planned should be specified ahead of time. Are they planning to use the two-sample t-test or the rank sum test, which one?

Also, the alpha value is set at 0.05. What is the reason for not making the correction for multiple analyses (primary and secondary outcomes)? ANOVA or regression analysis may be more appropriate.

Intention-to-treat may have different meaning to different researchers. What do they mean by intention-to-treat?
There was no mention of confounding factors. How do the investigators control for the effects of over-the-counter medications. Are they going to measure that or simply not allow their patients to take them?

They mentioned that they would measure expectations. How do they determine whether expectations have an effect or not?

Sample Size
Since no sample size calculation was done, how do they know that 30 participants “will be sufficient”? What is the rationale for the 2:1 design? Please explain.

Randomization and allocation
Allocation concealment is so important. Under this section, a very detailed description of the process of allocation concealment will strengthen the study design.