Reviewer’s report

Title: Acupuncture for dry eye: a randomised controlled trial protocol

Version: 3 Date: 20 November 2009

Reviewer: Gordon Doig

Reviewer’s report:

This is a very well written protocol paper describing a very well designed and important trial. I commend you on your efforts and wish you luck on your clinical trial.

Could I please request that you add additional details in the following areas:

1. Page 10, Statistical Analysis. I believe the sentence "We will conduct analysis mainly on an intention-to-treat basis" should read "We will conduct analysis on an intention-to-treat basis". Use of the work ‘mainly’ infers you will deviate from an ITT analysis. If you do intend to deviate from the ITT analysis, please explicitly report where you will deviate.

2. Page 10, Statistical Analysis. One of the primary purposes of randomizing patients is to obtain two groups that are similar. If groups are ‘not similar’, statistical adjustments may be made. Please explicitly describe what characteristics of the two groups will be recorded and reported such that a future reader of your results may determine that your two groups were indeed similar. Please also report the methodology you will use (Ex. Statistical test between groups for characteristics such as age, previous duration of dry eye, severity etc), what threshold will be used to determine balance (Ex. p-value > 0.10 or > 0.05 etc) and what will be done if imbalance is encountered (Ex. Include as covariate in ANCOVA).

Thank you sincerely for your submission,

Gordon S. Doig

Quality of written English: Acceptable