Author's response to reviews

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

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Author's response to reviews: see over
Dear professor, Gordon S. Doig
Trials
BioMed Central Ltd

Daejeon, Korea, 25/11/09

Dear professor, Doig

Re: MS: 1490737032320686 - Acupuncture for dry eye: a randomised controlled trial protocol.

We appreciate the more comments for improving our manuscript “Acupuncture for dry eye: a randomised controlled trial protocol (NCT00969280)”

We revised several important points including statistical analysis according to the reviewer’s recommendation.

According to the comments my colleagues and I made the further correction.

The responses are in following pages.

Yours faithfully,

Sun-Mi Choi, OMD, PhD

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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:

**COMMENT 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.

→Revised) We have now removed the word “mainly” in the first sentence of “Statistical Analysis” section at page 10, line 1.

“We will conduct analysis on an intention-to-treat basis (significance level p<0.05) using the SAS statistical package program (ver. 9.1.3).”

**COMMENT 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).

→Revised) We have now changed the “Statistical Analysis” section as you recommended at page 10, from line 2 of the “Statistical analysis” section.

“Baseline characteristics will be shown as mean ± standard deviation (SD) for continuous data including age, previous duration of dry eye, OSDI, VAS for self-assessment of ocular discomfort, TFBUT and Schirmer’s I test value. As for participants’ gender, n (%) of male and female in each group will be shown as baseline characteristics. We will conduct between-group comparison in baseline using two-sample t-test or Wilcoxon rank sum test for continuous data and using Chi-square test or Fisher’s exact test for gender composition considering p<0.05 as statistically significant. For primary and secondary outcome measures, the mean differences from baseline values to the end of treatment will be compared using two-sample t-test or Wilcoxon rank sum test. If any imbalances in baseline characteristics between groups are encountered, we will conduct ANCOVA (analysis of covariance) using these imbalanced variables as covariates and allocated group as fixed factor.”