Author’s response to reviews

Title: Chinese herbal medicine for impaired glucose tolerance: a randomized placebo controlled trial

Authors:

SUZANNE J GRANT (S.GRANT@UWS.EDU.AU)
DENNIS H CHANG (D.CHANG@UWS.EDU.AU)
JIANXUN LIU (liuix0324@sina.com)
VINCENT WANG (Vincent.Wong@sswahs.nsw.gov.au)
HOSEN KIAT (HOSEN.KIAT@CHI.ORG.AU)
ALAN BENSOUSSAN (A.BENSOUSSAN@UWS.EDU.AU)

Version: 5 Date: 5 March 2013

Author’s response to reviews: see over
4th March 2013

Tom Rowles
Executive Editor
BMC Complementary and Alternative Medicine

Re: BMC Manuscript 1150750098749884 - Effectiveness of Chinese herbal medicine for impaired glucose tolerance

Dear Dr Rowles,

Thank you for your reviewers’ comments. We greatly appreciated the reviewers’ constructive comments and have implemented their recommendations. We have responded to the each of the comments below

(1) METHODS: when they did the power analysis, who did they choose 0.6 (a moderate effect size)? Any previous experiences or it just a bold guess.

The calculations were based on the changes found in the previous study of Jiangtang Xiaozhi in people with diabetes (this trial is referenced in the Introduction and Discussion section of the paper). For a two arm trial, a sample of 50 participants in each group will detect changes in fasting glycaemia of 1.00 mmol/L, with a standard deviation (SD) of 1.6mmol/L. This estimate allows for a 10% withdrawal or non-compliance rate. This sample size has 80% power and a level of significance of p<0.05 (two tailed test). There was no previous trial of the herbal medicine in people with prediabetes on which to base the sample size calculation. Unfortunately, the sample size calculation did not take into consideration the transient nature of prediabetes and due to study constraints we could only afford sufficient sample size to detect a moderate (0.6 sd) difference between groups.
(2) **DISCUSSION:** They mentioned their study as considerably underpowered, why did they say so? Did they do any post-hoc power analysis?

This statement misrepresented what we intend to say and therefore has been deleted. As discussed in the ‘Limitation of Our Study’ session, our sample size may have lacked sufficient statistical power to detect a clinically significant change in FBG and to adequately account for the transient nature of the people with IGT. Future studies with a larger sample size and a longer intervention are therefore needed.

(3) The n reported in each group (39 vs. 32) is different than that is reported in the results (41 vc.30). Need to clarify.

The numbers in the first paragraph of the results section, 41 and 30, refer specifically to the number of patients with IGT and the number of patients with early diabetes.

(4) **Discussion:** The last third paragraph "the safety ...) reads better if being moved right before the last paragraph "In light...".

Thank you this change has been done.

We look forward to hearing from you. If you require further information, please don’t hesitate to contact me.

Kind regards

Associate Professor Dennis Chang