Author's response to reviews

Title: Acupuncture for menopausal vasomotor symptoms: study protocol for a randomised controlled trial

Authors:

Marie Pirotta Assoc Prof (m.pirotta@unimelb.edu.au)
Carolyn Ee Dr (ccee@unimelb.edu.au)
Helena Teede Prof (helena.teede@monash.edu)
Patty Chondros Dr (p.chondros@unimelb.edu.au)
Simon French Dr (simon.french@queensu.ca)
Stephen Myers Prof (smyers@scu.edu.au)
Charlie Xue Prof (charlie.xue@rmit.edu.au)

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Author's response to reviews: see over
Response to Editor’s comments

Thank you for reviewing our protocol. Please find below our response to comments.

1) “First, the section on Randomisation and allocation concealment mentions that there will be block sizes of 6. In a single blinded trial, it is unfortunate that this information is known to the investigators. How will allocation concealment be maintained for the last (and perhaps final two or three) participant within each block?”

I apologise for mis-reporting the block sizes. This problem was foreseen by the investigator who created our randomisation code, and random blocks of 8 or 12 were used to avoid “guessing” of the last few participants within each block (not block sizes of six as I had reported). Therefore, the blocks appeared in random order.

“Participants are randomly allocated to one of two trial groups: true acupuncture or sham acupuncture, using a computer-generated randomisation sequence, stratified by project acupuncturist using block sizes of either eight or twelve (with block sizes appearing in random order) within each stratum and an allocation ratio of 1:1. The research assistant responsible for allocating participants is not aware of the block sizes used.”

2) “the Trial status should be updated. Is enrollment complete?”

At the time of submission (22nd Jan 2014), the trial was still enrolling participants. Enrolment closed in March 2014 as we had successfully reached our required sample size. I have amended the manuscript as follows:

“The trial has received funding and recruitment commenced in late 2011. At the time of submission of this protocol, project acupuncturists had been trained, participant enrolment was progressing well and data collection was well underway. Trial enrolment closed in March 2014. We anticipate that all data will be collected by late 2014.”

I have also added the date of trial registration, and altered the title of the trial to suit journal needs.

Carolyn Ee