Author's response to reviews

Title: Acupuncture for menopausal vasomotor symptoms: a protocol for a stratified, participant-blind, randomised sham-controlled trial

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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 this oversight. 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. Only the first six allocations were used in the code. I have amended the manuscript to read:

“To avoid investigators being able to predict the last few allocations within each block of six, randomisation was actually performed using random blocks of eight and twelve, and only the first six allocations were included in the code.”

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.”

Carolyn Ee