Reviewer's report

Title: Acupuncture as prophylaxis for menstrually related migraine: study protocol for a multicenter randomized controlled trial

Version: 1 Date: 16 July 2013

Reviewer: Shefton Parker

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1. The study is well designed in most part, despite raising some concerns between the intervention and control arms selection. Verum vs sham acupuncture has been common comparators for evaluating the therapeutic effects of acupuncture in RCT’s. There is much debate about the various methods of applying sham acupuncture and views differ considerably regarding the most suitable method for applying sham acupuncture. In this case the researchers are suggesting to apply the sham acupuncture to "real acupuncture" points without theoretical therapeutic indication for migraine. This may not be entirely the case though as Chinese Medicine believes in the theory of "Ashi points" painful/tender (on palpation) points anywhere on the body that become acupuncture points if they are stimulated. Commonly these are refuted by researchers as having some impact on the condition being treated. In this case the sham acupuncture points themselves may be tender and on acupuncture may cause a 'release' leading to pain reduction.

This limitation considered I do not see this as a protocol change requirement but may impact on any significance of results.

2. The researchers compare an intervention verum group using a placebo drug to a control sham group receiving drug. To compare control and intervention clearly any additional care to the intervention should be reflected in the control arm ie. placebo drug. The design of this study raises the question if results will be able to detect any clinical difference between control and intervention groups, considering both arms are receiving active therapies. The authors appear aware of this limitation and have discussed the choice in relation to the difficulties in recruitment and compliance of participants if there were to be a control group that were non active. I acknowledge these limitations of the study and still see potential results providing some additional benefit to the current available research.

3. It should be highlighted that the study is aiming to recruit people from acupuncture clinics. This raises questions over the past experience of participants to acupuncture. Is there chance that participants have had acupuncture for their current condition (or other) and thus would have the knowledge that they were receiving sham acupuncture? Is there premise to exclude patients who have had acupuncture for their current condition or at the least record taken of those who have and have not to compare sub group responses? This should be discussed and reported by the researchers.
4. Further to the background the article suggests there “many studies …already reported encouraging results in the therapy of migraine by acupuncture.” Yet supplies no references. I would suggest providing more detail on the current evidence for broader acupuncture migraine research (RCT’s) (1) as well as a brief section on the potential and/or current understood physiological mechanisms for acupuncture in migraine.

5. In respect to methods I would encourage the researchers to consider the CONSORT, applicable extensions to the CONSORT and STRICTA guidelines (Standards for Reporting Interventions in Clinical Trials of Acupuncture) with reference to each in the protocol.

Minor essential revisions:

Please explode first use of acronyms ie. NSAIDS, DHE.

Abstract refers to ‘prevention’ of migraine and body refers to ‘treatment’ of migraine which is the main outcome? Prevention or treatment? They are two distinctly different aims.

Please include a table listing each study visit and the data (instruments) to be collected. Ie. baseline, visit 1 etc. showing what will be collected daily, weekly etc.

Discretionary Revisions

Please edit the discussion providing detail on previous acupuncture migraine evidence and mechanisms.

Discuss potential for bias of participants with previous experience of acupuncture.


Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.