Reviewer's report

Title: Preliminary results, methodological considerations and recruitment difficulties of a randomised clinical trial comparing two treatment regimen for patients with headache and neck pain

Version: 1 Date: 12 May 2009

Reviewer: Howard Vernon

Reviewer's report:

This MS presents the results of a randomised clinical trial of usual care vs usual care plus manual therapy for patients with headache and neck pain. The authors have presented the trial design in a previous publication. The authors indicate that there were major difficulties with recruitment for this trial (they deal with this in the Discussion) leading to the decision to stop the trial and report on their preliminary results.

The MS is well-written with an appropriate title and an well-defined question. The Methods are well-written, the data is well-presented and the Discussion is appropriate.

I have personal sympathy for the situation in which these authors find themselves, so I appreciate that a report of preliminary results along with a discussion of the problems and potential solutions in conducting such trials makes an important contribution to the literature. However, it should be made as clear as possible what the goals of such a publication are in both the abstract and text of the article.

Abstract:

Minor essential revision:

The authors should indicate that this is a report of a stopped trial and that the results presented are preliminary. The should indicate that their goal in publishing these results is to aid future systematic reviews and meta-analyses.

Background:

Minor essential revision:

1. Para. 1, line 4- are the references [2,3] cited to support the notion that TTH, migraine and CEH are the most prevalent headache types in primary care, OR, that (from the sentence above), they are often accompanied by neck pain and stiffness.

There are no references for the latter statement. Please provide appropriate references here.
2. Line 6: Please find a more appropriate term than "merely" to describe the treatment...etc.

3. Line 9: Please find a more appropriate term than "careful" to describe the positive effects of treatment...etc.

Methods:

Minor essential revision:
1. Under "Randomisation and blinding": Please justify why 'gender' was not used as a stratification factor when it is known that there is a strong gender bias in primary headaches.

2. Under "Interventions": While the trial design has been published previously, I think some additional detail on the method of "spinal mobiisations" is necessary.

3. Were multiple therapists used for the treatment? Were multiple sites used? The authors should describe how they trained these therapists and standardized the delivery of the therapy.

4. Some additional information on the methodology of the "step-up therapy" used by GP's should be included: medication types, dosages, side effect monitoring.

5. There is no indication in the Methods that adverse events / side effects were monitored. Please add some explanation here.

Results:

1. See below re: medication prescription AND adverse events.

Discussion:

1. Para.2: The authors should briefly recap what the main positive results were, rather than simply say that both groups "evolved in a positive sense".

2. Under "Treatment effects": the authors indicate that the US groups received more medication on prescription. However, this was not reported in the Results section. In order to make the claim here that UCMT offers a potential advantage in that it achieves the same level of improvement with fewer medications, the authors should provide sufficient data in the Results. Otherwise, they should remove this statement.

3. Only in the Discussion do the authors indicate that no side effects or adverse events were reported.

This should be reported in the Results section first, then commented on in the Discussion.

Level of interest: An article of importance in its field
Quality of written English: Acceptable

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.