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: 24 March 2009

Reviewer: Alex Burdorf

Reviewer’s report:

Compulsory changes

1. Given the inclusion at time of headache severe enough to seek care, by definition one would expect during follow-up to see improvement. The abstract suggests that both types of treatment have an effect, whereas one could also argue that both treatments do not add anything to the natural course. To provide more insight, substantially more information is needed on the actual UC delivered. If this turns out to be ‘wait and see’ (as contrast to the intervention arm with similar co-interventions in both arms) than the abstract should be reformulated.

2. With regard to the use of the HIT-6 cut-off value of 56 points, I would like to see information included on natural prognosis, if available. Does one expect a certain improvement whatsoever?

3. The flow chart suggest that informed consent was (partly) collected after randomisation, since in the UCMT group 8 persons did not receive the intervention. Information on informed consent procedures should be described in the recruitment paragraph. The discussion should present more background what really has happened here, could this have been avoided?

4. I am not entirely convinced that a one-way ANOVA is the appropriate technique for analysis, since one would like to adjust for baseline values and well-known prognostic factors. The analysis should demonstrate the change over time, preferably per measurement period, and the difference between both arms at each measurement period. This difference will determine effectiveness. The comparison of FU week 26 relative to baseline, as used in tables 3 and 4, is confusing when not adjusted for baseline value.

5. The value of the manuscript is in it candid discussion about failing enrolment. Many reasons are presented, but I would like to see more expert judgement here as to the core reasons: was it lack of patients, was it lack of practical effort of physicians (could be partly remedied by involving nurse assistant etc) etc. Also, the drop out of patients in the intervention arms is quite alarming...

Minor changes
1. I am not entirely sure how this RCT differs from previous RCTS on MT, in combination with exercise therapy. What is the underlying rationale why this specific MT RCT is required?

2. I like to remarks in the introduction about current guidelines, but it is not always clear if guidelines across countries differ and whether the same patient definition is applicable, e.g. the RCTs references 5-8 on different headache types, do this types include neck pain and/or stiffness?

3. The Dutch protocol for usual care is not very clearly described as to actual treatment decisions

4. Table 4, last 4 lines, the description does not match the presentation, eg absenteeism proportion absent/not absent..figures are not proportion, maybe except the last column.

5. I am not sure how power calculations have been conducted, eg it is simply impossible that in the current sample size the absenteeism has a power of 0.86 (beta). In fact, all dichotomous variables will have a power substantially below 0.50 when comparing both arms.

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

'I declare that I have no competing interests'