Reviewer's report

Title: Acupuncture for osteoarthritis of the knee: A pilot study for an open parallel-arm randomised controlled trial

Version: 1 Date: 17 March 2009

Reviewer: Claudia Witt

Reviewer's report:

Pilot studies are an important tool with the aim to test the feasibility for subsequent larger trials. This pilot is well done and provides relevant information which is necessary for planning the main study. In addition the paper is well written.

Major Compulsory Revisions

• Abstract: please provide information about the size of effect of the most important outcomes (e.g. by using the effect size or means and CI)

• Methods: statistical analysis: please provide more details (e.g. which covariates were used in the ANCOVA, in addition you mention regression model on page 6 under the heading outcomes). In the methods section should be clearly written which analysis was done.

• As far as I understand there are some relevant differences between groups for some of the baseline parameters (e.g. SF 36 subscales). This should be at least mentioned.

• Results: table 3 and 4 it would be good to have effect sizes (at least for the WOMAC), because this helps to compare the outcomes and to discuss them. In addition your sample size calculation is based on an effect size.

• Results: sample size calculation. Why did you not use the results of your pilot study also for assuming the change instead of using a clinically relevant change from the literature? An option might be to calculate the effect size for both. In addition this paragraph should contain all information which is necessary to allow the reader to recalculate the sample size.

• Discussion: I miss the discussion on the different outcomes which should explain why the WOMAC pain scale is suitable for a larger trial.

• Discussion: when comparing the results of pilot with other trials this should not be only done on the basis of meta-analysis, because this is secondary data. It would be interesting to compare your findings with our large trials which used a very similar design. Reference: Witt CM, Jena S, Brinkhaus B, Liecker B, Wegscheider K, Willich SN. Acupuncture in patients with osteoarthritis of the knee or hip. Arthritis & Rheumatism 2006;54(11):3485-3493.

Minor Essential Revisions:

• Introduction: para 3. There is detailed data for a cost-effectiveness analysis;

• Methods: Randomization, please include the software which was used to generate the sequence.
• Figure 2 and 3 please include measures of variance e.g. CI, and use other symbol for control group and white color for the background.
• Tables: they would look nicer with less frames
• Table 3 and 4. Please use outcome instead of characteristics and give information which measure of variance is shown (sd?).

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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