Author's response to reviews

Title: Feeding, stooling and sleeping patterns in infants with colic - description of patterns and the influence of minimal acupuncture in a randomized controlled trial

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Author's response to reviews: see over
Dear Miss Iratxe Puebla, The BioMed Central Editorial Team!

Hereby we resubmit the enclosed research paper “Feeding, stooling and sleeping patterns in infants with colic – description of patterns and the influence of minimal acupuncture in a randomized controlled trial”, for consideration for publication in BMC Complementary and Alternative Medicine.

The reviewer’s comments have been addressed in the revised manuscript, where changes are marked in red. A point-by-point response (in red) to the reviewer’s comments (in black) follow here.

Reviewer 1:

Table 5 is referred to but is absent from the report. Either the table should be added or reference to it deleted.
“Table 5” should be “Table 4”and is corrected in the text. Sorry!

Clarify the basis of feeding and stooling habits which were used in the trial “to assess whether or not the infants fulfilled the definition of colic.”
The paragraph is now changed: “Parents to otherwise healthy 2–8 week old infants, born after gestational week 36, never medicated with dicyclomine and searching help for excessive crying were invited to participate. After giving written informed consent the parents of 210 infants reported the crying and fussing of their infants in a diary for at least three days to assess whether or not the infants fulfilled the modified Wessel-criteria for colic: “crying/fussing for at least three hours a day, occurring three days or more in the same week” [1]. In the diary the parents also reported the feeding and stooling habits of their infants. During the registration period exclusion of cow’s milk from the infant’s diet was recommended if this had not been tried previously. Of these 210 infants 120 were not included as they cried less than the stipulated hours. Some of them may have improved as they were no longer exposed to cow’s milk protein. 90 infants were randomised and 81 completed all three intervention weeks (Figure 1).”

Punctuation outside of quotation marks should be placed inside.
Punctuations are now placed inside of quotation marks.

Clarify number of units in table 3. “A unit is a specific comment written in by the parent on the crying diary that, e.g., the stooling has become ‘less frequent.’” Without such a clear statement, it is difficult to understand the concept of units. For example, does 30 units mean that this has been written in on 30 separate occasions or by 30 different parents, or both? It is unclear whether this occurred in 30 separate diaries or whether it could have been repeated in the same diary.

We have changed “units” to “remarks”: “Table 3. Changes in stooling pattern and possible side effects of intervention as described by the parents in a questionnaire at the second to the sixth visit at the clinic. Categories, codes and the frequency of remarks on a certain topic in
each group are shown in this table. Each remark has only been given once in each questionnaire.”

Clarify number of infants released from study for suspected CMPI.
In the methodological chapter we describe how participants were recommended to exclude cow’s milk during the registration period if this had not been tried previously. We have changed the text to: “Of these 210 infants 120 were not included as they cried less than the stipulated hours. Some of them may have improved as they were no longer exposed to cow’s milk protein. The 90 infants who fulfilled the crying criteria were randomised and 81 completed all three intervention weeks (Figure 1).”

As we do not know how many of the 120 infants not fulfilling the colic criteria who improved due to no longer being exposed to cow’s milk we also discuss this under the headline Strengths and limitations: “Parents of all of the infants had been recommended to try a five-day period of not exposing the infant to cow’s milk protein during baseline. Infants who then improved were not included in the study, which therefore reduced the number of infants with an allergy to cow’s milk protein to a minimum.”

Provide baseline data for the entire sample.
We have provided baseline data for the entire sample in Table 1.

Separate results and discussion sections.
The author instructions for BMC CAM states: “The Results and Discussion may be combined into a single section or presented separately.” For this article, we consider presenting the results and discussion together as a more clear and space-saving way. If the editor prefers us to separate the result and the discussion we will do so.

Discuss confounding factors in more detail.
We added ” For example, the frequency of breastfeeding and the consumption of antibiotics, which both might increase stooling frequency, may vary in the countries where data is collected in the present study (Sweden) and in the referenced articles (Australia, Germany, Thailand, Turkey, UK, and the USA). “

Clarify which corroborating research was done on adults and which on infants.
This has now been clarified: “A possible explanation could be a reduction of pain as shown in adults [20] … gastric emptying as shown in adult patients with motility disorders [25]… gastric motility in healthy adult humans was not altered [27]… demonstrated to promote sleep in adults [28].”

Reviewer 2:
In the last table ,no p-value fitting in ,this should be corrected or reanalysed.
We conducted a content analysis on a manifest level, which usually do not include p-values.

The data collection on the sleeping pattern is unclear ,sleeping time is more accurate than the mother's subjective response of "better or much better ". 
We agree to the comment and this viewpoint is addressed in the discussion: “Limitations are that the size of the stools were estimated by parents, not exact measured, and that sleep was described by a multiple choice question but sleeping times were not entered into the diary. Further parents were not asked to evaluate the infant’s sleep during the base line period.”

**Quality of written English:** Needs some language corrections before being Published.
The paper was earlier checked by a professional bilingual translator at the language department of Lund University. Some further corrections have been done now. If the editor suggests so, we are willing to send it for a new revision.

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.
The statistics were checked by a professional statistician at Lund University. If the editor suggests so, we are willing to send it for a revision.

Yours sincerely,

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