Author's response to reviews

Title: General movements in preterm infants undergoing craniosacral therapy: a randomised controlled trial.

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*General movements in preterm infants undergoing craniosacral therapy: a randomised controlled trial.*

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Reviewer 1

Text location in this revision is difficult because there is no longer any line enumeration in the copy provided for review. This reviewer will use the page number at the right bottom of the page and authors may have to look for the line by the text provided by the reviewer.

*We are sorry for this mistake and have now numbered the lines of the manuscript*

References that are in sequence, i.e. (15, 16, 17, 18) can be contracted i.e. (15 – 18). Please change throughout the manuscript.

*We have changed the references, as requested.*

Abstract
Background

‘Within the last several years...tactile/kinaesthetic stimulation is associated...

Results

‘We did not observe any adverse events in either group

Conclusion

‘...or his/her presence, or whether the sum of these...’ please change this also on p.15, last sentence before ‘Conclusion’.

Introduction

The last sentence of the first paragraph does not flow logically from the opening sentences.

Better: ‘However, the stressful environment of a neonatal intensive care unit (NICU) may compromise theses vulnerable infants, in addition to the physiologic consequences of pre-term birth.’

p.4: ‘...decrease of cerebrospinal fluid flow could correspond...’ Do the authors mean ‘correspond’ or do they mean ‘correlate’; please clarify.

p.5: last line of introduction ‘... craniosacral therapy as an ideal form...’ please correct.

p.6, protocol: ... using a randomized block design with block sizes of 6... please correct

p.6: ...(CG) did not receive any OMT during this period... please change this sentence. The use of ‘observation’ is confusing. Did a therapist observe the control infant for 20 minutes?

p.7:... were unaware of patient allocation. Please remove the apostrophe and ‘s’.

Recording and analysis of GMs

Thank you for these comments: we have edited the manuscript to improve the written English.

p. 8:’...or assumed intervention (CG)...’ What do the authors mean with ‘assumed intervention?’ Please define clearly. When did the ‘assumed’
intervention begin? Did they wait a similar amount of time it took to evaluate and perform the OMT in the IG group before recording of the CG group began?

“assumed intervention” as described in the manuscript means......before and after each intervention (IG) or assumed intervention (CG)......we would highlight that during recording of the GMs nothing can be seen on the video tape, exclusively the babies GMs, to have the optimal blinded setting for the GM judgments, who were done by two experts in GM assessment (P.B.M., C.E.). The assessors were never involved in the care of the newborns (They did not belong to the Division of Neonatology)- the assessors did only receive the video tapes (without group assignment).

We have corrected this in the manuscript.

Statistical Tests:

‘We used nonparametric tests: for independent variables...’ Please use a colon after ‘tests’ instead of the hyphen. The reviewer had to read this sentence more than once to understand what the hyphen meant.

We agree with the reviewers comment and have corrected this in the manuscript.

Results

p.10: All included preterm infants... Please delete ‘included pre-term’. The sentence is clearer if it reads: ‘All infants tolerated...’

We agree with the reviewers comment and have corrected this in the manuscript.

Discussion

p.14: ‘...consistent in time or predominant from preterm birth...’. The authors probably mean ...consistent over time. If so, please change.

We agree with the reviewers comment and have corrected this in the manuscript.

p.14: The elaboration of optimality results in the discussion belongs into results.

Only their significance should be noted in the Discussion.

We agree with the reviewers comment, but this paragraph was requested by an other reviewer. We have corrected this in the manuscript- and now only the significance of the Motor Optimality Score is highlighted in the discussion. The elaboration of the score is visible in the results and in Table 1.

Strengths of the study

‘...the assessors of the GMs were completely blinded...’ should read

‘...completely blinded with respect to group assignment.’ Please change.
We agree with the reviewers comment and have corrected this in the manuscript.

In looking at Figure 2 a second time the reviewer noted that the error bars are much wider in both groups at the end of three weeks than at the beginning of the study. With intervention one would hope for ‘improvement’ or ‘maintenance’ of performance, resulting in narrowing of error bars, i.e. approaching normality. Maintenance seems to have been attained in the IG group using the optimality score. How then do the authors explain the wider range of variation in both groups at the end? This may be a point worth mentioning in the discussion.

We understand the idea, that one would hope that with improvement a narrowing of errors bars would be observed. In reality, we did not see this. In fact, we did not see an improvement at all, only a deterioration in the control group and no change in the intervention group. Therefore, it seems very likely, that there was no narrowing of error bars to be observed.

Response to reviewer 2

Abstract: Results
1 First sentence mentions "Preterm GM Optimality Score" Next sentence mentions "Motor Optimality scores" so the reader wonders whether the latter is a sub-score of the former? Or is it an entirely different outcome?

2 Also which of the two outcomes was defined a priori as primary and which as secondary should be stated in the abstract.

Thank you for this question; we agree with the reviewer and we apologize for this incongruent nomenclature:

GMs were described by a Global Judgment of the GMs (as normal or abnormal; furthermore abnormal GMs are classified into (1) “poor repertoire GMs” (PR), (2) “cramped-synchronized GMs” (CS), and (3) “chaotic GMs” (Ch). And beside this Global Judgment there is a special score describing the normal and abnormal GMs in a more detailed way by using a numbered summery of the scoring of the neck and trunk and upper and lower limbs- called Motor Optimality Score.

We have changed now the have a uniform nomenclatur.

Background:
3 Describes "craniosacral therapy" as a "developed out of" OMT. The therapeutic intervention in this study seems to have been craniosacral therapy. Given that, one wonders why the intervention is identified as "OMT" rather than the more specific "craniosacral therapy." The intervention is referred to as "OMT" throughout most of the text, in particular on page 7. The cummulative impression is actually a bit misleading, because one does not generally think of craniosacral
therapy as the meaning of "OMT" but of a more general manipulation of the joints and tissues.

We agree with the reviewer, but to change the terminus from craniosacral therapy to OMT (Osteopathic Manipulative Treatment) was requested by a former reviewer-based on the fact that osteopathic manipulative treatment (OMT) currently encompasses more than twenty types of osteopath-performed manual treatments.

Citation: "OMT is defined in the Glossary of Osteopathic Terminology as: “The therapeutic application of manually guided forces by an osteopathic physician (US Usage) to improve physiologic function and/or support homeostasis that has been altered by somatic dysfunction. OMT employs a variety of techniques.” Somatic dysfunction is defined as: “Impaired or altered function of related components of the somatic (body framework) system: skeletal, arthrodial and myofascial structures, and their related vascular, lymphatic, and neural elements. Somatic dysfunction is treatable using osteopathic manipulative treatment.” See also: WHO Guidelines on Basic Training and Safety in Osteopathy.

4 Recording an analysis of GMs: p. 9 "Besides the global GM judgement into .... we assessed the Preterm GM Optimality score...." It would be more readily understandable to say "In addition to the the global GM score... we also assess the Preterm GM Optimality Score...." Other sections: Thank you, we have corrected this in the manuscript.

5 p. 12 "LOT" is not defined earlier in the text. We are sorry, but this is not correct: we have defined the Abbreviation LOS: Length of hospital stay on page p4/line 62/63.

6 p. 14, first paragraph The last four sentences beginning "Therefore, we added a more detailed assessment.... IG remained the same (0=398)" should be in the "Results" section. We agree with the reviewers comment and have corrected this in the manuscript.

7 p. 15 Another limitation of our study is that cuddling or skin to skin contact like kangaroo care was similar in both groups, which could potentially have influenced our results." I don't think you mean to say this - the similarity described there would not bias your results. The next sentence identifies the physiotherapists' touch and presence as potentially confounding variables, i.e. they were part of the OMT intervention and might have contributed to the observed effect more than or instead of the OMT. You should state clearly the the touch and presence were "confounding variables in the treatment" and might account for the observed effect that you are "hypothetically" or "provisionally" attributing to OMT.

Thank you for this reasoning. We have corrected this in the manuscript.
Confusion about statistical analysis:
8 P. 9 "To document the improvement or deterioration of GMs the difference between the last and the first optimality scores were used." This implies an analysis of baseline to endpoint change scores.

9 P. 10 a confusing sentence "... for dependent variables (developmental trajectories of optimality scores across the observational period) we applied the Wilcoxon Signed Rank Test." The word "trajectories... across the observational period" implies, at least to me, an analysis of longitudinal data. Prior sections have described the collection of data at multiple time points, so this interpretation is plausible, but contradicts the p. 9 statement about analysis of baseline to endpoint change scores. Also Wilcoxon Signed Rank Test" implies, at least to me, an analysis of baseline to endpoint change scores.

10 p. 11 "The Preterm GM Optimality Score showed a significant decrease from the start to the end-point..." This again seems to refer to an analysis of baseline to endpoint change scores.

11 p. 14 (see recommendation above to reposition the last 4 sentences of the first paragraph). Again seems to be describing analyses of baseline to endpoint change scores.

12 Figure 2 is labeled "Trajectory of Preterm GM ...." and it does show the longitudinal data; combined with the ref on p. 10 to "...trajectories ...across the observational period" this again raises some doubt as to whether a longitudinal analysis was done. Perhaps you did a longitudinal analysis but chose not to report it? For some reason. Or if you did not do a longitudinal analysis, you might state why not. It seems that you had data that could have been analyzed that way, and that would have given you greater statistical power.

p8-p12:
We agree fully with the reviewer’s comment: first, we deleted the word “trajectories” in the whole manuscript to avoid further confusion. Furthermore we agree with the reviewer’s argumentation because we did only an analysis of baseline to endpoint changes and not a longitudinal analysis.
We have corrected this in the manuscript.

Minor Essential Revisions
None

Discretionary Revisions

13 Strengths of study - you might want to mention that the GM scoring was done by blinded assessors; that is a significant strength.
We agree with the reviewer,.

14 Conclusion: You might want to recommend that future studies include in the control arm a control for touch and presence of the therapist.
Thank you for this comment; we have added this in the manuscript.