Author's response to reviews

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

Authors:

Wolfgang Raith (wolfgang.raith@klinikum-graz.at)
Peter B Marschik (peter.marschik@medunigraz.at)
Constanze Sommer (constanze.sommer@medunigraz.at)
Ute Maurer (Ute.Maurer-Fellbaum@klinikum-graz.at)
Wilhelm Mueller (wilhelm.mueller@meduni-graz.at)
elisabeth Löwenstein (Elisabet.Loewenstein@gmx.at)
Claudia Amhofer (claudiaamhofer@hotmail.com)
susanne Soral (susanka@gmx.at)
christa Einspieler (christa.einspieler@medunigraz.at)
Berndt Urlesberger (berndt.urlesberger@medunigraz.at)
Alexander Avian (alexander.avian@medunigraz.at)

Version: 4 Date: 14 October 2015

Author's response to reviews: see over
Reviewer's report

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

Version: 4 Date: 16 September 2015

Authors:

Wolfgang Raith*(wolfgang.raith@klinikum-graz.at)

*Corresponding author

Peter B. Marschik(peter.marschik@medunigraz.at)

Constanze Sommer(constanze.sommer@medunigraz.at)

Ute Maurer-Fellbaum (ute.maurer@medunigraz.at)

Claudia Amhofer (claudiaamhofer@hotmail.com)

Alexander Avian (alexander.avian@medunigraz.at)

Elisabeth Löwenstein(Elisabet.Loewenstein@gmx.at)

Susanne Soral(susanka@gmx.at)

Wilhelm Müller (wilhelm.mueller@medunigraz.at)

Christa Einspieler (christa.einspieler@medunigraz.at)

Berndt Urlesberger (berndt.urlesberger@medunigraz.at)

Author's response to reviews: see over
Reviewer: Eric Jacobson

This ms. was very much improved by this round of editing. Especially the statistical analysis and reporting are much better. There are just a few important points that still need to be changed.

Major Compulsory Revisions:
1) Only really compulsory is to include GMA outcome in the Summary and in Table 2 or a separate table, as detailed in comments below.

We agree with the reviewer and have included the global GMA in the summary and in Table 2.

Minor essential revisions:
2) Summary, results, lines 19-21. Here you report the outcome for the GM Optimality Score but not for the GMA. If you list GMA as an outcome in "Methods" then you should also summarize the outcome in Results.

Changed as suggested

3) Summary, results, lines 21-22: The sentence "Post hoc analysis showed a trend toward higher values before ... and after.. the first session in CG. " The reader wonders "higher" in comparison to what? In comparison to the other group? Or in comparison to the values in later sessions of CG? This should be clarified.

We decided to reformulate this sentence, into “did not change significantly between baseline, during and end of intervention period...” because the formulation “... did not change significantly between baseline and end of intervention period..” suggest only this two time points were analyzed. In our analysis we included both time points of all six sessions and therefore analyzed 12 time points. Therefore writing “.. did not change significantly between baseline and end of intervention period..” simplifies the results too much.
4) Summary, conclusion, lines 28-29: "OMT seems to be safe in preterm infants."

You do not refer clearly to the evidence for this. Apparently it is the fact that the GM Optimality Score did not deteriorate in the IG group. This would more clear to readers if you added a phrase such as "in view of the fact that GM Optimality Score did not deteriorate in the group that received OMT..."

*Changed as suggested.*

The text now states: „In view of the fact that the global GMA showed no difference between groups and the GM Optimality Score did not deteriorate in the IG craniosacral therapy seems to be safe in preterm infants.“

5) Data collection, Recording and analysis of GMs, lines 167-181, you give a good detailed discussion of GMA and the GM Optimality Score, but should include some mention of their validity and reliability. You could move the sentences in lines 274-280 up to this point in the text.

*Changed as suggested.*

Results, General Movement Assessment, lines 223 ff. discusses GM Optimality Score, maybe this paragraph should have its own sub-heading?

*Changed as suggested.*

Lines 225-6: Same sentence as in the Summary "Post hoc analysis showed a trend toward higher values..." This is a bit confusing; "higher" compared to what?

If you mean compared to the IG, that should be stated.

*Changed as suggested*

The text now states ..........iii) a post hoc analysis showed a trend toward higher values before and after the first session in CG compared to the IG,...

Lines 226-27 "Afterwards GM Optimality Score are comparable in both groups."

By "afterwards" I think you mean "at end of the intervention period;" by "comparable" I think you mean "were not significantly different." It would be
clearer to English readers.

*The text now states:* „At all other time points GM Optimality Score were not significantly different between groups. ([Table 2, Figure 2]).”

Discussion, line 240 "Craniosacral therapy as one of the most careful therapies..." Not clear to the reader what is meant by "careful." Do you mean "gentle?" Or do you mean "safe?" or do you mean "non-invasive?" Better to use one or more than one of those more specific words.

*The text now states:* “Craniosacral therapy as one of the most gentle and non-invasive therapies of OMT is one of the most popular non-pharmacologic complementary therapies in adult medicine”

line 248 "LOS" not clear what this abbreviation means; I look back earlier in the text to find a definition but can't easily find it. Would be better to give the definition again here.

*We are sorry, but the first definition of LOS can be find in –BACKGROUND page 5 line 51/52*

*The text states:* There is increasing evidence that massage therapy and/or tactile/kinaesthetic stimulation (e.g. osteopathic manipulative treatment (OMT)) improves i) weight gain [ ], ii) motor- and neurodevelopmental outcome [ ], iii) reduces length of hospital stay (LOS) [ ], iv) increases bonding and attachment behaviour in preterm infants [ ].

Lines 274-280 From "GMA has been validated....." These lines should be moved up to the section where you first describe the GMA and GMA Optimality, i.e. lines 72-72. There should be mention of validity and reliability etc of these insruments at that point.

*Changed as suggested.*

Lines 293-94 Again the same sentence "The GM Optimality Score did not
change over time...in both the IG and the CG, respectively." Better to say "GM Optimality Score did not change significantly between baseline and end of the intervention period in the IG or the CG." No need to say "respectively."

changed

Respectively was deleted

Weaknesses, lines 312-13 "In a further trial....children in each group have to be...
..." Better to say "In a future trial...children in each group would have to be...."

Changed as suggested. The text now states: "In a future trial using the same approach, 57 children in each group would have to be included to detect a significant treatment effect (interaction of intervention*time) with a power of 80%.”

Table 2: Study outcomes. Here you display only the outcomes for the GM Optimality Score. But in the Summary and main text you discuss at length the GMA and you even report the statistical outcomes for GMA (in lines 216-22); you should also include GMA outcomes in Table 2 or in a separate Table.

Changed as suggested

Legend of Figure 2: "GM Optimality Score did not change over time... in both groups." Should say "...did not change significantly...between baseline and end of the intervention period.. in either group."

Changed. The Text now states “GMOS did not change significantly between baseline, during and the end of the intervention period in IG and CG (p =0.262).”

Discretionary:

Summary, methods, lines 14-17; two outcomes are mentioned GMA and GM Optimality score. Generally when there are two outcomes one is identified as
"primary" and the other as "secondary."

*Changed as suggested*

Table 2: Again, it would be better to identify one of your two outcomes - GMA and GM Optimality Score - as "primary, "and the other as "secondary."

*Changed as suggested*

Also one more round of light editing for English usage would be beneficial.

*Done.*