Author's response to reviews

Title: Manual therapy followed by specific active exercises versus a placebo followed by specific active exercises on the improvement of functional disability in patients with chronic non specific low back pain: a randomized controlled trial

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Author's response to reviews: see over
General comments

Again, we thank the reviewers for their additional remarks. We think they would help to improve the quality of the present manuscript. The corrections are described in the following lines.

For reviewer 1

Minor essential revisions:

1) Abstract: as suggested, we identified the study as a pilot (line 36):

“The aim of this pilot study was…”

2) Abstract conclusion: as proposed, the conclusion was re-written in line with the conclusion section of the paper (lines 60 to 62):

“This study confirmed the immediate analgesic effect of MT over ST. Followed by specific active exercises, it reduces significantly functional disability and tends to induce a larger decrease in pain intensity, compared to a control group.

3) Early stopping decision: we added an additional sentence (line 133) as suggested by the reviewer:

“This decision was taken without knowledge of study findings.”

Discretionary revisions:

As suggested, we decided to remove the following point which was obvious for most readers and researchers:

“Moreover, one additional limitation is that the therapist, providing the sham ultrasound, could be blinded to the sham (i.e., could not know that the ultrasound was not efficient.”

For reviewer 2

Minor essential revisions:

1) Line 345: as strongly suggested by the first reviewer, we decided to remove this comment as a limitation to the study:
“Moreover, one additional limitation is that the therapist, providing the sham ultrasound, could be blinded to the sham (i.e., could not know that the ultrasound was not efficient.”

2) Lines 386 to 388: The conclusion has been re-formulated in line with the direct results of the study:

“The present study confirms the immediate analgesic effect of manual therapy for CNSLBP. Followed by specific active exercises, it reduces significantly functional disability and tends to induce a larger decrease in pain intensity, compared to a control group.”

3) Tables 3 and 4: They were simplified according to the comments of the reviewer, and we added footnotes to facilitate their interpretation

- For Table 3: lines 673 to 684:
  * Statistical significance for primary outcomes ($P < 0.025$)
  
  Since the time by treatment interactions were not statistically significant, the analyses were repeated after dropping the interaction terms.

  Coeff= regression coefficients: same interpretation as for ordinary (least square) regression, CI= confidence intervals; VAS-pain, Visual Analogue Scale of pain; ODI, Oswestry Disability Index

  VAS-pain (immediate effect) was the pain difference before and after each session, and time was the number of the 8 therapeutic sessions.

  VAS-pain (average 24 hour) and ODI were calculated over time, i.e., before (baseline) and after the 8\textsuperscript{th} therapeutic session, as well as at 3 and 6 months after the end of the treatment.

- For Table 4: lines 689 to 700
  * Statistical significance for secondary outcomes ($P < 0.05$)

  Since the treatment by time interactions were not statistically significant for FABQ-wk, FABQ-pa and Sorensen, the analyses for these outcomes were repeated after dropping the interaction terms.
Coeff= regression coefficients: same interpretation as for ordinary (least square) regression, CI= confidence intervals, FABQ-wk, Fear-Avoidance Beliefs Questionnaire Work Subscale; FABQ-pa, Fear-Avoidance Beliefs Questionnaire Physical Activity Subscale; Sorensen and Shirado tests evaluate the erector spinae and abdominal muscles endurance, respectively. All variables were calculated over time, i.e., before (baseline) and after the 8 treatments as well as at 3 and 6 months after the end of the treatment.

Discretionary revisions:
Lines 103-104: interfere on was corrected by “interfere with”
Line 117: Patients’ was corrected by “patients”
Line 132: patients’ recruitment was changed for “recruitment process”
Line 260: is was corrected by “was”
Line 269: to was corrected by “and”
Lines 273-274: decreased stronger was corrected by “MT intervention showed a greater decrease in mean pain level compared to ST intervention”
Line 287: is was corrected by “was”
Line 300: functional recovery was corrected by “reduced disability”
Line 358: as proposed by the reviewer, we completed the sentence and added a reference: “i.e., a low correlation between the FABQ-wk and disability [55].”

Line 365: patients’ was corrected by “patient”
Line 370: i.e. was corrected by “e.g.”
Line 390: larger was corrected by “appropriate”
Line 391: evidences was corrected by “evidence”