Author's response to reviews

Title: The effect of massage therapy and/or exercise therapy on subacute or long lasting neck pain - the Stockholm Neck trial (STONE): a study protocol for a randomized controlled trial

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Author's response to reviews: see over
Dear Editors-in-Chief,

Thank you for considering to publish our manuscript “The effect of massage therapy and/or exercise therapy on subacute or long lasting neck pain - a study protocol for the Stockholm Neck trial (STONE) - a Randomized Controlled Trial Eva Skillgate, Anne-Sylvie Bill, Pierre Côté, Peter Viklund, Anna Peterson and Lena W Holm

We have tried to respond to the concerns from you and the reviewer point-by point below, and have made some changes in the manuscript. All changes are marked with “track changes”. Some of the changes suggested made by the reviewer are not possible to do since the trial has already started and cannot be changed.

We hope you find the manuscript improved and that you now are willing to publish it.

Best regards

Eva Skillgate

Reviewer’s requests:

1. The hypothesis of the study do reference to the effect of massage and exercise in low back pain. I suggest to focus in neck pain.
   1. The references to massage and exercise in low back pain were made to justify the hypothesis about a possible difference in effect between the treatment arms regarding neck pain, and to convince the reader that the research questions are relevant. We have reduced the text about this in the manuscript at page 4.

2. At some moments the authors state that the sample consists of 600 patients and others who are approximately 600. What is the correct sample number?
   1. The correct sample number based on the power analysis is 600, but we hope to include some more if possible. Our goal is to include at least 600 patients. We have clarified this at page 2, 5 and 12.
3. The inclusion criteria for participants are to have neck pain with headache and/or radiating symptoms in the upper limbs of subacute (30-90 days duration) or long lasting (>90 days duration) duration and in this case amostra poderá ser muito diferente.
   1. I think I understand your point even though you have written this comment partly in Portuguese (?). It is very common with headache and radiating symptoms in the upper limbs in patients with long lasting neck pain, and we do not want to exclude these patients if it is origin from myo-fascial tissues. Further, this concern about the inclusion criteria cannot be considered since the trial had already started, and since this is the design that was approved by funding agencies, the ethical committee and reported to the trial registration. The comment has not led to any changes in the revised manuscript.

4. Patients with age range between 18-70 years are very different and can affect the results.
   1. We have no reason to believe that the effect of treatment shall differ a lot between different ages, but we will look into that by also doing the analyses without the oldest persons. Further, this concern about our inclusion criteria cannot be considered since the trial had already started, and since this is the design that was approved by funding agencies, the ethical committee and reported to the trial registration. The comment has not led to any changes in the revised manuscript.

5. It is important to have some imaging exam and to verify if the patients have herniation disc. It is also important to verify the cervical spine curvature.
   1. We do not think that is clinically or ethically relevant to examine all study participants with imaging. If the therapists suspect a herniated disc – they have experienced licensed manual therapists to help them judge this, and if this experienced therapist find that the patient may have this diagnose – that patient is not included in the trial, and recommended to seek care at a general practitioner. The clinical importance of the cervical spine curvature is according to my opinion doubtful, but if it has an impact on the effect of the treatments tested in this trial – it will most probably not be a problem anyway since we have a randomized design. Further, this concern about our inclusion criteria cannot be considered since the trial had already started, and since this is the design that was approved by funding agencies, the ethical committee and reported to the trial registration. The comment has not led to any changes in the revised manuscript.

6. The primary outcomes: pain and disability. Why not range of motion?
   1. We find many advantages with measuring the primary outcome with a questionnaire. Examination of the range of motion requires that all study participants shall come back to the clinic multiple times during a year for a clinical examination and that is not doable. Further, this concern about our primary outcome cannot be considered since the trial had already started, and since this is the design
that was approved by funding agencies, the ethical committee and reported to the trial registration. **The comment has not led to any changes in the revised manuscript.**

7. It is important to describe how they are evaluated trigger points?
   1. We use manual trigger point diagnosis even though the reliability needs to be further investigated with studies of high quality. A trigger point is defined as a palpable small nodule within a taut band of skeletal muscle that reproduces the typical pain, with or without radiation when palpated. **This information is added in the revised manuscript at page 8.**

8. Six sessions is very short considering the intensity and the persistence of symptoms
   1. We have performed several large clinical trials on the effect of manual therapy (Skillgate et al 2007, Skillgate et al 2010, Lilje et al 2010) and have in these cases found that six sessions are enough to achieve effect. If this is through also in this case we cannot know for shore. Further, this concern about the method cannot be considered since the trial had already started, and since this is the design that was approved by funding agencies, the ethical committee and reported to the trial registration. **The comment has not led to any changes in the revised manuscript.**

9. The groups have different number of sessions. I suggest using the same number for all groups.
   1. The design of this trial aims to investigate the treatments the way they are carried out in a clinical setting. It is not relevant to have six sessions of advice to stay active. Further, this concern about our method cannot be considered since the trial had already started, and since this is the design that was approved by funding agencies, the ethical committee and reported to the trial registration. **The comment has not led to any changes in the revised manuscript.**

**Editorial requests:**

1. Please ensure the title conforms to journal style for study protocol articles. The title should follow the format ?___________: study protocol for a randomized controlled trial.? Please note that the title in the submission system should match that of your manuscript.
   a. **This has been changed to** The effect of massage therapy and/or exercise therapy on subacute or long lasting neck pain - the Stockholm Neck trial (STONE): study protocol for a randomized controlled trial

2. Please include the email addresses of all authors on the title page.
   a. **This has been added.**

3. Please include the date of registration with the trial registration number at the end of the Abstract.
a. This has been added.

4. Please include a figure title and legend section after the reference list.
   a. This has been added.