Author’s response to reviews

Title: Neck-specific training with a cognitive behavioural approach compared with prescribed physical activity in patients with cervical radiculopathy: a protocol of a prospective randomised clinical trial.

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Author’s response to reviews: see over
Dear Editor,

Thank you for the opportunity to revise our manuscript titled “Neck-specific training with a cognitive behavioural approach compared with prescribed physical activity in patients with cervical radiculopathy: a protocol of a prospective randomised clinical trial” By Åsa Dedering, Marie Halvorsen, Joshua Cleland, Mikael Svensson and Anneli Peolsson.

Kind regards

/Åsa Dedering

Head Dept Physical Therapy, Karolinska University Hospital

Please find our point by point response below.

Reviewer’s report

Title: Neck-specific training with a cognitive behavioural approach compared with prescribed physical activity in patients with cervical radiculopathy: a protocol of a prospective randomised clinical trial.

Version: 2 Date: 1 April 2014

Reviewer: Stephen May

Reviewer’s report:

Page 4: delete last sentence first paragraph – does not really follow
- Sentence deleted as indicated by the reviewer

Page 4: Anterior, Cervical Decompression and Fusion – do not need capitals
- Change made as indicated by the reviewer

Page 5: first line: which consisted of........... (delete brackets)...................... in patients with cervical radiculopathy (delete – due to cervical disc disease).
- Change made as indicated by the reviewer

Page 5; second paragraph – you mean trials not trails! (line 3)
- Change made as indicated by the reviewer

Page 5; last sentence, better as follows: Because patients with cervical.............referral to a specialist clinic it is important to test these approaches
and to compare them with the general recommendation, which is to stay physically active [3].

• Change made as indicated by the reviewer

Page 6; first paragraph: It has been suggested that (repeated word) a structured physiotherapy program............... , but this has not yet been scientifically evaluated.

• The repeated word was deleted as indicated by the reviewer

Page 6; second last line of introduction: need a gap between ‘ at 3’.

• Change made as indicated by the reviewer

Page 7: reference for cervical extension test. For both tests provide data on reliability and validity.

• The cervical extension test was removed

Page 7: using a parametric t-test could be challenged for two reasons: VAS is ordinal data, as not a ‘true’ measurement, and as pain is being assessed between groups and over time. A non-parametric ANOVA is more appropriate.

• Thank you, we agree that VAS could be seen as ordinal data. However the power analysis was made as if the VAS would be continuous data because in most studies the VAS was treated that way. Pain assessed on VAS is very common in the literature and we find it important to be able to compare our results with other studies.

Page 8; line 2: Flow chart

• Change made by adding the word “flow” as indicated by the reviewer

Page: who is the ‘test leader’

• The test leader is a specialized physiotherapist and co-author. The competence of the test leader was clarified in the manuscript

Page 8: ........‘serves as contact person’....... 

• Change made as indicated by the reviewer

Page 8: Background data that............... 

• Change made as indicated by the reviewer

Page 8: Clinical measurements that ........... and balance [28, 29]. These measurements have good reliability and known reference data.

• Change made as indicated by the reviewer

Page 11: last paragraph: ...........‘whereas in the second intervention they do not have’.............

• Change made as indicated by the reviewer

Page 12; Data analysis: all outcomes are non-parametric

• The whole section on statistical analysis was rewritten. We would like to keep the section on different statistical approaches
depending on the type of data since for example neck muscle endurance time in the physical examination is continuous data.

Page 13: Many patients are sick-listed for long time periods.
- Change made as indicated by the reviewer

Page 13: The current study aims to supplement knowledge as to optimal treatment......
- Change made as indicated by the reviewer

Page 13: Furthermore it may decrease the number of patients .......... and thus reduce the....
- Change made as indicated by the reviewer

Reviewer's report

Title: Neck-specific training with a cognitive behavioural approach compared with prescribed physical activity in patients with cervical radiculopathy : a protocol of a prospective randomised clinical trial.

Version: 2   Date: 1 April 2014
Reviewer: Arianne Verhagen

Reviewer's report:
This paper presents a protocol of a randomised clinical trial on the comparative effectiveness of two different strategies for patients with cervical radiculopathy. The topic is of interest for physical therapists.

General comments
1. The paper presents the protocol of a trial. The reporting of the protocol could follow the guidelines of the CONSORT statement a bit better than it does now. The method section should be revised according to the CONSORT statement. I now miss relevant information, for instance on whether or not trial participants are blinded. You also have to make a statement when they are not blinded and inform the reader of other measures to prevent bias due to non blinding (e.g. assessing patient treatment preferences, appointing caregivers to just one intervention they believe in most, etc). Most comments are made in order to clarify the design and improve the reporting quality.
   - Thank you for your comments. We have attempted to clarify the manuscript according to your suggestions
2. The manuscript includes non English references (e.g. ref 3 and 23), please avoid this because readers cannot find or read these publications.
   - The references were changed as suggested.

Specific comments
1. Abstract, method. Please describe the setting and be clearer on the fact that this is a two arm trial. Reading the abstract I got a bit confused about a third arm of no treatment or usual care. I also would like the authors to be clearer about the interventions that will be compared on its effectiveness. Now it is confusing; one intervention is ‘neck specific training and cognitive behavioural approach’ and the other intervention is ‘prescribed physical activity’. Maybe one term for each intervention would make it less confusing?
• The terms of the interventions were changed to “neck-specific training” and “prescribed physical activity”. More detailed descriptions of the interventions will be found in the manuscript. It also clarifies this is a two-arm-intervention trial.

2. Introduction. The introduction clearly is written in a period of grant application, but needs to be revised using more recently published studies. I miss relevant literature, for instance systematic reviews of Thoomes E (2012 and 2013) and v Middelkoop M (2013) and other trial evaluating conservative care in patients with cervical radiculopathy (e.g. Kuijpers B (2009)).

• The introduction was rewritten and the suggested references were added.

3. Introduction. I do not understand why the introduction is so strongly focusing on surgery as this is not an intervention under study. Please remove most information on surgery as it does not add anything for this trial. The authors might present information on the value of conservative intervention compared to surgery (see also v Middelkoop 2013).

• The introduction was rewritten and some of the information on surgery was removed. Some was kept since surgery is one of the studied interventions for cervical radiculopathy and surgery has been evaluated in comparison to conservative treatment. No studies which compare only surgical techniques are included.

4. Method, patient selection, page 7. Patient selection should be done in a valid and reliable way to prevent selection bias. Please clarify first what the clinical symptoms are of patients with cervical disc disease and nerve root compression that needs to be verified by MRI, and what the standard physical examination entails. Please also elaborate on the poor reliability/validity of the Spurling and extension test and how you deal with that. Please be more specific in describing the patient selection strategy and inform the reader about the changes of misclassification.

• We have clarified the patient selection section according to the suggestions including what the clinical examination entails. Patients need to have neck and arm pain that can be provoked.

5. Method, sample size calculation, page 7. I am not sure why the authors perform an additional power analysis; please explain. I am also not sure why the authors powered this study as a superiority trial, instead of an equivalence study; please also explain which intervention one regards as superior over the other.

• The power analysis showed a sample size of 56 in each group will have 80% power to detect differences in means of 15 mm. We have removed the following: the difference between a group 1 mean of 10 mm and a group 2 mean of 25 mm.
• We have also removed the part on the additional power analysis: An additional power analysis with 20% β-error (power 1- β=80%) and an α-error of 0.05 will be performed by an independent statistician before the inclusion of patients is closed.
6. Method, evaluation, page 8. Please follow the CONSORT guidelines and explain here the baseline and follow-up measurements. Please also explain which questionnaires will be used. The statement that all questionnaires have good reliability and validity is not enough.
   - We have now added that the protocol will follow CONSORT guidelines and clarified that the listed questionnaires will be used.

7. Method, primary outcome, page 8-9. As I see there are three primary outcomes. Based on which of them will the authors concluded about the effectiveness or not? Based on the statements under sample size I assume the VAS will be the outcome on which the conclusions will be based, but VAS neck or VAS arm pain? Please choose one of them combined with the time of outcome measurement.
   - The neck- and arm pain on VAS will be the primary outcome since the sample size was calculated using this.

8. Method, blinding. I miss any information on this aspect.
   - A new section on blinding was added to the manuscript.

9. Method, intervention, page 9. To ease reading this part of the method section it would be good to give the interventions a shorter name, now the name of the intervention is rather long and unclear. Please describe more clearly what the contrast is between both interventions. In my opinion both are active interventions and the only contrast that might be there is the behavioural approach. Is that sufficient contrast to find superiority of this intervention?
   - The interventions were renamed to the short version “neck-specific training” and “prescribed physical activity” which are described in detail in the section on Intervention groups. The intervention neck-specific training is more specific strength training compared to the prescribed physical activity which is more general. This is now clarified in the manuscript.

10. Method, analysis, page 12. Please make clear that you perform an intention-to-treat analysis (see CONSORT statement). The analysis section is rather short and misses relevant information. How do you deal with missing information, what kinds of repeated measurement analysis will you use?
   - The section on data analysis was rewritten and the intention to treat approach was added as suggested.

11. Discussion, page 12. Why suddenly discuss gender as a prognostic factor of surgery?
   - The part on gender and surgery was removed since we agree it did not add to the manuscript but rather was confusing.

12. Discussion, page 12. What do the authors mean by the risk of this study? Which risk? The risk of not being able to include de necessary number of patients, or the risk of bias, or maybe the risk of adverse events? Please clarify.
   - The section was rewritten to discuss possible limitations or risks of bias.

**Level of interest:** An article whose findings are important to those with closely
related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**
'I declare that I have no competing interests'