Author's response to reviews

Title: Nordic Walking in the treatment of chronic low back pain patients. A single blind randomized clinical trial.

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Author's response to reviews: see over
Dear Editorial Team

Thank you for sending reviewers comments, and for giving us the opportunity to respond and revise our paper. We are grateful for the suggestions and have carefully considered all comments. The comments were quite extensive and we have chosen to revise and respond as follows:

Reviewer #1 Rahman Shiri
The change from baseline was used as a dependent variable. It is unclear why again in the analysis, the effect of Nordic Walking on low back pain was controlled for the baseline levels of the outcomes.
Answer: This procedure follows the international guidelines for statistical analysis. See www.emea.europa.eu document: point to consider for baseline covariates CPMP/EWP/2863/99 section II.7.

Was the expectation of treatment used as a covariate for adjustment or as an effect modifier? Table 1 shows that supervised NW differed at baseline from two other groups regarding the expectation of treatment.
Answer: Neither. In the analysis of expectation the variable was the primary predictor of interest. This is clearly mentioned in the methods section on page 9.

Table 1: The columns do not have a heading. If the columns show three randomized groups, what are those supervised NW, unsupervised NW and advice to remain active that were presented in the rows.
Answer: We have redesigned the Table and the columns are now clearly labeled.

Was the effect of Nordic Walking on low back pain was modified by gender, age, smoking, overweight, expectation of treatment, pain severity, functional limitation, sickness absence, and use of pain medication?
Answer: We adjusted only for baseline LBP in the ANCOVA analysis. We agree that this is an interesting question. However, since our dataset is of limited size we decided to refrain from such analyses to avoid ambiguous results due to low power.

There are two contradictory statements in the first paragraph of the Discussion. 1) Supervised NW was no more effective than unsupervised NW or advice to remain active. 2) Supervised NW had a clinically significant effect.
Answer: This is not correctly quoted from the paper. We did not write that “supervised NW had a clinically significant effect”, we wrote that “a greater proportion of patients in this group [the supervised NW group] achieved a clinically important improvement” (page 12). This statement is justified based on the analysis of MCID.

No sub-group analysis was performed. Therefore, this study does not support that NW may be effective for selected sub-group of chronic LBP patients.
Answer: We agree. This is speculation on our part. We have stricken this sentence from the first paragraph in the discussion on page 12.

What were dichotomous outcomes? Were they medication use, other treatment for low back pain, and sickness absence?
Answer: Yes it was and also whether the patient improved beyond the MCID. This has been clarified on page 9 in the methods/analysis section.
The following sentences need to be clarified. "In the exploratory analysis the primary endpoint was re-evaluated. We defined a successful outcome if the change was equal to or greater than the MCID". What does abbreviation MCID stands for? Is it "Minimum Clinically Important Difference"? It seems that in addition to using the change from baseline as continuous outcomes, they were also dichotomized into two groups using MCID. This should be clarified.

**Answer:** We have changed the wording in the analysis section on page 9 and hope it is now clearer. Probably the confusion arose because we forgot to present the abbreviation MCID when it was mentioned the first time. We apologize.

In the Abstract you mentioned that the data was analyzed using intention-to-treat method. There is nothing in the statistical analysis on this issue.

**Answer:** This has now been specified in the last sentence of the analysis section.

Please clarify for which baseline variables mean improvement of the function scale of the LBPRS was adjusted for.

**Answer:** The only baseline variable adjusted for was pain level. Please see explanation above.

The results show that three groups differed at baseline regarding the prevalence of sickness absence due to low back pain. Why only return to work was used as an outcome, but not new onset of sickness absence due to low back pain during the follow-up.

**Answer:** We did not systematically collect data on onset of new sickness absence during the follow-up period. Based on personal communication with the project manager (Lars Morsoe), it is our impression that this was indeed very rare.

The proportion of patients with obesity should also be included in Table 1.

**Answer:** The patients were weighted prior to starting their treatment at the back center but not prior to the NW study. Therefore we do not have reliable data on obesity.

Values for expectation of treatment in Table 1 were displaced.

**Answer:** Has now been corrected.

The use of too many abbreviations makes the text hard to read. Moreover, there are several spelling errors and some long sentences need to be simplified.

**Answer:** We have re-read the text and tried to improve the above issues. Thank you for noticing.

This reviewer suggests beginning the Introduction with low back pain (paragraph 3), continuing with the effect of exercise on low back pain (paragraph 4), Nordic Walking (paragraphs 1-2), patient compliance with exercise therapy, and ending with the study aim (last paragraph).

**Answer:** We would prefer to keep the present sequence.

Introduction: Exercise may be moderately effective for chronic or subacute low back pain, but the effect of exercise on the prevention of low back pain is not clear yet (Chou et al. 2007, Keller et al. 2007, Hamberg-van Reenen et al. 2007, and Chen et al. 2009).

**Answer:** We did not write that exercise is effective in preventing back pain but rather that an active lifestyle appears to protect against back pain at practically all ages. This is based on results from epidemiological studies that are referenced.
Although NW is a popular and a presumably often used discipline in health programmes, the authors should provide a more profound theoretical derivation for the use of NW. A hypothesis as stated on page 7 is not presented. Why should chronic NW exercise affect lumbar or upper extremity muscles and why should it be better compared to classical aerobic exercises (P4, second paragraph)? This section is unclear and needs to be clarified.

**Answer:** This is a very good point. We have expanded the first paragraph in the introduction and added two references and moved the hypothesis from the method section to the end of the intro. Furthermore, we have added the hypothesis regarding activity level for the supervised group.

The methods are appropriate and well described. Please describe the patients more detailed. Patients with back and/or leg pain cover a wide spectrum of diseases. Please specify the subgroups. Due to the limited changes between the groups, I am not sure if it is a good idea to retain data about compliance and cardiovascular issues for further papers. To my mind these data belong to the presented results. The knowledge about compliance and cardiovascular effects are important to describe the chosen intensity of the exercise. I would rather recommend adding these data to this paper. Please add the groups in table 1 and provide abbreviations for the groups throughout the entire document. Please specify the therapy, which was carried out before the NW intervention.

**Answer:** These are all good points. I am afraid that we cannot further describe the subgroups in this sample due to the limited sample size. The idea here was to present NW as a possible general intervention for patients with low back with or without leg pain. Since there was no general effect to speak of, future studies will need to address the issue of sub-groups. We have now added information on the intensity of physical activity from the accelerometer measurements for the supervised and non-supervised NW groups in the methods and results sections including an extra figure. The implications of the findings are discussed.

The presented data are sound. However it is still unclear, if there are any significant changes after the intervention. Please clarify; show where differences are significant and add SEM in the text (Major Compulsory Revisions). Figures: Statistical significance should be indicated in all figures so that it is clear where differences occur. Error bars in only one direction would be adequate.

**Answer:** We have redone the figures and statistically significant within group changes are now indicated using p-values in the figures. The between group differences (which are not statistically significant) are indicated using the 95 % confidence intervals.

Due to poor statistical differences, it is difficult to discuss the data and even more it is difficult to draw clear conclusions. The authors seem to be aware of this problem. Statistical power calculations are provided (Please add the source for the used power calculation). Limitations are included in the discussion section. Maybe a differentiation of the patients in responder and non-responder to the different exercises could help to identify specific responder subgroups. If there are no statistical differences for the time effects (before vs. after) please shorten the discussion. A discussion based on speculations and tendencies would not be accurate for the publication in BMC (Major Compulsory Revisions).

**Answer:** The source for the power calculations have been added. We have re-considered the discussion and shortened it somewhat however we do feel that it is important to communicate the lessons we have learned in performing this study.

The advised modifications should be included in the abstract. Clarify the methods and results. Eliminate speculations, if there are no statistical significant differences.

**Answer:** Abstract has been revised. And see above.
The minor mistakes have all been corrected. Thank you for being so thorough.

Reviewer #3 Jaana Helena Suni

The major concern of the proposed paper is the lack of knowledge on both the intended dose (intensity, frequency, duration, total volume) of supervised Nordic Walking and the actual dose performed by the participants of this group. Furthermore, the dose of walking in group B should also be described somehow (diary and accelerometers are mentioned in Figure 1.) The authors refer to important reviews on former findings on exercise and LBP and are clearly well aware of the poor knowledge on what has actually been done in these former studies. Thus, the contents and dose of exercise is a critical factor and should be reported carefully.

**Answer:** We have now included information on the accelerometer methodology on page 8 and 9, described the analysis on page 10 and added results on page 12 and 13. Furthermore we have added a new figure Figure 5 showing activity for the groups.

The use of diary and accelerometers should also be described.

**Answer:** Please see above.

The statement (page 7 paragraph 2) “tempo was adjusted according to the lowest participants” needs explaining, while it ruins the idea of pre-planned exercise dose of the study.

**Answer:** We have re-worded that paragraph and generally agree that a uniform pre-planned exercise intensity is preferable. However even though we determined the intended intensity beforehand as described, some participants were just not able to comply.

Data on exercise compliance and results on the changes in cardiorespiratory fitness should be included in the paper. They are essential parts of being able to understand the results. The reader can not be expected to read these facts later from a (possible) future publication as suggested in the introduction.

**Answer:** We now have included accelerometer data but will not include the cardiorespiratory results in this paper. Cardiorespiratory response to different types of exercise is a large and different field and we think that including these data in this paper will result in a very long and unfocussed report.

The description of the randomization process is not clear. Was it conducted as an ongoing process during the two years of recruitment?

**Answer:** This is now specifically stated on page 7 in the randomization section.

Recruitment should be described in the methods section and not as a result. The recruitment time should be added to Figure 1 since it took two years. It is not clear how the training proceeded during this two year time. It seems that the small groups started training in different times during the two year period?

**Answer:** We have moved the sentence about recruitment period to the beginning of the methods section. It is correct that the small groups started their training as they were filled over the two years, thanks for allowing us to clarify. We have now added this sentence under the description of group A: “As soon as a group was filled the NW commenced resulting in different groups performing this intervention at different time points over the two years”. It is however difficult to see how this could have a bearing on the results.

Adjusted mean differences of the changes in the primary outcomes of LPB and disability in the three intervention groups should be reported instead of figures 2-4. It is not clear what are the analyses that indicate no significant differences between the groups.
We have reworked the analysis and are now reporting within group changes in the figures. The between group differences are indicated using 95% confidence intervals. We think this is quite clear and reader friendly.

What is the scale for Patient Spesific Function Scale? Abbreviations on EQ-5D should be explained in the text as well as scale use in it.

Answer: It is stated in the description that the PSFS is a numeric 11-box scale. We provide a reference for the EQ-5D which is a widely used health related quality of life outcome measure. We believe that is adequate for here.

The description of the expectation to treatment is not clear. Please, provide more information on the contents.

Answer: The participants were asked to state their expectations to treatment on a 5-point likert scale with response options ranging from “very good” to “poor”. The sentence has been somewhat reworded and is in our opinion clear and easy to understand.

Use wording “statistical analyses” instead of analyses.

Answer: Done.

Add abbreviation MCID on page 9 after the written text of it.

Answer: Done.

Describe what sandwich approach means.

Answer: We have added wording to the sentence describing the sandwich approach. We do not think that further elaboration is needed as this is a quite common method in the analysis of randomized trials.

In Table 1, there are three groups however it is not clear what they are. Also the abbreviations used in the table should be explained. The last part of the table about randomization is difficult to understand.

Answer: The columns have now been labeled. We have changed the legend to spell out the abbreviation NW. We have changed the wording in the table regarding the expectations, we hope this helps.

Test at 10 week follow-up in Figure 1 should be explained.

Answer: This relates to the cardiorespiratory outcome which will be dealt with in a separate analysis and paper. Therefore we have stricken the word “test” here. Thanks for pointing this out.

The authors question in the introduction whether Nordic walking is an effective mode of general physical activity in the treatment of low back pain. The question itself is clear, however, a hypothesis on what is the plausible biological mechanism could be included in the introduction [i.e increased cardiorespiratory fitness(?), decreased loading of the back while using the poles(?), etc.]

Answer: We have reworded the first paragraph of the introduction according to this and another reviewer’s suggestion.

The statement “cardiovascular issues” in the last sentence of introduction gives rise to a question whether the subjects had risk factors or symptoms of cardiovascular diseases, and was the main aim of the study to influence these? Please, explain this.

Answer: This has now been stricken from the paper. We agree that it was confusing.