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:

Thank you to the reviewers for carefully reviewing our paper one more time and for providing such useful and constructive suggestions.

We have addressed the issues raised below to the best of our ability and it is our opinion that the paper has improved considerably through this review process and is now ready for editorial decision. The paper focuses on the effect of a general exercise intervention, namely Nordic walking, on low back pain and it is our opinion that an increased focus on physiologic aspects of Nordic walking mainly related to cardiorespiratory fitness will detract from the main aim of this report and result in an unfocussed and confusing paper. We have incorporated many changes and clarified many issues and hope that this manuscript is now satisfactory.

Torsten Schiffer

It is still not clear, why NW should be an appropriate exercise to improve chronic back pain.

Answer: We appreciate Dr Schiffers insight but do not understand this comment. In the introduction, we review recent back pain literature which consistently concludes that general physical activity may be a treatment option for back pain patients. NW is one such intervention which appears to be particularly popular among people who do not normally exercise. Therefore it is potentially of benefit and thus the rationale for evaluating it in a randomized trial.

To my mind it is not enough to add data about accelerometer measurements to classify the selected intensity of the exercise. You cannot discuss the effectiveness of NW without a further description of the intensity/duration. The term/the intervention “Nordic walking” would be just an empty word. On page 7 you mention that you have predetermined the intensity (How did you control the intensity during the intervention?). These data should be placed in the paper.

Answer: We have added a description of how we arrived at the predetermined intensity to the text on page 7. It is also made clear now that not all participants
were able to comply with this intensity. These issues are now further discussed on page 17 top. Besides the accelerometer data, we did not collect further data on intensity, i.e. heart rate etc.

On page 16 you list the problems, which you have discovered during the study. Maybe you forgot one problem, that is to say that the selection of the patients was too inhomogeneous. Thus I would advice to present the sub-groups, which you have evaluated. There is no need to calculate or discuss these data. Since you did not examine sub-groups it is not allowed to draw conclusions like you did it in the abstract. Moreover you did not find statistically significant differences between your groups, so that your conclusion at the end of your paper “The mean improvements were, however, generally greater…” is not allowed.

Answer: This is a good point and this is now added on page 17, first paragraph. We did not perform frank sub-group analyses because the sample size does not allow this. We do not agree with the points raised regarding the potential benefit of NW for select patients. Based on this trial we cannot recommend NW as a general intervention for chronic back pain patients but given the almost consistently larger improvements in the supervised NW group, we consider it possible and even likely that stricter inclusion criteria a larger study and perhaps greater intensity during the intervention could result in clinically and statistically significant improvements. After all, statistical significance is very dependent on sample size.

A further problem in the discussion are in parts speculative explanations for not statistical significant changes. For example, what are “clinically important improvements” (page 15), if they are not significant.

Answer: Statistical significance and clinical significance are two different concepts. Statistical significance is determined based on statistical comparisons between groups. Clinical significance can be determined in many different ways. We have used the method described in the methods section page 9 bottom and page 10.

It is not proven that the use of poles increases the speed of the gait. Please add references. We have recently shown that the effort of the upper extremities has no effects on the walking speed on different surfaces. The complete first part of the introduction needs to be written more precise. Why should Nordic walker use their upper extremities muscles more than for example walker? (See 1) Please relate the effects of NW to the examined exercise disciplines according to the cited references.

Answer: Thank you for pointing this out to us. There is indeed controversy in this area. We have re-written the first paragraph and cited the very good study by Dr Schiffer.

Title: …chronic not chonic
Answer: Corrected

P14: incorrect use of dot and comma: 65,2; 5,000-5.5000; 240,000-300,000
Answer: Corrected. We use the American way.

MCID is not explained
Answer: MCID is explained in the methods section under statistical analysis.

Jaana Helena Suni

The revised manuscript still lacks the information on the intended dose (intensity, frequency, duration, total volume) of supervised Nordic Walking. Furthermore, it is not clear what was the base of exercise prescription at an individual level (Results from the ergometer test? Health status? Perceived exertion during walking?), and what were the instructions to the participants concerning the dose.

Answer: We have elaborated on the explanation of the supervised NW intervention on page 7 specifically stating that the dose and frequency were standardized but it was not possible to standardize the intensity.

The authors state in the discussion that physiological change was hardly the reason for better average result in NW group. How did you come into this conclusion? Did the fitness test results show this, or was the compliance so poor? The new additional information from accelerometers is of importance, however we still do not know what was the compliance compared to intended dose. For instance, how many supervised exercise sessions did the participants complete in average and what was the range of that? Thus, I still feel that more precise data on exercise compliance and some facts about cardiorespiratory fitness changes should be reported.

Answer: The accelerometer data presented in the paper clearly show that the difference in activity level between the supervised and the unsupervised NW group was practically nonexistent. Therefore any difference between the groups is unlikely to be explained by physiological changes as a result of the intervention. We are working on a separate paper dealing with the fitness testing and cardiorespiratory changes. It is our opinion that including further information on the cardiovascular aspects in this paper would require a complete re-write and result in a less focused paper.

Since I did not comment the discussion part of the former version, I would now like the authors to comment and discuss the following point. Why did you select bicycle ergometer as the test method of cardiorespiratory fitness while the mode of training was walking? (i.e. why was walking in the treadmill not used as the test mode?) It has been shown that walking is a better test mode among chronic LBP patients*. Furthermore, there is biomechanical evidence that brisk walking results in lower lumbar spine torque and muscle activity, as well as reduced spine loads with energy conservancy from arm swing than slow walking.**

**Callaghan JP, Patla AE, McGill SM. Low back three dimensional joint forces,
Answer: Again, we would prefer to deal with the cardiorespiratory issues in the sister paper. However, we must admit that we chose the bicycle test out of habit since we use it at our institute for fitness testing in a range of other projects not specifically related to the low back.

I find the second paragraph of the discussion irrelevant while return to work was a secondary outcome and the content is very speculative.

Answer: We tend to agree however the issue of return to work was raised by one of the other reviewers in the first round so we would prefer to keep it. We have added that the argument presented is speculation.

I still find the randomization part of the table 1 difficult to understand.
Answer: We are not sure what you mean as there is no information on randomization in Table 1.

A clear hypothesis, based on a plausible biological (or possibly psychosocial) mechanism, on the reason for selecting Nordic walking as the effective exercise mode for patients with LBP is still lacking. In my opinion, a clear hypothesis would improve the scientific value of the report.

Answer: We have reworded parts of the introduction according to the comments by reviewer #1 and we believe that we present the rationale for choosing this intervention.

The order of the topics in the discussion is somewhat “jumpy”. Discussing the compliance first, the primary outcomes secondly, and other issues after that would make the article easier to follow.

Answer: We have switched the two paragraphs.

Rahman Shiri

Sick leave, medication use and receiving concurrent treatment are not continuous outcomes (Page 10, paragraph 3).

Answer: Correct, has been corrected.

Patients with chronic back pain (± leg pain) were included in this study (Abstract, Methods section). Therefore, chronic low back pain in the title and throughout the paper should be replaced by chronic back pain.

Answer: Thanks for pointing this out. Rather than going this way, we have stressed that the inclusion criteria id pain in the low back both in the abstract and the methods section.

In the following sentence it is unclear what the individual baseline level is? Is it the baseline level of the outcome or the baseline level of expectation? "The analysis of the influence of expectations on the outcome was performed in a regression model adjusting for individual baseline level."

Answer: It is the baseline level of the outcome as stated.
Borderline significant should be defined in the Methods, Statistical Analyses. For instance, a $P < 0.05$ was considered statistically significant, while $0.05 < P < 0.1$ was borderline significant.

Answer: We have defined these concepts on page 11 at the end of the methods section.

The following sentence needs correction; at 26-week is missing. .....in the unsupervised NW group the improvement was borderline significant at 52 weeks and non-significant at 11 and 52 weeks ($p=0.1480/0.2060/0.0695$),

Answer: This has now been corrected.

Non-significant p-value is reported with only two decimal digits and very low p-value with $<0.001$. It is better to report p-value separately after each follow-up than all three p values at the end. It is not necessary to report all significant p values. Back pain improved over time in all three groups. The follow-ups were exactly at 11, 26 and 52 weeks, so using "after 11, 26 or 52 weeks" may not be appropriate (page 13, paragraph 2).

Answer: We have now shortened the p-values. This works better. We would however prefer to keep the reporting of the p-values where they are in the text.

Some linguistic errors in the manuscript could be corrected, e.g. The proportion of participants who changed from being on sick leave at baseline to not being in sick leave after.

Answer: We have re-read the manuscript and hope that there are fewer errors now.