Author’s response to reviews

Title: The effect of the stay active advice on physical activity and on the course of acute severe low back pain. A randomized controlled study.

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Author’s response to reviews: see over
Response to reviewers

Dear reviewers, we appreciate your time giving us valuable and straight comments for improvements of our manuscript. They helped us to sharpen our formulations, as well as to make the aims, and the study contributions clearer. Major revisions as a response to your comments have been performed concerning the title of the work, conclusion in the abstract, the introduction section with clearer explanation regarding the originality of this work, as well as correcting the aims, and including new references. Additional results were added concerning the within-group change in pain intensity. Finally, the discussion section has been revised to correspond to the aforementioned changes and to the scope of this work. We consider that we improved rationale structure and clarity in of the paper. Separate sections regarding strengths and limitations, as well as practical applications have also been added. Below we have responded point-by-point to your comments. We hope that our responses will satisfy your high standards.

Reviewer 1

Comment 1
The methods used in this research are valid, appropriate but the patients included in study could be described more precise regard to some other clinical characteristics and included and especially excluded criteria. It is not so clear why only patient with pain intensity assigned as 5, due to also presented fact that pain was assigned as moderate from 4 to 7.

Response 1
Thank you for your remarks. Some complementary clinical characteristics as well as wide information regarding inclusion and exclusion criteria have been added. Regarding assessment of pain intensity, you are right. The description of the NRS scale in the paper is wrong. We were describing instead the Verbal Rating Scale (VRS). We have corrected and explained it properly in Methods. Thank you. The Numerical Graphic Rating Scale (NRS, 0-10) is a box scale consisting of 11 numbers (0 - 10), from no pain, to 10, indicating pain as bad as it could be. The patients were asked to place an “X” at the number that represents their pain. The VAS scale was used to self-assess the patient’s pain intensity at the initial clinical examination, and was rated on a 100 mm scale, ranging from 0 “no pain” to 100 “worst possible pain”. In addition, drawing in the dorsal and ventral views, the patient marked the location(s) of the pain.
Cover letter

**Reviewer 2**

**Comment 1**
The grammar of the paper needs closer attention. Overall, many sentences need rewording to improve the quality of the paper.

**Response 1**
The manuscript has gone through an additional proofreading to improve the quality of the language.

**Comment 2**
You measured the Modeled daily pain intensity (NRS) over the 7 days follow-up in patients advised to stay active (SA) in spite of pain (solid line) or to adjust activity (AA) to their pain (dashed line) advice. For me it will be more consistent in discussion if you add a statistical analysis if there is a significant difference in the same group before and after the follow up period.

**Response 2**
Thank you for this comment. Initially, pain intensity was measured by mean of the VAS scale. However, in the diary in order to follow pain intensity in a more precise way, pain intensity was measured by mean of the NRS scale. Hence, we cannot apply different measures in the analyses because they are different scales that measure pain intensity in different units. Thus, we used day 1 as the best reference-point for the activity and pain trajectories modeled, and compared the trajectories between the two groups, as it was the main purpose of the study.

In addition, there were no differences between the groups regarding the reported cause of ALBP, occupation or initial pain intensity (VAS).

After your remark, we made the suggested analyses and now we performed tests to evaluate differences between day 1 and day 7 for each group, separately. For the SA group the pain intensity decreased from 5.0 to 2.8 (p<0.001) and for the AA groups it decreased from 4.8 to 2.3 (p<0.001). This information was added in the Results section. However, the conclusions of this study regarding pain intensity over time are still the same; first, pain intensity decreased in the same rate in both groups and, second, no differences between the groups of comparisons (AA vs. AA) were found.

**Comments 3 Abstract**
The abbreviation of ALBP is not mentioned at its first time of appearance. Please move the abbreviations of (SA) an (AA) in their adequate places, just following their definitions. The conclusion is not clear to me, it should be rewritten.

**Response 3**
The abstract has been adjusted accordingly. We are using now the names stay active group and adjust active group and not their abbreviations (SA and AA) in the result section. In the abstract, we have provided the short group names in brackets, in methods. The conclusion has been rewritten to be clearer, as suggested. Thank you.
Comment 4 Introduction
In the first paragraph, second line, please give reference to this statement “The highest prevalence can be found in Western Europe, with almost 16% of the males and almost 15% of the females affected”.

Response 4
The statement is taken from reference 1 in previous sentence. For clarity, it is added also to the referred sentence as requested.

Comment 5 Introduction
It is useful to highlight if there is or not studies indicating that resting in less activity is better than that being in activity.

Response 5
You are right. Nevertheless, the evidence is rather limited to a few studies. That is a further contribution with this study. According to a Cochrane review (Dahm et al, 2010; reference 12) presenting three studies; two were in favor for the stay active advice and one showing no difference and even more days of sick leave with the stay active advice. However, this later study was judged as having high risk of bias and with a sample not applicable to the general population. We have expanded somewhat the introduction section, presenting the evidence of the stay active advice, which additionally, promote in the very early phase of acute LBP, physical activity, and further, prevent disability and according to wide research, recurrence of LBP.

Comment 6 Introduction
It should be better to clarify more clearly the originality of the study according to literature.

Response 6
We agree with you and definitively, this information should be more clearly stated in our manuscript. Now we have focused the originality of our study based on the strengths of this study, i.e., early recruitment of the patients, with acute severe pain, and the early advice to the treatment strategy, evaluating clearly the effect of the intervention, and further, prospectively. In addition, the objective measure of physical activity to evaluate early compliance in a prospective way is an additional original and desirable characteristic in research among patients with ALBP. Now all these aspects are posited, in the Introduction and in the Discussion section.

Catching patients with acute severe LBP as soon as possible after the onset of pain, and to follow them during the natural course of pain progression, was to prove that “The earliest one encourage a patient to movement and return to daily activities, the easiest the patient complies to be physically active and move on from the pain. Of course, taking into account all considerations for the patient and treating the pain. Theoretically, this should prevent pain avoidance and disability. This is the standpoint with the paper. A message to GP is to motivate the patients with ALBP and follow them in this early/acute stage of LBP. Thus, the compliance has a huge importance in clinical practice. We state in the introduction section the problems related to the attitudes of the GP and the way to treat acute LBP, as several researcher and the IASP has revealed.

These finding are answering our postulates, now added in the Introduction section, regarding the management of first time ALBP, which varies and reflects uncertainty about the optimal approach in general practice. Hence, our findings have important clinical applications to attempt a public health problem, namely the first with depression in Sweden. The proper references have been included.
Comment 7 Methods
The abbreviations: MRI and STIR are not defined. MRI= Magnetic Resonance Imaging. STIR=Short Time of Inversion Recovery (a part of the MRI technique).
Response 7
These abbreviations have now been defined.

Comment 8 Methods
Can you mention if the battery of questionnaires covering history of ALBP refers to any reference?
Response 8
Yes it does. The questionnaires used are referred to the following reference and added to the Methods section:

Comment 9 Methods
In the paragraph of physical activity in methods, the amount of physical activity is not well defined to say that stay active group was really active; moreover, it is better to specify the sports activity allowed to the patients and to eliminate sports that can aggravate the injury in their back.
Response 9
Thank you for this comment. We used a simple pedometer to record the number of steps taken each day during the 7 days follow-up and we also employed population cut-offs for physical activity level based on step counts from a healthy population. With these cut-offs we could say something about the physical activity level over the study follow-up, and whether the groups were active or not. In addition, in the diary the patients reported all physical activities performed under the 7-day follow-up, so we were aware of the level of physical activity in this additional way. This additional reporting is described in the method section but is not presented as a result.

Comment 10 Results
The titles of figure 2 and figure 3 are so long, can you reduce it?
Response 10
Our suggestion is to include the first sentence for each figure as the title and the rest of the text as figure legends, in line with the journal instructions. This revision has now been performed and it is described in Figure legends at the end of the manuscript.

Comment 11 Results
In the second line of the paragraph of pain intensity change trajectory in results: (Table 2, Model 1, linear term p>0.001); the value of p must be “<”
Response 11
Thank you for your remark. This is an error and it has been adjusted.
Comment 12 Discussion
Sections should be included where you can state the ‘practical applications’ (how can these results be practically applied) and ‘limitations of the study’ (what were the short-comings, or methodological issues, of the study). Both these sections provide valuable information for the reader to be able to judge the outcomes of the study for themselves and help apply the information in a practical manner.

Response 12
This was an additional valuable comment, thank you. In consequence, a section called Strengths and limitations and another called Practical applications have been included.
Comment 1
I have to admit that I did not like your paper. The research question is too narrow. I can only hope that you have also long term results for example of 12 months follow up to see whether your Intervention had any effects on recurrences. Otherwise only this research question is far out of wasting money (with all those MRI's and clinical examinations by an orthopaedic surgeon).

Response 1
The issues raised by you are very important and we agree that they need deeper clarification. We have made this clearer now in the introduction part. We agree with you and definitively, this information should be more clearly stated in our manuscript. Now we have focused the originality of our study based on the strengths of this study, i.e., early recruitment of the patients, with acute severe pain, and the early advice to the treatment strategy, evaluating clearly the effect of the intervention, and further, prospectively. In addition, the objective measure of physical activity to evaluate early compliance in a prospective way is an additional original and desirable characteristic in research among patients with ALBP. Now all these aspects are posited in the introduction and in the discussion sections.

One important observation was that with an inexpensive treatment strategy “stay active” and the pedometer, a considerable larger increase in step count, for additional health benefits, could be promoted among patients advised to stay active, even the similar pain experience in the adjust activity group, which could be evaluated as exceptional from another research perspective.

Acute severe LBP seems to have a natural course of about a week. The first questions may then concern any alteration during this early course. To be able to evaluate the effect of the stay active advice on ALBP, we first need to capture the patient in close connection to the onset of pain, and thereafter, immediately start with the intervention. This has not been performed in previous research, which have made difficult to establish any direct effect of the intervention on onset acute severe LBP. We aimed to follow the course of ALBP and the influence of the two treatment advices, i.e. early or short-term effects. We were able to start with the intervention close to immediately after pain onset, evaluating in the short-term the effect of the intervention. However, patients not following the advice are common in clinical practice. A study of compliance is therefore warranted.

The next step is to investigate later effects. We have collected under the next six months information regarding intensity of pain, LBP related disability/daily activities, and sick leave due to LBP. We have the purpose to analyze this information.

Comment 2
1. Is the question posed by the authors well defined?
Yes, however I would argue that it does not make much sense. The only interesting point would be to see the long term results – do the more active subjects have less recurrences, say, in the next 12 months?

Response 2
Our intention with this first study was to determine whether the stay active advice really had any positive effect on return to the usual level of physical activity during the natural course of ALBP. We found that it did. Even we do not prove recurrence/chronicity because it was not the objective, we are be able to assume that between 2 to 56% of the patients with acute LBP
should continue with back problems and disability, as prior research has established. In Scandinavian countries, particularly in Sweden, the degree of disability and early retirement due to LBP, have been the highest in Europe. (Breivik H. et al., 2006). This public health problem is now presented in the Introduction section.

(See response to question 1, 4 and 5 for complementary information).
We have added clearer rationales and statements for our research question and reformulated the aims in the Introduction section.

**Comment 3**
2. Are the methods appropriate and well described?
To a large part yes. I did not understand say 1 step count, which was told two times with different numbers (abstract). I found it funny that the sample size calculations were done like you should, but then the sufficient number of subjects were not included. This was because money went out. At first around 100 subjects were all examined by MRI, which mus cost 70-80 000.- Euro, and then claim the money went out…

**Response 3**
Thank you for your remark. This has been changed and corrected: step count told two times was unfortunately an error in the abstract. It should be “At day 7…” the second time. Concerning the sample size, unfortunately, changes in the financial situation did not allow us to complete the targeted number of participants, which we regret. However, this limitation seemed not to have any great effect on the results on physical activity, but, possibly on pain intensity differences between the groups. Additional participants may not have changed much of the results in the present study. However, possibly it will have some effect on long-term results, as it is often more difficult to find significant results over time and the number of drop-outs often increases, but is not the case in this paper.

**Comment 4**
3. Are the data sound?
It seems, however, the research question is hardly interesting

**Response 4**
We consider the research question as relevant in clinical management of acute LBP. The originality of the paper is based on the early recruitment that has not been performed previously. In prior research, it makes hard to draw any conclusion about the intervention effect. Conversely, in this study, we were able to evaluate the compliance to the intervention, as well as the influence of the intervention on pain intensity during the natural course of ALBP, i.e. acute lumbago. The compliance was confirmed.

A part of our results is that the intervention is feasible, promotes activity even though it hurts during the natural course. Hence, to handle with pain is a complex problem that needs clear treatment strategies to encourage patients to avoid fear of movement. This finding has been highlighted when presented among clinicians and in a prior Congress of pain in the World Congress of Pain (IASP, 2011). Using these simple and inexpensive methods of the stay active advice together with a pedometer, promotes such an increase in physical activity level in patients with ALBP that is exceptional in itself.
We refer to the response to comment 1 and 5 too.
Comment 5
6. Are the discussion and conclusions well balanced and adequately supported by the data?
Well, I would discuss a point: one might think out a research question as follows let’s take 100 subject with common flue. Then half of them would be encouraged to drink a lot of tea, and the others should only drink tea if they wanted to. Then you would see that the ones asked to drink tea (asked through an important doctor) did so. However, you would not see any differences in improvement of the flu. Would someone publish that?

Response 5
Really, we appreciate your critical issue because it motives us to improve the written formulation of our intention with this study, i.e. the context of our hypothesis. You are right interpreting in that way. However, we will like to point out that the main goal performing this study is to encourage GP to promote physical activity as soon as possible among patients with acute severe LBP, because of the high prevalence of recurrence of LBP and chronicity because of this. In addition, low level of physical activity has been associated with increased risk for high-intensity LBP and disability (ref 31).

Catching patients with acute severe LBP as soon as possible after the onset of pain, and to follow them during the natural course of pain progression, was to prove that “The earliest one encourage a patient to movement and return to daily activities, the easiest the patient complies to be physically active and move on from the pain”. Of course, taking into account all considerations for the patient and treating the pain. Theoretically, this should prevent pain avoidance and disability. This is the standpoint with the paper. A message to GP is to motivate the patients with ALBP and follow them in this early/acute stage of LBP. Thus, the compliance has a huge importance in clinical practice. We state in the Introduction section the problems related to the attitudes of the GP and the way to treat acute LBP, as several researcher and the IASP has revealed.

These finding are answering our postulates, now added in the Introduction section, regarding the management of first time ALBP, which varies and reflects uncertainty about the optimal approach in general practice. Hence, our findings have important clinical applications to attempt a public health problem, namely the first with depression in Sweden.

Comment 6
7. Are limitations of the work clearly stated?
No – see point 6.

Response 6
We have now expanded the discussion section with a special section concerning strengths and limitations.

Comment 7
8. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
Yes. However, it seem obvious that no one of this research group ever published anything in this issue (according to reference list)

Response 7
We agree that we have limited publications in this type of interventions. However, our research group has considerable experience in pain management and research in the field from different perspectives, i.e. previous publications in the musculoskeletal pain complexity, as well as in research dealing with physical activity and epidemiology.
Comment 8
9. Do the title and abstract accurately convey what has been found?
Partly yes, I was confused with the day one step count.…

Response 8
Unfortunately, this was a mistake by us. As we explained in response 3, the correct phrase the second time should be day 7. Thank you for your remark. We have corrected it properly now.