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.

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Author's response to reviews: see over
Cover letter

Dear editor

We appreciate your careful concerns for this very relevant issue. Below we provide our responses to your comments and we hope that they will give sufficient information to satisfy your request.

Comment 1
TRN - We notice that you are reporting a clinical trial but have not cited a trial registration number. This must be obtained before we can proceed to your manuscript.

Response 1

You are right regarding the registration number and we are aware of it. However, we would like to explain the following situation. This study was presented as a RCT for the Ethical Review Board at the Sahlgrenska Academy, University of Gothenburg. The Review Board considered that the intervention in our study, i.e., the treatment advices that were provided to our patients, was a part of a routine care without any inclusion of new or invasive therapies. In addition, the intervention did not represent any risk for the patients or a worsening of their conditions. The intervention included two regular treatment advices in general praxis for back pain, which are the recommended treatments according to European guidelines of management of acute back pain (van Tulder et al 2004; ref no 4 in the manuscript).

Therefore, no clinical trial registration was required by the Ethical Review Board. That is the reason why in our manuscript we did not write this number. Still, we here provide the registration number of the approval by the Review Board: Reference No. 366-08.

After a group discussion, we decided to denominate the research design to a prospective randomized study to evaluate the effect on physical activity and the course of acute low back pain of two different treatment advices provided in routine care. This suggestion removes the epithet RCT from our study, which would be more correct based on the following considerations:

1. The patients were randomized to one of two treatment advices already existing as part of general praxis, i.e. no new interventions or invasive therapies were implemented and evaluated.
2. As the treatments were part of general praxis, there was less rigorous control of extraneous factors than is the case in clinical trials.
3. The main outcome of this study was the physical activity behavior and not a health outcome per se. Although, the target of our research is to identify treatment regimens that improves the course of back pain and prevents its recurrence. However, the back pain progression is evaluated from treatment advices in clinical praxis.

Therefore, we propose revisions of change the term “randomized controlled study”, in the title, in the aim in the abstract, in the aim presented at the end of the introduction section and the description of the study design at the beginning of the method section and instead to include the term a “prospective randomized study”.

Comment 2

Please confirm in the manuscript Methods that the study was conducted in Sweden.

Response 2

This information has been provided in the Method section under the headline Design. Here we added:"… was conducted at the Department of Orthopaedics, Sahlgrenska University Hospital, Gothenburg, Sweden…”

Yours sincerely,

The authors