Author's response to reviews

**Title:** Cognitive, fear-reducing information or individual symptom-based physical training in chronic LBP. A pragmatic, randomized, controlled trial with 1-year follow-up.

**Authors:**

Pia H Sorensen (piahayn@hotmail.dk)
Tom Bendix (tbendix@health.sdu.dk)
Claus Manniche (claus.manniche@slb.regionsyddanmark.dk)
Lars Korsholm (korsholmlars@gmail.com)
Dorte Lemvigh (dorte.lemvigh@slb.regionsyddanmark.dk)
Aage Indahl (aage.indahl@rehabilitering.net)

**Version:** 5  **Date:** 28 June 2010

**Author's response to reviews:** see over
RE:
MS: 8176680173244681
Cognitive, fear-reducing information or individual symptom-based physical training in chronic LBP. A pragmatic, randomized, controlled trial with 1-year follow-up.
Pia H Sorensen, Tom Bendix, Claus Manniche, Lars Korsholm, Dorte Lemvigh and Aage Indahl

Dear BMC.

Thanks for the recent note indicating that we are close to having it ready for publication. And thanks to the two reviewers George and Vlaeyen, still bringing improvements into our articles!

We have improved several sequences and made the descriptions more clear. We specifically agree with reviewer George that the Background’s paragraph 4 and 5 was “blended” !? Because also our language editor (an Australian, former language editor on medical Journals) has been through this 3rd edition (but not the 2nd one) again, we are confident that the language is now acceptable. She has, however not been through this covering letter.

All changes since last edition are marked with green colour. Regarding the language editing we have not marked the changes that are evident improvements. The language is now British English. All ‘z’ (minimize, etc) have been substituted with ‘s’. These changes are not marked with green colour. Similarly: physical therapist → physiotherapist; program → programme. Also cognitive treatment (COG )has generally been substituted with Educational approach = EDUC. Center is still spelled in American, because our -Back Research Center’ has been named so.

Other replies on the reviewer comments:

George’s comments AND OUR Replies

Minor Essential Revisions
1. The Introduction could more clearly delineate between the “injury” and “non-injury” models – the explanations are blended in paragraphs 4 and 5 of the Introduction.

PLEASE SEE ABOVE

2. The link of the injury model to terms like “fear-avoidance and kinesiophobia to maligners” is confusing to this reviewer. Please clarify and provide appropriate references, or make it very clear this is your opinion.

THE WORDS YOU MENTIONED HAVE BEEN REMOVED

3. Remove the genetics and disc degeneration information – these factors are interesting but continue to have a limited role in the current study. This is distracting information for the primary purpose of the trial.

‘GENETICS’ HAS BEEN REMOVED, AND ‘DISC DEGENERATION’ NOW HAS A MINIMAL – BUT NECESSARY, WE BELIEVE – PLACE ONLY.

4. Typically power analyses are done with the same outcome reported in the study. The authors should indicate why the study was initially powered on return
to work rates, but ended up reporting pain and activity limitations as the primary outcomes. This is important information for a study with many null comparisons.

ITS TRUE THAT THAT CHANGING FOCUS REGARDING PRIMARY / SECONDARY OUTCOMES IS NOT “BY THE BOOK.” HOWEVER, WE HAVE NOW MENTIONED WHAT WE DID - AND WHY.

5. Use of MRI and discussion of findings for all patients seems contrary to the intent of a “non-injury” model, and this application could have potentially decreased its effects. The authors should consider alerting readers to this potential issue in the Discussion.

MRI AND ‘NON-INJURY MODEL’. IT WOULD BE EASY TO MENTION WHAT YOU SUGGEST. HOWEVER, THE ARTICLE IS VERY LONG NOW, AND I THINK THAT WHAT IS MENTIONED IN ‘METHOD’ ….

[To avoid a possible variation across the participants in level of confidence caused by some having had an MRI and others not, all had a standard lumbar MRI]

…. IS SUFFICIENT. NONE OTHER REFEREE HAS COMMENTED THIS. WE THINK IT SHOULD BE EVIDENT THAT INJURY-MODEL ASPECTS COMES IN WHEN IT IS DECIDED THAT THERE ARE NO RED FLAGS, WHICH MRI SUBSTANTIALLY CAN HELP STATING.

6. Is this really the first study on this topic? It seems that the Linton et al, 2005 study had a similar design, CB, CB+PT, and a usual care group.

THE STUDIES BY LINTON, YOU MENTIONED ARE VERY DIFFERENT FROM OURS: IN ONE OF THEM (CLIN J PAIN 2005: 21(2): 109-19) COGNITIVE TREATMENT WAS ACTUALLY COMPARED WITH NOTHING (BECAUSE BOTH GROUPS HAD MINIMAL INTERVENTION), AND ALSO IT WAS TESTED IF ADDING PHYSICAL TRAINING TO COGNITIVE INTERVENTION MADE A DIFFERENCE. IT ALSO SEEMS AS IF THE COGNITIVE INTERVENTION DIFFERED FROM OURS.

THE OTHER STUDY HAVING 5-YEARS FOLLOW-UP REPORTED IN 2005, HAD COMPARED COGNITIVE WITH INFORMATION. THUS, NONE OF THEM COMPARED COGNITIVE WITH A (REASONABLY) UP-TO-DATE PHYSICAL TREATMENT.

7. The first paragraph of the Discussion contains results from post-hoc and exploratory analyses – these really should be presented in the Results section. SOME SAYS THAT ‘POST HOC’ ANALYSES SRE NOT RESULTS BECAUSE IT IS NOT PART OF THE PLANNED STUDY. SOME SAYS LIKE YOU. WE HAVE MOVED THE SECTION TO ‘RESULT’, WHICH IS FINE TO US.

8. At the risk of being self-serving, our group has reported RCT’s involving the combination of physical treatment with fear-reduction cognitive interventions (George et al, Spine 2003 and George et al, Pain 2008) and these references may be added to the Discussion of other studies on page 14.

WE HAVE READ THESE ARTICLES WITH GREAT INTEREST. HOWEVER, THE SPINE ARTICLE COMPARES FEAR-AVOIDANCE PHYSIOTHERAPY WITH STANDARD PT IN SETTING WITH LBP OF < 8 WEEK DURATION. ALSO THE OTHER ARTICLE DEALS WITH DIFFERENT KINDS OF PHYSICAL TRAINING ADDED VARIOUS ASPECTS OF PSYCHOLOGICAL ATTITUDES, AND NOT COGNITIVE ASPECTS ALONE VRS. TRAINING ALONE. THEY COULD RELEVANTLY BE DISCUSSED IN OUR ARTICLE, BUT WE THINK THAT THE EXTENSION OF THE MANUSCRIPT CALLS FOR CUTTING DOWN FURTHER – ALTHOUGH RELEVANT - DISCUSSIONS.

9. The authors were resistant to adding limitations, but I still think consideration
of a few limitations is warranted – not all readers of this manuscript will be researchers who are knowledgeable of the limitations.

LIMITATION. HAVE THOUGHT MUCH ABOUT YOUR SUGGESTION AGAIN. WE STILL THINK THAT LIMITATIONS SHOULD APPEAR FROM THE ARTICLE, AS EXPLAINED LAST TIME. IT IS TRUE THAT SOME READERS OVER INTERPRETE SCIENTIFIC MESSAGES, BUT WE THINK THAT EVERY ARTICLE – USUALLY DEMANDED TO BE SHORT – CAN NOT EXPLAIN SUCH BASIC COMPONENTS. WE STILL THINK THAT “… RECONSIDERED ..” DOES NOT MEAN THAT PHYSICAL TRAINING IS ‘OUT’, - JUST THAT IT SHOULD NOT AUTOMATICALLY CONTINUE AS A FIRST CHOICE CORE TREATMENT – WHICH IT PRETTY MUCH IS TODAY IN CHRONIC LBP.

Needs some language corrections before being published

HAS BEEN PERFORMED

Vlaeyens comments:

Reviewer’s report:
The authors have seriously tried to integrate the comments and suggestions made by the reviewers. In case they did not agree with some of these, and did not follow up on them, the authors provided necessary arguments. Generally, I think that the paper has improved significantly, and most of the issues that needed clarification are resolved now. It is a pity that because of word limits some of the suggested issues for discussion are not included, and I hope that the authors still are willing to consider adding at least a number of them. For example, the question in what way their approach differs from the exposure in vivo approach deserves some text, given the attention for these in the recent literature. An issue which was also raised by another reviewer as well (as a discretionary revision).

PLEASE SEE GREEN PARAGRAPH P.14 (“However, it is possible ….”)

ALSO, WE HAVE TAKEN THE STEP TO NAME THE INTERVENTION ‘EDUCATIONAL APPROACH – ABBREVIATED ‘EDUC.’ WE HAVE STILL USED THE WORD ‘COGNITIVE’ SOME TIMES BECAUSE WE STILL THINK THAT ‘ACTING BY UNDERSTANDING, OBTAINED BY EDUCATION’ IS INCLUDED IN THE MEANING OF THE WORD ‘COGNITIVE.’

Nevertheless, I still think that the English writing style can be improved, and suggest that the authors contact a native English scientific translator (as a minor essential revision).

HAS BEEN DONE

---------------------

Thus, we now think we have accommodated the referee’s queries. On behalf of the authors –

Best regards

on behalf of the authors

Tom Bendix