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.

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Version: 4 Date: 12 April 2010

Author's response to reviews: see over
Dear BMC and referees.

We have now thoroughly been working with all your comments. We are extremely pleased to have had such careful assessments and having got so many suggestions on improvements, which have really lifted the article. Thanks a lot!

We know that there is no limitation in BMC, but still we had been striving to not making the article too long: It is well known that: the longer the article is, the fewer readers. We still go for such principle, but have realized that some extension was needed to accommodate most of the referees comments. Especially for the clarification of our non-injury, cognitive model, a certain expansion has taken place, because several referee comments told us that this issue was not explained satisfactorily. And we agree.

However, with so many comments it would be impossible to follow all of them because this would make the article extremely long.

All suggestions/queries have been commented upon with RED CAPITAL LETTERS after each comment.

Changes have been written with blue letters, except evident smaller language improvements.

‘Disability’ has been replaced by ‘activity limitations’ according to CONSORT.

Also, the sequence of the outcome and discussion elements have been changed to be identical over the various chapters. Now, the sequence of outcomes and additional measures to illustrate treatment aspects have got the same courses during Method, Results and Tables, and also grouped more logically. This is an evident improvement, and especially thanks to rev #1 for this input! Also the sequence of COG – TRAIN has been the same during the entire article, but not indicated with blue color.

This is also the explanation that numbering of Table 4 and 5 have been exchanged.

We agree that it was not clear which role e.g. number of treatments within the project had. Has been clarified.

We are embarrassed realizing that we have used data that were not quite sufficiently checked, although we had done so several times. We have thoroughly been through the data and calculations again, and found some minor changes, although not altering any conclusions. We have chosen to report all p-values <.001 as such.

We will be happy to let our professional language editor go through it, but will prefer doing so when we are sure that the (almost) final edition is reached.

Kind regards

- on behalf of the authors

Tom Bendix
Reviewer #1's report

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

Version: 1 Date: 20 December 2009
Reviewer: Paul Hendrick

Reviewer's report:
Major Compulsory Revisions

Abstract
1. The abstract states that there was a trend for the primary outcome being reduced (in the cognitive group) and that fear avoidance “was better” in the cognitive-treatment group at two time points. It is not clear if these findings are significant or not – p values and significance values should to be stated – also for whether there is a difference (significant) in treatment sessions. It is also not clear what “all other variables were equally influenced by the two treatments” means.

THERE ARE RELEVANT P-VALUES IN ‘RESULTS’/TABLES. USUALLY P-VALUES ARE NOT PRESENTED IN AN ABSTRACT, AND IN THIS CASE IT WOULD NEED A LONGER EXPLANATION THAN WHAT IS THE MEANING WITH AN ABSTRACT. WE FIND IT FAIR TO USE THE PHRASE: “...A TREND TOWARDS DISABILITY BEING REDUCED MOSTLY IN THE COGNITIVE-TREATMENT GROUP...” WHEN DIFFERENCES IN THE SAME DIRECTION AT ALL THE THREE FOLLOW-UPS REACH P-VALUES OF RESPECTIVELY .09 / .12 / .09, AND WHEN A HIGHLY SIGNIF. REDUCTION WAS SEEN IN THE FEAR-REDUCING GROUP (P< .001) CONTRASTING A N.S. REDUCTION (P= .17) IN THE TRAINING GROUP.

HOWEVER, HAVING STUDIED MCID FURTHER, WE HAVE ADDED “...ALTHOUGH OF DOUBTFUL CLINICAL RELEVANCE.”

2. Background. Many people still believe that mechanical stress on the intervertebral disc (IVD) is the dominant cause of degenerative changes [24], and that LBP is a sign of vulnerability of a weak back in need of protection. Please clarify who the “many people” are and update the reference – (the reference is from 1976) and provide a more detailed description of where this thinking has come from and sits currently

WHEN DISCUSSING THIS ISSUE WITH COLLEAGUES THAT ARE NOT SPECIALIST IN LBP VIRTUALLY ALL ARE SURPRISED THAT LOADS PLAYS A MINIMAL ROLE AND THAT GENETICS BY FAR IS THE DOMINATING CAUSE. THIS IS ALSO CLAIMED BY E.G. VIDEMAN ET AL SPINE, 2007; 32:1406–13. TALKING TO PATIENTS VIRTUALLY ALL BELIEVE THAT DISC DEGENERATION IS LOAD RELATED. AGREE THAT THE POSITIONING OF THE REFERENCE WAS MISLEADING. THE ENTIRE PARAGRAPH HAS BEEN CHANGED, BECAUSE WE FELT THAT THE MESSAGE THAT THE INJURY MODEL DOES'NT WORK WAS NOT SUFFICIENTLY CLEAR.

3. The authors quite rightly point out that genetics play a role in degeneration of the disc however they should also discuss and acknowledge the role that cumulative loading plays in disc degeneration (DD). The following are an example of the body of literature which discusses and investigates the role of loading in DD
WE SPECIFICALLY ALLUDE TO VIDEMAN AND BATTIE’S STUDIES, BECAUSE THEY HAVE DEMONSTRATED THAT MOST OF THE CORRELATION BETWEEN PHYSICAL LOAD AND DD IS INTERACTION WITH GENES. THEY STATE THAT ONLY 1-2% OF DD CAN BE EXPLAINED BY PHYS. LOADS. ACTUALLY, TWO OF THEIR TWIN STUDIES EVEN SHOW A PROTECTIVE EFFECT OF CUMULATED PHYSICAL LOADS REFLECTING A SLOW ADAPTATION TO HIGHER PHYSICAL LOADS


TEXT HAS BEEN CHANGED ACCORDINGLY.


THIS ARTICLE SPECIFICLY STATE THAT LOAD DID NOT HAVE ANY INFLUENCE. ALSO A LATER STUDY BY SPECTER GROUP DEMONSTRATED NO CORRELATION WITH PHYSICAL LOADS.


Seidler, A., A. Bergmann, et al. (2009). "Cumulative occupational lumbar load and lumbar disc disease-results of a German multi-center case-control study (EPILIFT)." BMC Musculoskeletal Disorders 10(1).


4. Study Population. Please provide details of whether patients were receiving or had received treatment prior to entry to the study. CLBP patients were recruited from the clinic at a multidisciplinary non-surgical Back Center. The patients were referred to the clinic from general practitioners and chiropractors from across the Funen county in Denmark.

MOST PATIENTS HAD HAD TREATMENT PRIOR TO REFERRAL TO THE BACK CENTER. WE HAVE NO ACCURATE RECORDING ON THIS MATTER. TEXT HAS BEEN CHANGED.

5. Please justify and reference the reason for the inclusion criteria. LBP for at least 4 out of the previous 12 months and a mean LBP score over the last 14 days of >4 (scale 0-10).
THIS WAS A CHOICE TAKEN BY US. IN OUR MIND: AS LONG AS WE DESCRIBE A REASONABLE GROUP OF CHRONIC PATIENTS WE DO NOT THINK THAT REFERENCES ARE NEEDED. A SLIGHT CHANGE TEXT HAS BEEN MADE.

6. Procedure. Please fully explain exactly how the randomization process outlined below was carried out. The patients who were considered eligible for inclusion were then asked to provide written informed consent and subsequently to visit a secretary who managed the randomization, using unmarked sealed envelopes, containing a note on which was randomly written either:

WE HAVE NOW INCLUDED A NOTE THAT THE BLINDED INVESTIGATOR WAS NOT PRESENT AT THIS TIME. OTHERWISE WE THINK THAT OUR DESCRIPTION IS CLEAR AND SUFFICIENT.

7. Interventions - During the first visit, both groups received an additional specific physical examination, particularly in the physical training group, explanations of the MRI scan, of the objective findings from the baseline examination, and if possible, a clarification of the pathology causing the patient’s symptoms. Please explain and justify (with refs, if necessary why an additional physical, examination was performed and what did it consist of? – Also the sentence is not clear and needs to be re-worded – the clarification of the pathology causing symptoms opens up a real Pandora’s box – as much of the literature suggests the relationship between MRI findings and symptomology is variable

WE HAVE NOW CLARIFIED THE OBJECTIVE EXAM AT THE FIRST VISIT. WE Agree WITH THE PANDORA BOX; THAT IS WHY WE SAID: “...IF POSSIBLE…” WE COULD WRITE WHOLE PAGES ABOUT THIS, BUT ALSO LIKE TO ACKNOWLEDGE THE WISH FOR NOT MAKING ARTICLES LONGER THAN NECESSARY. A SHORT CLARIFICATION HAS BEEN GIVEN.

8. Cognitive intervention – see comment above – please clarify this statement and in particular what the positive aspects means - Information on pathoanatomy and physiology included a view of the results of their own lumbar MRI scan, emphasizing the positive aspects rather than focusing too much on possible abnormalities, unless they had particular significance.

THIS HAS GOT A FURTHER CLARIFYING SENTENCE.

9. The Vicious cycle (Figure 1) – has this been adapted from a previous model and/or how did you arrive at this model – please provide refs (if necessary) also please clarify what role confidence plays in this process – what does the confidence relate to?

WE HAVE MADE THE CYCLE OURSELVES, BUT ALSO DROPPED THE FIGURE IN THE NEW VERSION. ALSO ANOTHER REFEREE FELT THAT IT WAS TOO DETAILED.

10. Symptom-based physical training. Please provide details of the exact amount of treatment administered – in terms of sessions/week and designated start and end-point (did participants have X no of treatments or stop when symptoms had resolved?). Was a home program of exercise and or advice included and how was this monitored.

WE FEEL THAT THE AMOUNT OF SUPERVISED TREATMENTS WERE SUFFICIENTLY DESCRIBED, AND GIVING THE VARIATION IN NUMBER OF TREATMENT ALSO GIVES THE ANSWER TO YOUR OTHER QUERIES. A NOTE ON HOME PROGRAM HAS BEEN ADDED.
11. Also, please provide refs for each of the treatment approaches – esp. the neuromuscular stability program and the individual program and intensive dynamic exercise program (if these are taken from protocols of previous studies) Also, were validated measures of neuromuscular control (for example) employed?

WE HAVE A SUBSTANTIAL AMOUNT OF REFEREES IN INTRODUCTION AND AN FURTHER UPDATE IN THE DISCUSSION. THERE WERE NO FIRM TEST PROCEDURES AFTER THE TRAINING SESSIONS. Pia

12. Please justify the numbers for the current study – was a power calculation performed and/or how did the authors decide upon the numbers chosen?

A NOTE ON POWER CALCULATION HAS BEEN ADDED

13. Assessment and outcomes measures. Please provide further details and clarification of the outcome measures employed

a. what measure of physical activity was employed and has this been previously utilized in a LBP population

HAS BEEN CLARIFIED. WE DON'T THINK THAT EXACTLY THIS VERSION HAS BEEN USED OF OTHERS.

b. The measures of Disability and Pain – only one ref (1994) is provided – have these measures been more recently employed in CLBP populations – has MID or MCID been looked at with these measures in chronic population?

THE REF FROM 1994 IS USED BECAUSE THIS ONE DESCRIBES THE VALIDATION. THIS RATING SCALE HAS BEEN USED IN MORE THAN 50 RCT-STUDIES AFTER THAT TIME. WE HAVE ADDED THE SENTENCE IN THE MANUSCRIPT: ‘...THESE TWO OUTCOME MEASURES HAS A WIDESPREAD USE OVER THE PAST TWO DECADES, ESPECIALLY IN RCTs FROM DENMARK.’

BECAUSE WE FOUND RMQ LESS ACCURATE - HAVING TWO RESPONSE OPTIONS ONLY - THAN THE ABOVE DISABILITY Q., WE PREFERRED THIS RATING-SCALE OVER ROWLAND MORRIS, WHICH WE ONLY MADE FOR ENABLE A COMPARISON TO OTHER STUDIES. HOWEVER, WE GRADUALLY REALIZE THAT IN FUTURE STUDIES RMQ IS PREFERABLE DUE TO THE GENERAL STANDARD.

c. It is not clear from the descriptions which are the primary and secondary outcomes – what was the rationale to have these specific outcome measures?

d. Please explain why treatment times differed (were this not standardized, so that each group received relatively the same amount of treatment – please explain)

WE FIND IT VERY CLEAR WHICH ARE THE PRIMARY AND SECONDARY OUTCOMES. HOWEVER, WE HAVE BEEN MORE CONCISE ON WHAT IS PRIMRY, SECONDARY AND ‘OUTCOMES TO ASSESS OTHER TREATMENT ASPECTS

WE ALSO THINK THAT IT IS VERY CLEAR TO RESEARCHERS THAT PAIN AND DAILY ACTIVITY RESTRICTIONS ARE HIGHLY RELEVANT MEASURES FOR ASSESSING THE PATIENT’S STATUS AFTER A TREATMENT. LIKewise, FROM THE INTRODUCTION WE FIND IT FAIRLY INDICATED WHY THE SECONDARY MEASURES WERE TAKEN. ALSO TESTING AND REPORTING THE OTHER VARIABLES (WORK ABILITY, PHYSICAL ACTIVITY AT LEASURE: QUALITY OF LIFE, USE OF MEDICAL SERVICES, NUMBER OF SESSIONS DURING THE STUDY TREATMENTS, AND TREATMENT PREFERENCE) ARE VERY EVIDENT
IN STUDIES LIKE THIS. ALSO CONSIDERING OUR INTEREST OF AVOIDING TOO LONG ARTICLES, WE DON'T FEEL FURTHER DESCRIPTION TO BE PRIORITIZED.

14. Statistical analysis It states that The primary endpoints were reduction in pain and disability – how were these points determined? – What was deemed a significant change in the outcome measures (MCID) WE HAVE STUDIED THIS FURTHER AND HAVE ADDED A COMMENT. THANKS!

15. Please explain how the treatment effect with 95% confidence interval (CI) was estimated at each of the three follow-up stages for the primary and secondary outcomes WE AGREE THAT IT IS INAPPROPRIATE TO MENTION 95% CI, IF WE DON'T USE THEM. IT HAS BEEN DELETED. WE FIND IT ADEQUATE TO PRESENT DATA AS WE HAVE DONE NOW.

16. Results. The authors state that the Participants in both groups (n=105 and 102) were comparable at baseline, as shown in Table 1 and 2. However, no p-values or statistical tests appear to be to shown. P-VALUES SHOULD NOT BE USED FOR BASELINE VALUES. P-VALUES ELUCIDATE WHETHER A DIFFERENCE BETWEEN MEANS OR MEDIANs IS RANDOM OR NOT. FINDING TWO RANDOMIZED GROUPS DIFFERENCES ARE RANDOM. FROM THERE, POSSIBLE DIFFERENCES SHOULD BE ASSESSED IN TERMS OF LOGIC, AND – IF NOTICEABLE – CONSIDERED HOW THEY SHOULD BE HANDLED. IN THIS CASE THERE WERE NO SUCH DIFFERENCES.

17. Please explain if an intention to treat analysis was carried out for those lost to follow-up WE HAVE NOW PERFORMED AN SENSITIVITY / INTENTION-TO-TREAT ANALYSIS, ALTHOUGH IT IS HIGHLY DEBATABLE HOW REASONABLE IT IS WITH THE FRAME OF THIS STUDY AND THE RESPONSES WE HAD.

18. The authors should be clear if there is a statistically significant and/or clinically meaningful change in the outcome measures – particularly the primary outcome measures (including p values) A COMMENT ON MCID HAS BEEN ADDED EARLY IN THE DISCUSSION

19. Non-responders Comparisons of the baseline characteristics of non-responders and responders are shown in Table 4 for the most relevant variables. Of the other baseline characteristics, no obvious differences were seen except for a small trend towards non-responders being generally younger, men and smokers. – Where is this information in the text or tables? A MORE CLEAR PRESENTATION ON THIS MATTER HAS BEEN GIVEN (TABLE 4 AND 5: NUMBERS HAVE NOW BEEN REVERSED)

20. Patient Preference. The groups were too small for meaningful statistical analyses (Table 5), but at least fulfilling treatment preferences did not lead to better outcome. Please clarify what statistical tests were run to make this statement WE DON'T UNDERSTAND THIS QUESTION. WE DID NOT FIND IT REASONABLE TO PERFORM ANY FORMAL STATISTICAL TESTING – AND HAVE MENTIONED THAT.
21. Discussion. We have demonstrated that, among patients with chronic LBP, a
cognitive intervention with few consultations is at least as effective as an
individualized, multidisciplinary physical training approach. Please clarify this
statement in relation to the current findings. There is still some concern that the
main measure discussed is the number of treatments
WE HAVE CHANGED THE PRESENTATION, CLARIFYING THE MEANING WITH
INCORPORATING NUMBERS OF TREATMENTS.

22. The discussion should really discuss further the findings from this study
–Why for example did the TRAIN group improve their Pain but not disability and
therefore why did we see this difference between the 2 groups in the change in
disability BUT not in Pain – when you look at the numbers on the disability scale
(presented) the median value for the TRAIN group goes form 14 to 13 however
the COG group changes from 14 to 11 – this makes it all the more important to
talk about whether this change represents a meaningful clinical change rather
than just a statistically meaningful change. Further discussion of the treatments
and their effects on the outcome measures is warranted
A COMMENT ON MCID HAS BEEN ADDED EARLY IN THE DISCUSSION

23. It can be argued that physical training should be supervised for a longer time
period than was used in this study, and with higher loads. – Please explain and
justify the numbers/sessions and training loads employed in the current study (in
relation to current literature)
WE HAVE – AND HAD ALREADY IN THE FIRST EDITION - A CHAPTER IN THE DISCUSSION
(“IT CAN BE ARGUED THAT PHYSICAL TRAINING SHOULD BE SUPERVISED FOR A
LONGER TIME PERIOD.....”) ADDRESSING THIS ISSUE.

24. Also, their threshold of 2 as a minimally clinically important difference for the
Rowland-Morris Disability Scale should conservatively have been 5.[64] The
following is a reasonably contentious statement – there is much debate on the
MCID of the RMDQ for particular LBP populations
A THOROUGH STUDY IN THIS FIELD IS THE ONE BY LAURIDSEN ET AL.
RESPONSIVENESS AND MINIMAL CLINICALLY IMPORTANT DIFFERENCE FOR PAIN
AND DISABILITY INSTRUMENTS IN LOW BACK PAIN PATIENTS. BMC MUSCULOSKELETAL
DISORDERS 2006, 7:82. IT SAYS 5 FOR WITH-IN GROUP CHANGES. THEN SOME
FURTHER CALCULATIONS ARE NEEDED, BUT ANYWAY: THE THRESHOLD OF ‘2’
CERTAINLY SEEMS TO BE TOO OPTIMISTIC.

25. The authors should provide a more detailed and reasoned debate on the
limitations of the current research and also the clinical implications
WE FIND THAT THE LIMITATIONS APPEAR FROM THE ARTICLE AND ESPECIALLY THE
DISCUSSION, AND DUE TO LIMITATIONS OF EXTENSION OF SUCH AN ARTICLE, WE HAVE
CHosen NOT TO DESCRIBE THIS ANY FURTHER.

Minor Essential Revisions
1. Background – Please re-word and clarify the following sentence. One reason
is that cognitive interventions have generally demonstrated similar effectiveness
for self-reported disability[1-5] and sick leave[5-12] as have traditional
treatments.
HAS BEEN DONE
2. Background – please provide a reference for this statement. However, subgroup analyses, suggest greater effectiveness for such treatments in people with particular clinical profiles.

WE THINK THAT THE REST OF THE BACKGROUND SECTION PROVIDES LOT OF INFORMATION FOR THAT STATEMENT. A “(WILL BE DISCUSSED)” HAS BEEN ADDED.

3. Background-The specific aims of this study were to compare the effects of prescribing either a cognitive treatment designed to improve confidence in the robustness of the spine, with a symptom-based physical training treatment in cLBP patients on the primary outcomes of back pain and disability, and secondary outcomes of work ability, sick leave, LBP attitudes, fear-avoidance beliefs, physical activity levels and number of external health-care contacts. This sentence is quite long and cumbersome to read and might be best as two separate sentences or shortened

AGREE! IT IS STILL LONG BUT DIVIDED INTO SECTIONS.

4. Procedure – Furthermore, they were informed that the current waiting period for assessment and treatment at the clinic was more than 3 months, whereas participation in the study would result in an MRI scan, with earlier diagnosis and treatment. this factor in terms of potential selection and recruitment bias should be acknowledged or discussed

A SMALL CHAPTER ADDRESSING THIS HAS BEEN ADDED IN THE DISCUSSION.

5. Procedure – Please clarify what is meant by the following sentence and the rationale. A diagnosis was not given to the patient at this point, and the objective findings were explained to them in a neutral way

TO US THE SENTENCE IS SUFFICIENTLY CLEAR, AND – IN THE INTEREST OF SPACING – DOES NOT HAVE TO BE EXPLAINED FURTHER.

6. MRI. Please explain the following statement – has this been reported on before? As individualized MRI scan sequences might have caused undue confidence or fear in the participants, all but three patients had a standard lumbar MR

THIS AND THE NEXT QUERY HAS BEEN REPHRASED AND MORE CLEAR.

7. Please explain - One patient had a sacroiliac MRI, only.

HAS BEEN DONE.

8. Cognitive intervention. Please can you provide a reference for the following statement. A conception that pain episodes from high-load movements are temporary and do not cause permanent damage, may leave the spine capable of natural movements and accordingly less pain.

THE ENTIRE DESCRIPTION OF THIS ISSUE HAS BEEN CHANGED SUBSTANTIALLY.

9. Symptom-based physical training. This program was conducted in a group setting but was concluded with an assessment of each individual’s final muscle control. Please clarify what is meant by this statement and what validated measures were employed to measure such muscle control.
ONLY A SUPERFICIAL TEST TO GIVE ORAL FEED BACK TO THE PATIENT. NOTHING FORMAL. IT WAS A PRAGMATIC STUDY.

10. In addition, participants in the TRAIN group were treated in a "best practice" manner that augmented their physical training with other therapies. This meant that several health professionals could be involved as deemed relevant: conferences (multi-disciplinary approaches to pain management) on continued treatment plans, a nurse (medication or pain management), a chiropractor (manipulative therapy), or a doctor (steroid injection). Please clarify who made the decision on which of these health professionals the patients saw and how it was made.

WE HAVE MENTIONED THAT THE DECISION OF ENROLLING OTHER HEALTH-GROUP MEMBERS WAS TAKEN BY THE P.T. WE FIND IT MUCH TOO DETAILED TO DESCRIBE THIS FURTHER.

11. They had completed training courses in kinetics control and had several years' experience with cLBP patients. Please refer the following statement in relation to kinetic control (in relation to neuromuscular stability exercise prescription in LBP) –

WE FIND IT MUCH TOO DETAILED TO DESCRIBE THIS.

12. Assessment and outcomes measures – Quality of life is the only outcome measure whereby it states timing of the measure – is it the case that all outcome measures are administered at these 3 time points?

WE SIMPLY DON'T UNDERSTAND THIS QUESTION. YOUR SENTENCE ‘...whereby it states timing of the measure’ IS NOT FROM OUR ARTICLE ?? BECAUSE THEY ARE ASKED HOW TREATMEN MAY HAVE INFLUENCED THEIR QUALITY OF LIFE, THEY WAS NOT ASKED THIS AT BASELINE. ROWLAND MORRIS WAS ONLY ASKED AT BASELINE (ES EXPLAINED ALREADY), BUT OTHERWISE ALL QUESTIONS WERE ASKED AT ALL 4 TIMES.

13. Statistical analysis Please state the baseline variables included in the model - Treatment groups were compared using an ANCOVA analysis with adjustment for baseline values

WE THINK THAT THIS IS SUFFICIENTLY STATED

14. Results. A consistent trend (p=.09 - .12) favouring COG was seen. – Please explain this statement and refer to the Table

HAS BEEN CLEARIFIED

15. Figure 4 is not very clear – It is not clear what the numbers represent (are these actual amounts of disability and or pain change or % change?) –

THANKS AGAIN: WE DO AGREE THAT THE FIGURE AS WELL AS THE TEXT WAS CONFUSING. BOTH HAVE BEEN IMPROVED (NOW FIG. 3)

16. Please refer the reader to the relevant Table for the secondary outcome measures in the text

DONE

17. Moreover, 22% of the patients in TRAIN compared with 0% in COG were discussed in multi-disciplinary conferences and 36 % of the patients in TRAIN
had between 1 and 6 phone consultations compared to 2% with COG. - Please explain how this process was monitored.

IT WAS NOTED IN A SPECIAL FORM.

18. Type of Physical Training: The authors state that initially, 28% had directional preference exercises, 42% stabilizing exercises, 25% dynamic exercises, and 5% were unknown. – Did these interventions change over time? – HAS BEEN CLARIFIED

19. Number of treatments in the project: COG: The patients had 1–6 sessions (median=3, IQR=2-3, mean=3), each lasting between 30 and 60 minutes. TRAIN: They had more sessions (range=1–20, median=6, IQR=4-10, mean=7), each lasting between 30 and 60 minutes. Moreover, 22% of the patients in TRAIN compared with 0% in COG were discussed in multi-disciplinary conferences and 36% of the patients in TRAIN had between 1 and 6 phone consultations compared to 2% with COG. It is not clear where the following information is contained in either the text or Table 3

THIS IS ONLY IN THE TEXT. THE REFERRAL TO TABLE 3 HAS BEEN MOVED.

20. Non-participants Patients who initially didn’t respond to our written project invitation or refused to participate (n=81) were comparable with those who consented with regard to age, gender, BMI, LBP and disability, but the non-participants had less sick leave during the previous 12 months. Please advise where is the following information is presented in the text?

TO PRESENT A TABLE FOR THIS WOULD BE TOO EXTENSIVE, IT HAS BEEN MENTIONED THAT “…(not presented in table …).”

21. Table 3 – could this info be shortened – do we need all the IQR data for each individual (for example) – perhaps only presenting the totals at each time point (how much is individual data is discussed?)

WE HAVE REMOVED MEDIANS AND IQR … AGREE! WE FIND, HOWEVER, THAT IT IS INTERESTING TO SEE WHICH KIND OF TREATMENTS PEOPLE CHOSE. AND ALSO THAT ALMOST HALF OF cLBP PATIENTS KEEP TRACKING TERAISTS – IRRESPECTIVE TYPE OF INTERVENTION FROM US.

22. Non-responders. Sixteen patients (eight in each group) didn’t respond to all three follow-up questionnaires. – Which table does this info refer to?

TO PRESENT A TABLE FOR THIS WOULD BE TOO EXTENSIVE,

23. Patient Preference Before randomization, 4% stated that they would be much better with COG, and 21% would prefer TRAIN; 73% had no preference while 2% didn’t respond – is this the same as stated that participants were asked if they preferred one Rx over another?

WE HAVE CHANGED IT: NOW ONLY PREFER IS USED.

24. Miscellaneous No side effects were recorded. – Please clarify this statement – within both groups over the treatment period and during follow-up?

HAVE ADDED ‘WITHIN ANY TREATMENT GROUP’. WE HAVE NOT RECORDED POSSIBLE SIDE EFFECTS FROM CONTINUOUS TRAINING’
25. Numbers needed to treat analysis was not performed due to similar effectiveness of both treatments on most variables. Please clarify and refer to this statement.

AN ‘I-T-T ANALYSIS HAS BEEN ADDED’ – PLEASE SEE COMMENTS ON YOUR QUERY ‘MAJOR #17’

26. Discussion. Please elaborate and clarify what you mean with the following paragraph and the relevance to the current results. The more marked effect of COG in the Norwegian studies,[6,8,9] may be explained by a more effective handling of the cognitive components, but also that in the early nineties the alternative treatment had “be-careful” and “pay-attention-to-the-back” as core elements, seemingly increasing inappropriate pain-focussing.

HAS BEEN CHANGED SLIGHTLY, BUT ACTUALLY WE THINK IT IS SUFFICIENTLY CLEAR.

Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

1. It would be useful to include a procedural time-line (as a Figure) to better show the procedures.

WELL, YOU MAY BE RIGHT - WE HAVE, HOWEVER, NOT DONE IT.

2. Figure 2 does not really provide a great deal of info and perhaps a time-line and or numbers of participants could be added to give more relevant info.

NOT FOR A PHYSIOTHERAPIST, BUT WE STILL THINK IT CLARIFIES THE STRATEGY FOR OTHER READERS.

3. Table 2 is a little difficult to follow – it would probably make more sense to focus on the primary outcome measures and perhaps have a 2nd table for the secondary outcome measures.

IF THE EDITORS THINK TABLE 2 IS TOO BIG, THEN IT IS OK FOR US TO DIVIDE IT INTO TWO TABLES.

4. Results - FBBQ, quality of life, work ability/sick leave and reported physical activity levels: showed no significant differences across time or between groups. However PA (within group) for the TRAIN group certainly showed a trend towards sign which might be worth mentioning.

WE DON’T AGREE. PAIN IS USUALLY REDUCED OVER TIME FROM THE DATE THE PATIENTS VISIT A HEALTH-CARE PROVIDER. AT THAT TIME PAIN LEVEL IS USUALLY HIGH (THE REASON FOR HIS/HER VISIT). THIS IS ACTUALLY THE REASON FOR MAKING AN RCT. WHEN THE REDUCTION IS EQUAL ACROSS THE TWO GROUPS, A REDUCTION CAN NOT BE ATTRIBUTED THE TREATMENT

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:
I declare that I have no competing interests
Reviewer #2's report
Title: Cognitive, fear-reducing information or individual symptom-based physical training in chronic LBP. A pragmatic, randomized, controlled trial with 1-year follow-up.
Version: 1 Date: 21 December 2009
Reviewer: James Rainville
Reviewer's report:
Review for BMC Musculoskeletal Disorders: Article PDF # 8176680173244681
Cognitive, fear-reducing information or individual symptom-based physical training in chronic LBP. A pragmatic, randomized, controlled trial with 1-year follow-up.

This manuscript reports the results of a RCT of 2 different treatment approaches for chronic low back pain – 1) Cognitive intervention delivered through patients education, or 3) Individualized symptom-based exercises as directed by a physical therapist. The research design was well planned and executed, with successful recruitment and randomization of 207 subjects. Primary outcome measures were pain and disability, and assessment points were appropriately at 2, 6 and 12 months after treatments. The number of subjects lost to follow-up was small. Several secondary outcome measures focused on cognitive and disability, which were areas directly targeted by the cognitive intervention, and no measures targeted any physical parameters such as strength or range of motion that were the focus of the physical training. Additional secondary outcomes focused on subsequent use of medical services, and therefore were equally relevant to both interventions.

The findings of this studies revealed that cognitive intervention resulted in a reduction of disability and a strong trend towards reduction of fear-avoidance beliefs (the target of this intervention), while no changes in these outcomes were noted in the individualized symptom-based physical therapy group. (Figure 4. Connecting lines on bars for images on left and right should be made similar.) HAS BEEN DONE, AND THE FIGURE (NOW FIG. 3) AND ITS LEGEND HAVE BEEN IMPROVED.

Modest and equivalent reduction of pain was noted in both groups. All other outcomes were unaltered by either treatment. Amounts of additional medical care during follow-up were similar.

To support the validity of the study, the authors compare baseline characteristics of responders and non responders to any follow-up questionnaires, and found negligible differences (Table 4), and the results based on subject’s preference for randomized treatment as without effect (Table 5).

The only weakness of this manuscript is the discussion section, in which the authors has chosen to under-stresses the finding of this study. They state that cognitive intervention is at least as good as symptom-based physical training, where actually it is better as it was the only treatment that resulted in reduced
disability. The limited effectiveness of the exercise treatment as used in this study is under-stressed.

“THE SIGNIFICANCE OF OUR FINDINGS MAY SEEM UNDER-STRESSED.” THIS HAS NOW BEEN FURTHER DISCUSSED IN THE FIRST PARAGRAPH OF DISCUSSION’ WE HAVE NOW CHANGED THE WORDENING FROM ‘DISABILITY’ TO ‘ACTIVITY LIMITATIONS’ IN ACCORDANCE WITH CONSORT.

The discussion reviews prior studies supporting the chosen physical therapy and exercise approach that have reported promising results, and possible reasons for the limited results noted in this study. All of which are well stated. Comparison with other studies using cognitive interventions is also well done.

(I would like to add my thoughts about the findings from the authors, though my thoughts are neither a criticism of the paper nor ideas that deserve to be addressed in this manuscript. It is possible that the limited effectiveness of their paradigm of “state of the art symptom-based exercise” resulted because the paradigm was based on unsubstantiated theories that are derived from the injury model of low back pain. As such, the evaluation process and subsequent exercise recommendations communicate the importance of pain. This is in direct contract to the message of the lack of importance of pain as communicated in the cognitive treatment. Perhaps it is around this point that we should re-conceptualize exercise as an intervention.)

THANKS A LOT! WE HAVE CHANGED OUR DESCRIPTION BOTH IN THE INTRODUCTION AND DISCUSSION, NOW FOCUSSING MUCH MORE ON ‘INJURY-’ AND ‘NON-INJURY MODEL’ ISSUES.

Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests: I declare that I have no competing interests.
Reviewer #3's report
Title: Cognitive, fear-reducing information or individual symptom-based physical training in chronic LBP. A pragmatic, randomized, controlled trial with 1-year follow-up.
Version: 1 Date: 4 January 2010
Reviewer: Julia Glombiewski

Reviewer's report:
This is a well designed study of an importance in its field. The language is acceptable. The manuscript does not have to be seen by a statistician. Strength of the study are:
- Blinding the examiners
- Big sample size
- Performing an ANCOVA and correcting for baseline values
- Long-term follow-ups
I recommend accepting the study for publication after the authors have performed some minor revisions:

Minor essential revisions:
- Effect sizes: You state within the “methods” section that you estimated treatment effect size with 95% CI. Please provide pre-post effect sizes and confidence intervals at least for the primary outcome measures for both treatment conditions (e.g. for 12 months follow-up) to allow comparisons of the effect sizes with those reported in other studies and meta-analyses. You also might consider discussing the comparison of effect sizes in your study and those reported in other studies. I think since the cognitive treatment in your study was very short it would be of interest to see if it was comparable to other cognitive-behavioural treatments that normally consist of more sessions.

IT IS NO GOOD TO MENTION 95% CI IF WE THEN DON’T USE IT FOR PRESENTATION. WE HAVE DELETED THE SENTENCE “... 95% CI ....” THUS, NOW OUR REPORTING OF DATA FITS INTO THE STATISTICAL-METHODS DESCRIPTION. ALSO, EFFECT SIZES HAVE BEEN ADDRESSED IN THE BEGINNING OF THE INTRODUCTION

- ITT: I also recommend providing ITT (last observation carried forward) pre-post effect sizes for the longest follow-up. You should consider and discuss the possibility that patients who did not respond to follow-up questionnaires, did not improve as much as those who responded.
HAS BEEN PERFORMED

- Non-responders´ baseline statistics (Table 4): please provide statistics (ANOVA or t-tests). There might be some significant differences between non-responders and responders (e.g. concerning FABQ).
STATISTICAL SIGNIFICANCE IS NOT RELEVANT HERE. THE IMPORTANT THING IS TO MAKE A PROFESSIONAL JUDGMENT IF THE DIFFERENCE BETWEEN RESPONDERS AND NON-RESPONDERS COULD BE OF CLINICAL IMPORTANCE. SINCE THE NON-RESPONDER GROUP IS SMALL A NON SIGNIFICANT P-VALUE COULD MISLEAD TO A FALSE CONCLUSION.
Discretionary Revisions:
- Could you give a reason for using medians and IQRs instead of means and SDs?

MOST DISTRIBUTIONS IN THIS FIELDS ARE SCREW. HOWEVER, NOW HAVING CALCULATED MEANS AND SDs (NOW PRESENTED IN TABLE 2) WE SEE THAT THEY DO NOT DIFFER MUCH FOR MOST VARIABLES. STILL IT IS NOT CORRECT WITH PARAMETRIC STATISTICS WHEN SD IS LARGER THAN MEAN – PROVIDED NUMBERS CAN ONLY BE POSITIVE – UNLESS LOGARITHMIC TRANSFORMATION IS MADE. PARAMETRIC STATISTIC IS USED FOR METAANALYSES, BECAUSE RELEVANT METHODS THEN CAN BE USED, AND BECAUSE VERY LARGE NUMBERS FROM SEVERAL STUDIES ARE ANALYZED. WE USE A PARAMETRIC METHOD FOR COMPARING TREATMENT GROUPS (ADJUSTED LINEAR REGRESSION), BUT IN THAT CASE THERE BOTH POSITIVE (WITH IMPROVEMENT) AND NEGATIVE (WITH WORSENING), AND IN THAT CASE NUMBERS ARE USUALLY NORMALLY DISTRIBUTED.

- Additional treatment in the TRAIN group: as far as I understand, additionally to the “treatment beside the project” (Table 3) patients in the TRAIN group (but not in the COG group?) received medication and manipulative therapy. If you controlled for that, it would be interesting to know how many patients started taking new drugs and how the new medication influence treatment outcomes. You might consider discussing the fact that if COG patients did not receive any additional medication or manipulative therapy, the trend in favour of cognitive treatment is even more remarkable!

WE HAVE DECRIBED THESE ISSUES MUCH MORE DETAILLED. USE OF MEDICATION HAS, HOWEVER, ONLY BEEN REPORTED ROUGHLY.

- Patient preference: it is strength of your study to assess patient preference. Nevertheless, since you did not find any effects I recommend deleting the table and reporting the most important results (briefly) within the text. IN OUR MIND IT IS IMPORTANT TO GIVE THE READER AN OPPORTUNITY FOR ASSESSING THE NUMBERS, THOUGH IT IS NOT SIGNIFICANT.

- Fear-avoidance research: The fear-avoidance model and exposure treatments based on this model are widely discussed across the literature. I suggest discussing similarities and differences between COG and fear-avoidance based treatments. I am interested in a discussion of the results of the three recent RCTs on fear-avoidance model based exposure treatments and your results (e.g. concerning the outcome variable “disability”).

WE HAVE CHANGED THE WHOLE DESCRIPTION OF THE VARIOUS MEANINGS OF ‘COGNITIVE TREATMENTS’ AND FEAR AVOIDANCE ETC. WE THINK THAT IT FITS INTO WHAT YOU WANTED.

IN ACCORDANCE WITH ‘CONSULT STATEMENTS’ WE HAVE REPLACED ‘DISABILITY’ WITH ‘ACTIVITY LIMITATIONS.’

Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:
I declare that I have no competing interests.
Reviewer #4's report

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

Version: 1 Date: 5 January 2010

Reviewer: Steven George

Reviewers report:
This paper from Sorensen et al describes a well implemented and rigorous RCT comparing a CBT approach with a symptom based physical training group. Primary outcomes were comparable among the groups and in the secondary outcomes lower fear-avoidance was associated with the CBT group. The papers primary strengths are its experimental design, use of validated measures, clearly stated primary and secondary measures, 1 year follow up point, and consideration of a relevant and important topic. There are, however, some areas in which this manuscript can be improved and I have outlined these below:

Major Revisions

1. The Introduction focuses too much on the role of the IVD and physical loading for this current study. There are no measures of IVD degeneration (or any other patho-anatomy) and physical loading in the current study, so this information could potentially distract readers from the primary aim of the current study. HAS BEEN CHANGED SUBSTANTIALLY, ALSO ADDRESSING THIS COMMENT.

2. The Introduction and Discussion would be enhanced by considering other CBT techniques that have been studied with LBP as the authors have primarily focused on the model proposed by Indahl. There are other cognitive models that have supporting data. Factors from these models that converge and diverge with the Indahl model would be of interest to readers. THIS HAS ALSO BEEN ADDRESSED IN THE NEW VERSION.

3. Along the same lines the authors should highlight the lack of spinal manipulation in their physical training approach. Spinal manipulation is a physical intervention that has been recommended for patients with acute and chronic LBP (Chou et al, 2007). Considerable work has been done in identifying LBP patients appropriate for spinal manipulation and these studies have been associated with larger effect sizes in patients with acute and sub-acute LBP. Although not as much work has been done in chronic populations the lack of consideration of spinal manipulation deserves mention in this paper. There is potential that patients could have received additional benefit from receiving spinal manipulation in the physical training approach. IT IS TRUE THAT IN CHOU ET AL’S REVIEW (ANN INT MED 2007) IT IS STATED THAT MANIPULATION HAS SOME EFFECT IN cLBP, BUT ALSO THAT IT DOES NOT ADD ANYTHING TO PHYSICAL TRAINING. WE ARE AWARE THAT ANOTHER STUDY AND A
4. The symptom based physical training procedure needs to be better described. This section should have more references or the authors should have provided more detail to support the face validity of this particular treatment approach. A major weakness of this paper is that this symptom based physical training approach has not been previously described in the literature and lacks supporting psychometric data. In my opinion there is not a lot of clinical evidence to support identification of these subgroups as described in the manuscript. For example, there is a preliminary clinical prediction rule for identification of subjects that would benefit from lumbar stabilization (Hicks et al, 2005), but this prediction rule was not included in the current study. Furthermore there is no empirically validated way of determining which patients with chronic LBP would benefit from the intensive dynamic exercise program. Centralization is the one exception because there is ample evidence for its use in a sub-group. However, more detail is needed than “...a complete MDT examination to find a possible directional preference – page 9” as even MDT examination is not standardized.

5. The ANCOVA models seem to focus on the main effects of treatment and time, when it is the interaction that is of primary interest for treatment analyses. Please clarify whether any of the p-values reported in the text or table were for the interaction.

6. There is no consideration or plan for missing data in the paper to determine how those not completing follow up affected results. The authors compare
non-responders to responders in Table 4, but typically trials included an intention to treat or sensitivity analysis to determine influence of those lost to follow up.

A SENSITIVITY ANALYSIS HAS BEEN ADDED

7. There is no sample size estimation or power estimate provided for this paper, which is an important issue for a trial reporting null results.

OUR INITIAL POWER CALCULATION HAS BEEN ADDED

8. The Discussion lacks a consideration of the study limitations, some of which have been previously highlighted in this review. I encourage the authors to consider adding those, and other relevant limitations. For example, the 2 group design do not permits the authors making conclusions about the absolute effect of any of these interventions. Therefore, their conclusions about reconsidering the role of physical training may be overstated, because they lack the data from the current study that either of these intervention has an absolute effect.

OUR SUGGESTION OF “…RECONSIDERING…” IS BASED ON THE RESULT THAT THE RATHER SHORT-LASTING COG IS AT LEAST AS GOOD AS THAT OF TRAINING. WE HAVE NOW GIVEN THE LIMITATION THAT USING HICKS ET AL’S ‘PREDICTION RULE’ MIGHT HAVE GIVEN OTHER RESULTS.

IT’S DIFFICULT WITH LIMITATIONS. ALL ARTICLES COULD MENTION: “… UNDER THESE CONDITIONS … WITH THESE PATIENTS … WITH THE PTs WE HAVE USED ETC. … ETC.” WE FIND THAT EVERY RESEARCHER SHOULD KNOW THAT. I (TB) HAS DEFINITELY BEEN BETTER TO RUN THIS TYPE OF COGNITIVE TREATMENT AS COMPARED TO MY BEGINNING WITH THIS PARTICULAR METHOD IN 2004, BUT EVEN THAT WOULD NOT BE ACCEPTABLE MENTIONING.

IT IS TRUE THAT THE ABSOLUTE EFFECTS CAN NOT BE CONCLUDED UPON. WE HAVE, HOWEVER, ALREADY ELUCIDATED FROM THE LITERATURE THAT THIS FORM FOR SYMPTOM-BASED TRAINING DOES GENERALLY HAVE AN EFFECT, ALTHOUGH IT WAS CERTAINLY NOT EVIDENT FROM OUR STUDY – WHERE THE ONLY CHANGE SEEN OVER TIME FOR LBP PROBABLY JUST REFLECTS NATURAL HISTORY OF PEOPLE, SEEKING TREATMENT AT A TIME WHERE – USUALLY - FLUCTUATING LBP IS ON “A TOP OF A WAVE”. WHETHER OR NOT THE ‘TRAIN’ TREATMENT IS EFFECTIVE, WE STILL THINK IT SHOULD BE RECONSIDERED, BECAUSE THE COG-INTERVENTION IS SHORTER, CHEAPER (NOT CALCULATED AND NOT MENTIONED IN THE ARTICLE, BUT OBVIOUSLY IT IS) AND AT LEAST AS EFFECTIVE.

Minor Revisions

1. In the general intervention section (page 7) the authors note that both groups received “additional specific physical examination, particularly in the physical training group, explanations of the MRI scan, …” Please clarify if this procedure was exclusive to the physical training group or not. If it was not exclusive please provide the percentage of subjects in each group that received the additional physical examination.

AGREE: A CLARIFICATION WAS NEEDED AND HAS BEEN PERFORMED. THANKS!

2. Along the same lines the authors note that information on “patho-anatomy and physiology… emphasizing the positive aspects rather than focusing too much on possible abnormalities, unless they had particular significance.” Please clarify if this procedure was standardized for the CBT group and provide the percentage
of subjects that received positive or negative information during this consult. Also please clarify that this information session was NOT part of the physical training intervention.

WE DON'T HAVE RECORDING OF HOW MANY RECEIVED POSITIVE/NEGATIVE INFORMATION. THE POSITIVE FOCUS WAS MORE PRONOUNCED IN THE COG GROUP, WHICH SHOULD NOW APPEAR FROM THE DESCRIPTION OF THE NON-INJURY MODEL USED.

YOUR LAST SENTENCE: IT IS TRUE THAT THE INFORMATION DIFFERED ACROSS THE TWO GROUPS AS WE BELIEVE HAS NOW BEEN CLARIFIED SUBSTANTIALY. THE TRAIN-TREATED PATIENTS HAD THE INFORMATION P.T. PATIENTS USUALLY HAVE, DIFFERING FROM WHAT THE COG GROUP HAD, BUT IT WOULD NOT BE CORRECT SAYING THAT IN 'TRAIN' POSITIVE INFORMATION WAS NOT GIVEN.

3. Typically in RCT's the follow up period is based on the date of randomization, not the duration of the treatment. The variation in the follow up period (ranging from 2-4 months as per page 10) should be noted as a limitation in the manuscript because the analysis is comparing patients at different time points.

WE DO NOT QUITE AGREE. LBP FLUCTUATES LIKE WAVES: AT THE TIME OF INCLUSION THEY WERE COMPARABLE. THEN, THE SPONTANEOUS COURSE WOULD BE EXPECTED TO FOLLOW "IDENTICAL", AVERAGED WAVES. THEREFORE IT WOULD NOT BE FAIR TO COMPARE STATUS E.G. 13 MONTHS AFTER INCLUSION OF ONE GROUP WITH THAT OF 15 MONTHS FOR THE OTHER. A POSSIBLE DIFFERENCE COULD REFLECT DIFFERENT PHASES ON THE WAVES, AND NOT TREATMENT EFFECT.

THE LONGER DURATION FROM TREATMENT TO THE RESPECTIVE FOLLOW-UPS MIGHT – IF ANYTHING – SPEAK FOR A MORE LONG-TERM EFFECT, BUT WE WOULD BE CAREFUL WITH SUCH AN INTERPRETATION.

4. The rationale for using an ANCOVA with baseline values needs to be presented. Typically there is an a priori determined rationale for use of co-variates or their use is based on preliminary statistical analyses. Justification of this analytical approach is warranted because this is an RCT with no obvious baseline differences.

THE INCLUSION OF BASELINE VALUES IS IN ACCORDANCE WITH INTERNATIONAL GUIDELINES FOR STATISTICAL ANALYSIS. SEE, E.G., THE EUROPEAN MEDICINES AGENCY DOCUMENT ON “POINTS TO CONSIDER ON ADJUSTMENT FOR BASELINE COVARIATES” (CPMP/EWP/2863/99) SECTION II.7 “CHANGE FROM BASELINE’ ANALYSES WHEN THE ANALYSIS IS BASED ON A CONTINUOUS OUTCOME THERE IS COMMONLY THE CHOICE OF WHETHER TO USE THE RAW OUTCOME VARIABLE OR THE CHANGE FROM BASELINE AS THE PRIMARY ENDPOINT. WHICHEVER OF THESE ENDPOINTS IS CHOSEN, THE BASELINE VALUE SHOULD BE INCLUDED AS A COVARIATE IN THE PRIMARY ANALYSIS. THE USE OF CHANGE FROM BASELINE WITHOUT ADJUSTING FOR BASELINE DOES NOT GENERALLY CONSTITUTE AN APPROPRIATE COVARIATE ADJUSTMENT.”

THIS DOCUMENT IS AVAILABLE ON WWW.EMA.EUROPA.EU

5. The authors note that “No side effects were recorded – page 14”, but do not explicitly mention adverse events. Please clarify if any adverse events were recorded.

IN THIS CONTEXT WE DO NOT FIND IT NECESSARY TO DISTINGUISH BETWEEN SIDE- AND ADVERS-EFFECT
6. I would discourage the authors from using the term “state of art” to describe the physical training approach described in this study (Conclusion – page 16). As previously stated this approach is not empirically supported and therefore cannot be considered “state of art”.

TOTALLY AGREE! THIS HAS BEEN CHANGED. THANKS!

7. The authors follow CONSORT guidelines for the most part, but I would encourage the authors to look at the CONSORT guidelines for non-pharmacological studies and providing a check list of those completed to facility review of the revised manuscript.

SEVERAL POINTS HAVE BEEN UPDATED ACCORDINGLY. THANKS!

8. Tables – the authors should present mean (sd) in all tables to allow for calculation of effect sizes for future systematic reviews and also these data better match the central tendency that was used in their ANCOVA models. As previously mentioned please clearly indicate whether Table 2 reports any of the interaction effects for these models.

HAS BEEN ADDED.

9. Figure 1 is not necessary for interpretation of this manuscript, and I recommend its removal, especially since the authors do not include measures for confidence, focusing, tension, and awkward movements.

HAS BEEN REMOVED

10. Figure 2 does not include how many subjects were included in the analysis as recommended by CONSORT.

HAS BEEN COMMENTED UPON IN THE TEXT

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests: I declare that I have no competing interests
Reviewer #5's report
Title: Cognitive, fear-reducing information or individual symptom-based physical training in chronic LBP. A pragmatic, randomized, controlled trial with 1-year follow-up.
Version: 1 Date: 7 January 2010
Reviewer: Johan Vlaeyen

Reviewer's report:
This manuscript reports on the results of a randomized study comparing the effects of information aimed to reduce fear of pain and an individual symptom-based physical training in patients with chronic low back pain. The study is one of the few that systematically examines the effects of verbal instruction as a fear reduction approach in the area of chronic pain, and the authors are complimented for undertaking such a study. The strengths of the study are the relatively high number of participants and the up-to-date choice of primary and secondary outcome measures. Despite these strengths, there are a number of issues that need to be addressed.

The word “cognitive” is misleading, and would suggest that the authors use the term fear-reducing information.
WE HAVE GIVEN AN EXTENSIVE DESCRIPTION OF THE WORD ‘COGNITIVE’ AND CLEARIFIED ITS TWO DIFFERENT MEANINGS. PLEASE SEE ‘BACKGROUND.’

I was wondering whether one of the key issues in the fear reducing intervention is the difference between pain and disability (it is not because you are in pain that you cannot perform daily activities), and between harm and hurt (it is not because you feel pain that there is something dangerously wrong I your back). If that is correct, the authors might stress this a little more, as it may influence the participants propositional knowledge about the meaning of pain.
WE THINK THAT THIS HAS NOW BEEN ADDRESSED CAREFULLY

The manuscript might be strengthened if the authors would be willing to conduct a mediation analysis, testing whether the difference between both interventions in disability is mediated by a reduction in pain-related fear. Such an analysis might shed some light on why the intervention worked, and not just on which intervention works best. It would also be in line with recent studies also testing mediation [see: Smeets et al. Reduction of pain catastrophizing mediates the outcome of both physical and cognitive-behavioral treatment in chronic low back pain. J Pain 2006;7(4):261-271., Turner et al. Mediators, moderators, and Pain 2007;127(3):276-286. Leeuw M, et al. Exposure in vivo versus operant graded activity in chronic low back pain patients: Results of a randomized controlled trial. Pain 2008;138(1):192-207.]
HAS BEEN PERFORMED AS A POST-HOC ANALYSIS AND DESCRIBED IN ‘DISCUSSION’. A GOOD IDEA … THANKS!

During the first visit, both groups received a clarification of the pathology causing
the patients’ symptoms (page 7). I was wondering whether this explanation was individualized, or whether all patients received the same standard explanation. In the latter case, what was the explanation?  
HAS BEEN CLARIFIED. PLEASE SEE ‘INTERVENTIONS’

Were both treatments manualized, and if so, is there a source so that readers can consult whenever they wish to. For example, the participants were given a CD with a PowerPoint presentation on general biologic and cognitive aspects of back pain for studying at home(page 8). Is this CD available, and if so please mention the source. For example a footnote can be added with the following text: “The CD is available and can be obtained from the first author.”  
WELL, THE CD IS IN DANISH LANGUAGE, AND IT IS MADE AS AN EXTENSION OF THE FIRST CONSULTATION, - NOT AS A ‘STAND ALONE.’

Please explain what is meant by “centralization”, as not all readers will be familiar with this concept (page 9).  
OK, HAS BEEN DONE

A 15-item questionnaire covering activity limitations over 2 weeks was utilized, but no information about the clinimetrics is provided in the manuscript. Please provide information about reliability and validity, and if possible also a references.  
WA HAVE ACTUALLY GIVEN THE REF WHEN DESCRIBING ‘ACTIVITY LIMITATIONS’, (MANNICHE ET AL …1994) COVERING THIS ISSUE

What is the correlation/overlap with the RMQ and why did the authors not restrict to the more known RMQ?  
BECAUSE WE FOUND RMQ LESS ACCURATE - HAVING TWO RESPONSE OPTIONS ONLY - THAN THE ABOVE DISABILITY Q., WE PREFERRED THIS RATING-SCALE OVER ROWLAND MORRIS, WHICH WE ONLY MADE FOR ENABLE A COMPARISON TO OTHER STUDIES. HOWEVER, WE GRADUALLY REALIZE THAT IN FUTURE STUDIES RMQ IS PREFERABLE DUE TO GENERAL STANDARDIZATION.

The description of the statistical analyses is unclear, and should be elaborated on more.  
WE – INCL. OUR STATISTICIAN (LK) - ARE HAPPY WITH THE DESCRIPTION. SOME CLARIFICATION HAVE, HOWEVER, BEEN DONE, AND FURTHER TESTS HAVE BEEN MADE (SENSITIVITY / ITT)

Did the authors statistically control for gender, duration of pain and MRI findings?  
NO. WE THINK THAT THE CELLS WOULD BE TOO SMALL.

Table 3 in the text seems to correspond with Table 2 in the appendix.  
THANKS! HAS BEEN CORRECTED

In Table 2, does the disability measure correspond to RMQ, or the other disability measure. Why is only one measure reported, whilst there were two measures described?  
BECAUSE ROWLAND-MORRIS IS ONLY USED TO ENABLE A COMPARISON WITH OTHER STUDIES, ONLY BASELINE VALUES (MEDIAN AND IQR) ARE PRESENTED IN TABLE 1. WE DON’T LIKE R-M BECAUSE IT HAS ONLY Y/N AS ANSWER OPTIONS, AND HAD – BEFORE STARTING OUR STUDY – ANOTHER STUDY IN OUR CENTER, SHOWING THAT THE
RATING-SCALE FOR ‘ACTIVITY LIMITATIONS’ WERE MORE SENSITIVE THAN R-M. HOWEVER, WE HAVE REALIZED THE IMPORTANCE OF THE ISSUE OF STANDARDIZATION ACROSS VARIOUS STUDIES, AND WILL USE R-M IN FUTURE STUDIES.

THAT TABLE 2 REPORT ‘ACTIVITY LIMITATIONS’ WITH ‘RATING SCALE’ AND NOR RM, SHOULD BE CLARIFIED NOW. THANKS!

Discussion: how can bio-feedback be used to investigate whether certain movements induce fear? Do the authors mean EMG recordings, and guarded movements (see: e.g. van der Hulst, Marije MD, MSc * +; Vollenbroek-Hutten, Miriam M. PhD * ++; Rietman, Johan S. et al. Back muscle activation patterns in chronic low back pain during walking: a "guarding" hypothesis. Clin J Pain;26(1):30-37.)

THE BIO-FEED-BACK / EMG DISCUSSION HAS BEEN DROPPED – IN PART IN THE INTEREST OF ARTICLE LENGTH/ELEMENTS, AND ALSO BECAUSE IT MAY NOT VERY RELEVANT IN OUR MODEL. HOWEVER, FOR RESEARCH IT COULD BE INTERESTING.

How are the results of their study to be interpreted in the context of similar studies, such as: de Jong et al. Fear of Movement/(Re)injury in Chronic Low Back Pain: Education or Exposure In Vivo as Mediator to Fear Reduction? Clin J Pain 2005;21(1):9-17.


A LARGE-SCALE RCT WITH YOUR’S AND OUR’S MODELS WOULD BE EXTREMELY RELEVANT AND INTERESTING!

There are a number of typos that need to be corrected.

Judgment: Major revision