Reviewer'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.

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

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


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.

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).

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:

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

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.

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?

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.

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?

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?

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
   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?
   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)

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)

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

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 shown.

17. Please explain if an intention to treat analysis was carried out for those lost to follow-up

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)

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?
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.

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.

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 from 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.

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).

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.

25. The authors should provide a more detailed and reasoned debate on the limitations of the current research and also the clinical implications.

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.

2. Background – please provide a reference for this statement. However, subgroup analyses, suggest greater effectiveness for such treatments in people with particular clinical profiles.

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

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.

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.

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 MRI.

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

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.

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.

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.

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) –

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?
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

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

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? –

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

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

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? –

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

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?

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?)

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?

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?

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

25. Numbers needed to treat analysis was not performed due to similar effectiveness of both treatments on most variables. – Please clarify and refer this statement

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.

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

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

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

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

**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