Reviewer’s report

Title: The effect of changing movement and posture using motion-sensor biofeedback, versus guidelines-based care, on the clinical outcomes of people with sub-acute or chronic low back pain - a multicentre, cluster-randomised, placebo-controlled, pilot trial

Version: 2
Date: 19 February 2015
Reviewer: Hannu Luomajoki

Review to paper: “The effect of changing movement and posture using motion-sensor biofeedback, versus guidelines-based care, on the clinical outcomes of people with sub-acute or chronic low back pain”

Thank you for the opportunity to review this interesting paper. From the clinical point of view, the intervention used is very innovative and it makes sense that this kind of approach could indeed lead to superior outcomes by patients with low back pain. However, there are some major risks of bias by this report.

The authors have mostly noted themselves some possibilities and shortcomings by the study, but I still want to point them out here.

Major Compulsory issues

The study protocol was not published and the procedures have been changed along the way. This is a huge flaw. Thinking sceptically, for example the authors may have chosen the main outcomes after having seen the results.

The cluster randomisation is a delicate issue. The recruitment and sampling can been biased hugely through the fact that the recruiting clinicians knew already which treatment these patients would receive. And since it is not known how many patients would have been eligible, the clinicians may have manipulated the sample greatly (by recruiting patients seemingly not motivated or not promising for the intervention). Also the ones receiving the specific intervention can have been motivated much more through clinicians beliveing this intervention being superior.

The study is to a large part sponsored by the device producent and the authors were paid through this sponsor may introduce a main bias for motivating the authors getting positive results for the device.

Minor issues for improving the quality of reporting

Abstract
I think the paper should also present concrete numbers for the power analysis for a fully powered trial
Background
P. 4, line 20, a word is missing
You name advantages of cluster randomisation – maybe you should name also disadvantages (but this can be done also in discussion)

Methods
Design
Is there an explanation why the protocol was not published?

Participants
Since the recruitment through the treating clinician may introduce a major bias, please explain the recruitment more detailed.

Page 8. lines 6-8 suits possibly better to results section?

Setting
I am a bit confused about the clinicians: what was the difference between 2 physicians and 4 GP’s? Were there really only 3 physios included? Did really the 7 doctors treat the patients up to 8 times? (I think this is typically physio job). Further on, can you name also who was doing what (like eg. Were physios treating the specific group and MD’s the controls?)

Page 11. Line 11. How could you measure hip movements if there was no sensor below the hip?

A Note: the refs 45.-46 are only congress proceedings which will have been peer reviewed only through abstract submission...

Page 14. I do not get a clear picture what the evidence based care group was doing…? And who was giving the therapy (they came 6-8 times to therapy). Please explain more detailed what this therapy included.

Again, please declare who did which therapies (MD’s versus physios). I guess the clinicians treating the control group will have clearly known that the sensors in the back are only placebo. This introduces a major flaw here.

Page 18, blinding… is very positively put… I think the clinician were very aware of these being the control group.

Page 19. Line 6, logistic?

Results
Participant flow. It is not clear when was randomised? At first the clinics and then in the clinics, the patients were recruited? So, those clinicians recruiting knew what treatment these patient would get? Please explain more detailed.

Discussion
Page 29, lines 1-4, I do not understand this sentence, please explain more clearly what this means.

Data calculations
Maybe you should present clear numbers what the sample size estimation for a sufficient trial would be?

Limitations
You could be more critical here.

**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 do not have any competing interests