Reviewer's report

Title: Brief psychosocial education, not core stabilization, reduced incidence of low back pain: results from the Prevention of Low Back Pain in the Military (POLM) cluster randomized trial

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Reviewer: Chris G Maher

Reviewer's report:

All of my comments are minor essential revisions and I have grouped them under the questions suggested to BMC reviewers.

1. Is the question posed by the authors new and well defined?
There have been very few trials evaluating prevention of LBP. Those that have been conducted have been small and of mixed quality. The POLM trial is unique because it is a large prospectively registered RCT. The trial is very important because it evaluated exercise and/or education; two contemporary prevention strategies where there is uncertainty about effectiveness.

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?
In the main the methods are appropriate and well described and I will offer some suggestions below which I feel would further strengthen this manuscript.

(i) POLM seems a bit like the back pain version of the Framingham study. It is a massive study and many papers will arise from it. I missed a brief explanation in the introduction about the family of studies and how this paper fits into that family.

(ii) Could you please provide more detail on treatment allocation so that the reader can understand the method used to conceal allocation.

(iii) I presume both exercise and education interventions were done in a group but was this at the level of a ‘company’ or a smaller organizational unit within a company? For exercise programs how many soldiers per drill instructor were there? We need to know this information to appreciate how the treatments were administered.

(iv) On page 10 you say that the planned fixed effects were the variables that differed between clusters after randomization. Do you actually mean differed between group? You have 4 groups and 20 clusters and while I can see you have checked fro between group differences I cannot see this for cluster ( and I would not advise doing this either).

(v) Please clarify if data in Table 3 and the survival curve are adjusted.
(vi) This is a small issue but on page 11 you talk about the survival analysis in
time units of months but the figure is in days. I would harmonise your time units
across the two.

3. Are the data sound and well controlled?
The trial protocol offered 3 primary outcome measures: episodes of LBP,
duration of LBP and severity of LBP. Because of problems with follow-up the
authors have had to change and base their outcomes upon healthcare data from
the military database. I will deal with each primary outcome separately.

(iii) Normally in a trial if this happened there would be a major problem but I think
the authors have fallen on their feet here. Switching from an episode of
self-reported LBP to an episode of health care for LBP has probably
strengthened the trial. Many people would argue that it is in fact the episodes of
health care utilization that are the key issue. So I have no problem with this
switch. My advice would be to be more explicit throughout the whole manuscript
that you are measuring incidence of LBP care seeking.

(ii) I thought the duration of LBP outcome was unclear. On page 10 you say it
was the number of months that a soldier reported LBP but I thought you did not
actually use the soldier self-report data. I was under the impression that you used
the military database and so I presume this is the duration of healthcare
utilisation? I think it would if we had some more clarity on this issue.

(iii) It seems to me that you have abandoned trying to find a new measure from
the military database to reflect your original interest in ‘severity of LBP’. Please
confirm that is the case.

4. Does the manuscript adhere to the relevant standards for reporting and data
deposition?
This is a well reported trial.

5. Are the discussion and conclusions well balanced and adequately supported
by the data?
In my view the authors were perhaps a bit too cautious in their interpretation of
their results. They report an absolute risk reduction of ~3% but if you expressed
this as a relative risk reduction it would be ~17%. Sometimes I think we are too
hard on ourselves in the back pain field. In the cardiovascular field a brief low
cost intervention that gave a relative risk reduction of 17% would be judged as
important. For example the ADVANCE trial published in the New England
Journal of Medicine in 2008 was bullish with the result that intensive glucose
control in diabetics caused a 10% relative risk reduction in vascular events. The
simple education intervention could be applied to large groups of people and so
provide substantial benefits at the population level.

In the discussion I would be less critical of the switch to an endpoint based upon
healthcare utilization rather than the pre-planned self-reported low back pain. At
the moment on page 13 it reads all bad, but really there are some benefits from
this switch (e.g. you have data on 96% of participants at 2 years which many trials do not) and the way the switch was made in a blinded fashion was exemplary.

I would like to see a section added to the discussion trying to explain the results. Looking across the family of POLM papers I can see that the education changed beliefs (as measured by Back Pain Beliefs Questionnaire) which provides a plausible mechanism for the lower incidence of LBP. But unfortunately that story is not in the current discussion. I would encourage the authors to consider adding this information.

6. Do the title and abstract accurately convey what has been found?
   Yes

7. Is the writing acceptable
   Yes

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

‘I declare that I have no competing interests’