Author's response to reviews

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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Author's response to reviews: see over
Dear Dr. Lee and Reviewers:

Thank you for your comments on our manuscript. We were encouraged by the overall support for this paper and also for the suggestions for revision. We now submit a revised manuscript for your consideration. Changes to the manuscript are highlighted in this letter, with changes to the manuscript indicated by bold font and yellow highlight.

Reviewer #1 (Chris G. Maher)

This reviewer had several minor essential revisions grouped under question categories for BMC reviewers. Our responses to each are under the appropriate question category.

1. Is the question posed by the author new and well defined?
   There were no comments to address for this question.

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?
   (i) As requested we have added a description of the family of studies that will arise from this trial in the 3rd paragraph of the Introduction. Essentially there will be studies related to ultrasound imaging, predicting of first episode of low back pain, and an economic analysis. We did not include preliminary studies already published because those were referenced in the same paragraph. In the 4th paragraph of the Introduction we have indicated that the current paper should be considered the reporting of the primary findings.
   (ii) As requested we have provided more information on how treatment allocation was concealed.
   (iii) As requested we have provided more information on the exercise and education groups in the manuscript. The entire company did exercise at the same time, but each subgroup of the company (platoon) was led by the drill sergeant. We have clarified that point in the manuscript. For the education program the company was split into 2-3 groups to allow for fitting the auditorium and to allow for flexibility in scheduling.
   (iv) You are correct, the phrase should have been differed among “intervention groups” and not “clusters”. This was corrected.
   (v) The data presented in Table 3 and Figure 2 were not adjusted. This is now indicated in the Table and Figure key.
   (vi) The methods have been updated to include days to LBP as opposed to months. A more thorough explanation for this is provided below.

3. Are the data sound and well controlled?
   (i) As requested we have made it more explicit throughout the paper that our definition of incidence was contingent on seeking care. This has resulted in changes to the manuscript in the Abstract, Methods, Results, Discussion, and Conclusion. We did not change the term every time incidence is mentioned because it became quitecumbersome to read. However we have emphasized the health care seeking aspect of the measure in key places so we are confident the reader will realize the nature of the incidence measure used in this study.
   (ii) Sorry for the continued confusion here. The duration data was taken from the dates in which the Soldier was enrolled in the study to the date of the first episode of seeking care for LBP as per the M2 database. Therefore we were able to calculate this in the number of days. The confusion stems from our not totally removing language from the previous analysis plan
which relied on monthly increments (the precision afforded by the self-report data collection). The switch in the database allowed us to investigate this in daily increments.

(iii) The abandonment of the severity outcome is a good point that we did not directly address in the original paper. We have added a statement indicating that we did abandon this measure as these data were not available from the M2 database.

4. Does the manuscript adhere to the relevant standards for reporting?
There were no comments to address for this question.

5. Are the discussion and conclusion well balanced and adequately supported by the data?
Thank you for your comments here and in response we have followed your lead by adding the relative risk reduction estimate to bolster our argument that these effects may have some relevance. Also we have added some additional information to support the switching of the outcome measure and also added the requested information on trying to explain the results.

6. Do the title and abstract accurately convey what has been found?
7. Is the writing acceptable?
There were no comments from this category to address.

Reviewer #2 (Raymond Ostelo)

1. As requested, we have clarified that this was a 4 arm trial in the last paragraph of the Abstract, Introduction and also in the Methods (Randomization subheading). The aim of the trial was indeed to compare 3 different conditions for their low back pain preventative options using the TEP condition as the comparative standard. This primary comparison of interest was stated in our hypothesis.

2. Thank you for the comments on the change of our primary outcome measure. We appreciate the reviewer understanding the circumstances warranting a change. In response to the reviewer’s specific questions about health care utilization – we did not have the nature of the health care utilization well defined for the primary trial analysis. We felt that since our original primary outcome was for incidence that we should use the health care database to generate an incidence estimate based on seeking health care. We realize that describing this measure as “health care utilization” may not be entirely appropriate as readers, similar to Reviewer #2, will want to know more about the nature of the utilization and these are data we do not have for the primary analysis. Therefore, we have followed terminology Reviewer #1 suggested and clearly indicate our incidence measure is for “those seeking health care for low back pain”.

3. We agree with the Reviewer comments on the appropriateness of TEP as the control condition for this group but have left the stipulation that there was not a “no exercise” group to avoid reader confusion that TEP could be considered a “true” natural history control condition.

4. As requested we have provided clarity on the “collapsed intervention groups”. This was only done after analysis was done on the 4 intervention groups as originally intended. The collapsing was done to allow for efficient communication of results. The timing of this collapse of intervention groups is now more clearly communicated in the Results as it was not our intention for readers to think that these data were analyzed as a 2 arm trial when in fact the analysis was true to the original design. This was, however, how the data played out and was determined to be the “best” way to present the primary results in a concise manner. In the POLM trial the “take home” message was that there was
about a 3% decrease in incidence by adding to any of the exercise programs, which indirectly supports our hypothesis as there was no added benefit of changing the exercise program. To directly answer the Reviewer’s question about which would replace TEP – our data supporting supplementing TEP with PSEP as opposed to changing to CSEP.

5. We appreciate the Reviewer’s skepticism on the effect of a 1 session of education as we were also surprised with the results. We have addressed this comment in 2 ways. First, Reviewer #1 has asked for more information on the preliminary POLM study that showed the education program was effective in improving 12 week beliefs, so we have provided more information on that study as it adds credibility to the effects reported in this primary study currently under review. Second, we have referenced a recent literature synthesis on the FAM to balance the Discussion so that readers are aware of other evidence on this topic. We did not expand on this topic because it is worth noting to the Reviewer that systematic reviews for cognitive behavioral treatments have typically involved patients with chronic low back pain, while this study investigated a primary prevention model. Therefore these reviews were not cited and we believe it is feasible that lower doses of education could be effective when individuals are pain free and psychosocial education is used for primary prevention. Obviously more research is needed in primary prevention settings before this matter can be addressed more definitively.

6. In response to the question about the 17% incidence rate being “common”, it appears from other epidemiological studies that rate of seeking health care is consistent with what is expected for this population. We do agree with the comment about the exact nature of the utilization being difficult to interpret, and we included that comment as a limitation of the paper. We do have a plan to investigate the specific parameters of health care utilization in a later analysis (assuming the M2 database allows such queries), but for this paper we are focusing on the incidence estimate as that was our original plan.

7. We have reviewed your suggestions for the Conclusion, and agreed with the suggestions and implemented as suggested. These changes were also made in the abstract to reinforce key points from the conclusion.

Small issues

1. We did not expect adverse events but have been counseled to explicit indicate whether there were adverse events so that other authors can use this information when conducting systematic reviews.

2. We have more clearly described the number of intervention arms throughout the paper.

3. We have implemented the primary limitation (applicable to military populations only) in the Abstract and Conclusion.

4. We have decided to leave the limitation about not having a “no exercise group” in the paper. We feel it is important to note that we cannot comment directly on the preventative benefits of any of these exercise programs, only the relative effects. Therefore we left this in the manuscript.

5. We have been clearer on our LBP incidence measure throughout the manuscript in response to suggestions from both Reviewers.
6. We have removed the mass media description. As previously mentioned we cited a recent review of the FAM for balance but did not provide a major overview because this study was done in a primary prevention setting while other studies were not.

On behalf of the authors I would like to thank the review team for providing feedback that helped to improve this manuscript. I would also like to thank the Editor for allowing us to respond to the reviewers’ comments. I look forward to hearing if this paper is now acceptable for publication in *BMC Medicine*.

Sincerely,

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