**Title:** Predictors of web-based follow-up response in the Prevention of Low Back Pain the Military Trial

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**Author's response to reviews:**

**Associate Editor's comments:**

I think a very important question is whether it is possible to provide a more detailed analysis of follow-up response beyond a simple dichotomous approach. Another matter is whether it is possible to assess whether access to the internet is actually a barrier for some.

We added a secondary analysis to assess the response rate difference over time. The following text was added to the discussion in reference to the study’s limitations:

“This study reported predictors of response to a web-based survey using a dichotomous outcome to represent response rate. This decision was made because the primary outcome of the trial is a dichotomous measure (occurrence of low back pain) and we wanted these analyses to be parallel. Our additional analysis showed that response rates significantly decreased over time. Also, it would be interesting to assess whether internet access was a barrier for some of the Soldiers in this study, in particular those who were deployed in remote settings around the world. However, this information was not available to us, hence we can only speculate that response rates may be lower for those Soldiers who did not internet access during the follow-up phase of the study.”

Reviewer 1

Reviewer: Jerrilyn Cambron
Major compulsory revisions

This is an interesting article and I thank the authors for submitting it. However, the one major issue in electronic follow-up within this trial is the ability for the soldier to access a computer. Is it possible for the authors to include and analyze information on location of the soldiers (even ‘within’ or ‘outside’ of the US) and/or ability to access a computer at their location during the follow-up? This seems to be the most critical factor in the results presented and much more relevant than variables such as income or BMI.

We agree this information would be interesting to have, but unfortunately we are not able to make any judgment about the extent to which access to computers/internet was a hindrance to follow-up. The following sentence was added to the discussion to address this limitation.

“Also, it would be interesting to assess whether internet access was a barrier for some of the Soldiers in this study, in particular those who were deployed in remote settings around the world. However, this information was not available to us, hence we can only speculate that response rates may be lower for those Soldiers who did not internet access during the follow-up phase of the study.”

Minor essential revisions

The participants in this study were training to become combat medics. Because they were focused on the medical field, I would have expected them to have a higher response rate than soldiers in the non-medical field, just as doctors and nurses have higher response rates in cohort studies compared to subjects in the general population. How do the authors think this would be the case in this study?

The reviewer makes an interesting point, however we can only speculate that this might be the case since we did not include subjects in non-medical fields. We have added a sentence in the discussion to reflect this possibility.

“The participants in this study were training to become combat medics. One might expect that their response rate would be higher than Soldiers in non-medical fields, similar to how medical personnel demonstrate higher response rates compared to subjects in the general population. However we had no comparison group in the current study so we can only speculate that these follow up rates might be higher than if this study targeted subjects in the general population.

I was a bit unclear as to the dichotomous outcome of ‘whether a soldier responded to any one of the 12 monthly surveys.’ It seems as though the authors included any response to one of three emails as a positive response but any response to a telephone call as a non-response. Is that correct? If so, please
include information on how many responded at one email, two emails, three emails, and at the phone call. Because this manuscript deals with response rates and predictors of response rates, this information is important and interesting.

The emails were sent to remind the soldiers to complete the monthly web-based survey. For Soldiers who did not respond to any of these emails, the telephone call was made after the 1-year survey to collect the primary outcomes related to low back pain, which did not influence this paper’s outcome of responding to the monthly surveys. The dependent variable used in this paper is “whether a soldier responded to any one of the 12 monthly surveys.”

There are a few times in the manuscript and table where the variable for income is divided by <$20K and >$20K, but =$20K is not included. It would be helpful to have the odds ratios for each variable included in Table 1, particularly because the authors use those data in the results section.

This was corrected.

Reviewer 2

Reviewer: Cecilia Bergström

Introduction

1. I would suggest adding the abbreviation "POLM" to the title.

We have made this change.

2. Please clarify the last two sentences in the 3rd paragraph in the background. As it is written now, it is somewhat confusing.

Edits were made accordingly to these two sentences in the manuscript to clarify the confusion.

Methods

1. As the study included human subjects it would be important to state if ethical approval were granted. As presently formulated, this is not clarified.

Ethical approval and consent is stipulated in the last 2 sentences under the “Settings and Participants” section of the methods as follows:

“The institutional review boards at the Brooke Army Medical Center (San Antonio, TX) and the University of Florida (Gainesville, FL) granted approval for this project. All subjects provided written informed consent prior to their participation.”
2. Assigned company drill instructor is being considered a potential predictor of response rate and risk adjustment variables. However, there is no information if these drill instructors had any influence on the response rate. Further, no information of drill instructors are found in Table 2 which contains all the other characteristics considered as predictors.

The drill instructor (and gender) variable was accidentally omitted from Table 1. The related information has been added in Table 1.

3. The reporting on the Soldiers level of physical activity is somewhat confusing. Please try to re-write this section.

We have re-written this section to be more clear.

4. Were the soldiers informed why information on i.e. current evidence on LBP etc. was given? It could be of interest to know this as none of these Soldiers participating in this study had LBP.

Yes, and text was added to this effect in the section that describes the Psychosocial Educational Program.

5. Under the subheading "physical examination of trunk musculature" it is somewhat unclear whether the straight leg raiser was used as an orthopedic test or as a mean of ROM or measuring the symmetry of m. multifidi.

The straight leg raise was performed both in the more classic sense of its being an orthopaedic test (ie, examination) and separately during the USI examination to assess the lateral abdominal muscles during active raising of the leg off the table. Some text was added to this section to clarify this point.

6. More information about the web-based survey is desired, though novel. Has it been tested before? Has it been externally and internally validated? How many questions did the Soldiers need to reply to at each monthly survey? This is very important, as "too many" or "too few" question could possibly influence the response rate as well. Further discussion on this is also necessary.

The following text was added to the methods section to clarify this point:

“The web-based survey started with an email prompting to visit the study hosted, confidential, secure web-site. Once the website was accessed, Soldiers were asked one initial screening question – “have you had any back pain in the past 30 days?” A “no” answer ended the survey and Soldiers were thanked for their participation. A “yes” answer prompted the Soldiers to complete more information on the back pain episode including how many days it lasted, if it resulted in loss of military activities, and if health care was consulted.”
We utilized standardized measures to describe the severity of the episode including measures for pain (NRS), disability (Oswestry), and psychological distress (FABQ and PCS). Although we are unable to report psychometric properties specific to the survey, all items were either commonly used questions from epidemiological studies or from previously validated questionnaires.

7. Soldiers who reported a LBP episode were prompted to complete a more detailed follow-up questionnaire. How did this questionnaire differ from the original one? How many more questions were there? Was there a difference in response rate between soldiers with episodes of LBP compared to the ones who did not experience LBP? How was an episode of LBP defined?

See above in #6.

8. There is a dash (−) missing in non-responders in the last sentence under the subheading “web-based follow-up surveys”.

This was corrected.

9. From my understanding, soldiers were cluster randomized to complete a traditional exercise program. However, it becomes increasingly difficult to follow the different groups after the initial part of the methods. This part needs to be further clarified as there is an obvious difference between the groups. A table/flow-chart would be helpful. Sometimes a picture (flow-chart/table) says more than a thousand words. Adding to the confusion is the last sentence under the subheading “physical examination of trunk musculature” which preferably should be a paragraph of its own. A clarification and a better overview of the design are in order.

We have clarified the design further in the section titled “Design Overview”. There were actually 4 groups:

1) TEP w/ PSEP (n=945)
2) TEP w/o PSEP (n=1,212)
3) CSEP w/ PSEP (n=1,049)
4) CSEP w/o PSEP (n=1,089???)

Since the group assignment is less relevant for this analysis, we elected not to include another flow chart/table to avoid too many tables and figures. We also did not want to draw too much attention to the different groups since in this secondary analysis, we collapsed the study into a single cohort for the purpose of determining predictors of 1-year response rates to the web-based follow-up survey. This is stipulated in the last sentence of this section. To further clarify the design, we have added the sample sizes for each of the 4 groups in the Design Overview section, which should help clarify the overall study design for the
primary analysis, which remains to be completed. We do specify that receiving PSEP or not and receiving the physical/USI examination or not were considered as potential predictors of follow-up based on their potential to represent an attention affect.

The soldiers were cluster randomized to intervention groups. The sample size and number of responses by group are added to Table 1. Since we considered receiving PSEP or not (and receiving the physical/USI examination or not) as potential predictors of follow-up based on its potential to represent an attention affect, the groups were not included as a predictor variable.

10. Data analysis:

Mixed linear models need to be further described. What final model fitted the data best? Further description of the final model used is also needed.

We have clarified the analysis plan. The model included all potential predictors and other pre-specified explanatory variables, even though Table 2 only reported results for the statistically significant predictors.

Results

1. First sentence of the first paragraph – please refrain from starting a sentence with a number as it interrupts the flow when reading.

This was corrected.

2. In the 55% who had college education, please clarify if that included those with “some college education”.

The 45.5% of subjects who marked “some college” are those with some college education but did not graduate. The other category now called “Graduated from college or higher” includes those Graduated from college, Some post-graduate college and Completed post-graduate.

3. Most of the result section repeats information already available in the tables. A suggestion is to leave out the p-value as they are clearly stated in the tables.

We have removed the p-values in the results section per the request and now refer more liberally to the tables in the results section to avoid too much redundancy.

4. The last sentence of the result section is somewhat unclear. Exactly which factors were adjusted for?

The factors that were adjusted for include age, sex, race/ethnicity, level of education, income, length of service, military status, and assigned Company drill
instructors. This is specified in the section titled “Demographic Characteristics” within the methods.

Discussion

1. Last part of the second sentence, first paragraph under the heading "Discussion" only one reference is referred to using plural form …"response rates observed in similarly designed studies”. Also, in this study the response rate was 18.9% and in the cited study the response rate ranged from 35.2% to 55.3%. I would not call the results in this study consistent with the cited study (Buchbinder et al).

We have clarified in this sentence that our follow-up rate was lower compared to standard randomized clinical trials that incorporate face-to-face contact to secure follow-up data and compared to at least one similarly designed study that depended heavily on web-based surveillance systems without direct face-to-face contact with the subject during the follow-up phase of the study.

2. In the last part of the first paragraph in the discussion the increase in response rate after non-responders was called up by a phone call center is discussed. I would also like to have this information in the result section reported as additional findings. Were additional analysis made which included these 10% additional responders and if so, did it change the results of the analysis?

For the purpose of this analysis, we were interested in determining the predictors to the web-based survey so didn’t want to confound the analysis by including additional responses obtained via the phone call center for those who did not respond to the web-based survey. We have clarified this point in the discussion.

3. Second paragraph:

It is not correct to say that “soldiers who smoked were 42.0% less likely to respond” as it refers to risk ratio (RR). Instead it should say “soldiers who smoked had 42.0% lower odds of response”.

This was corrected.

4. Second paragraph in the discussion there is only one reference when using plural form …”data are consistent with recent studies”…

This was corrected to reflect a single study.

5. Seventh paragraph:

It is argued that the significant results in this study may be a result of “too much power”. However, I find this very misleading. An argument in regard to a Type I Error would be more appropriate.
We now specify the potential for Type I error rather than a problem of “too much power”.

6. The discussion on the reason for the discrepancy of response rate is at its present form somewhat dispersed in the discussion section. I would suggest keeping it together to make it more reader friendly.

We reorganized the manner in which this was presented in the discussion, which should address this concern.

7. I am not sure what the query of health records would do to response rate.

The query of the health records is similar to the phone call center, essentially an additional strategy that was used to secure follow-up. The data from the health record query will be used for a separate cost effectiveness analysis once the primary results of the trial are available. We only mention the query of the health records for the purpose of explaining the overall follow-up strategy in the study. However, the data from this query were not included in the response rate since this analysis was limited to prediction of response to the web-based survey.

8. As a reader, I am interested to see response rate over time as well, as it has a tendency to decrease over time. Was there a difference in response rate in the beginning of the trial versus the end? Why did the authors made the decision only to include one response during 12 months as an outcome? After all, soldiers were prompted to response to this questionnaire each month. A discussion about this decision is needed.

We agree that the response rate over time is of great interest to readers. And we have conducted an additional analysis to assess the time effect along with a plot of response rate over time in the added Figure 2. We did not include these additional analysis results in the original submission for technical reasons – due to large number of soldiers, the SAS GLIMIX procedure could not fit a model that includes random subject affect to account for within subject correlations over time. The added results of the time effect came from a model that included a random company effect, but not random subject effect. On the other hand, the effect of the other predictors and explanatory variables were still reported based on the model using a single dichotomous outcome instead of the longitudinal binary outcomes, even though the results were similar.

9. I would like to know if other studies have shown that higher education has been associated with higher response rates. If so, references are needed.

An appropriate reference was added.

10. Is the next to last sentence in the 5th paragraph of the discussion needed? (“soldiers receiving PSEP had response rate of 19.1%…”). I think it would be
sufficient with a reference to Table 1.

We have added a reference to Table 1 per the request.

11. A discussion on other follow-up methods would be in order mostly due to the low response rate of this web-based survey as well as in other studies. Maybe more novel methods of follow-up should be considered as well?

This is discussed in some level of detail in the 1st paragraph of the discussion, in which we discuss the other follow-up strategies that were employed in the POLM trial to secure additional follow-up. However, the follow-up from these methods were not considered in the response rate for this analysis given the purpose of this study being to determine predictors of response to the web-based survey.

Figures

1. A suggestion is to remove the frame around Figure 1 as it is confusing to the eye. Also, why is only information on number of companies mentioned in the last boxes?

This was done.

2. I would suggest another figure shown the different “attentions” given to the Soldiers – please see previous comments.

Tables

1. In table I, please add n=4295 in the title or incorporate it into the table.

This was added to the title.

2. It appear that information about company drill instructor has not been included in the tables – please see previous comments regarding this.

This has been added in Table 1.

3. I think that the tables would improve in layout if information was somewhat condensed. Please see suggestion below.

This was done per the suggestions.

4. The way numbers are written in tables and manuscript need to coincide. Presently, numbers are written in tables .75 but in the manuscript it is written 0.75. Another suggestion would be to use semi-colon instead of a comma when writing out the CI.

Leading zeros were removed throughout to be consistent. We also now use
semi-colons to write out the CI.

5. Also be consistent if you are using a comma (,) in numbers or not i.e. comma (,) is missing in the numbers in table I "Length of Service" but only for the subheading "<5 months".

This change was made.