Author’s response to reviews

Title: Targeted Interventions to Prevent Chronic Low Back Pain in High Risk Patients: Development and Delivery of a Pragmatic Training Course of Psychologically Informed Physical Therapy for the TARGET Trial

Authors:

Jason Beneciuk (beneciuk@phhp.ufl.edu)

Steven George (steven.george@duke.edu)

Carol Greco (greco@pitt.edu)

Michael Schneider (mjs5@pitt.edu)

Stephen Wegener (swegener@jhmi.edu)

Robert Saper (saper@bmc.org)

Anthony Delitto (delitto@pitt.edu)

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Targeted Interventions to Prevent Chronic Low Back Pain in High Risk Patients: Development and Delivery of a Pragmatic Training Course of Psychologically Informed Physical Therapy for the TARGET Trial

Jason Beneciuk, DPT, PhD, MPH; Steven Z. George, PT, PhD; Carol Greco, PhD; Michael Schneider, DC, PhD; Stephen T. Wegener, PhD; Robert Saper, MD, MPH; Anthony Delitto, PT, PhD

Thank you to the Associate Editor and Reviewers for comments and suggestions provided. Responses to reviewer comments are provided in boldface font below. All changes within text of revised manuscript are highlighted and indicated using boldface font.

Associate Editor Comments:
Dear Dr. Beneciuk,

Your manuscript "Targeted Interventions to Prevent Chronic Low Back Pain in High Risk Patients: Development and Delivery of a Pragmatic Training Course of Psychologically Informed Physical Therapy for the TARGET Trial" (TRLS-D-18-01016) has been assessed by our reviewers. Although it is of interest, we are unable to consider it for publication in its current form. The reviewers have raised a number of points which we believe would improve the manuscript and may allow a revised version to be published in Trials.

I look forward to receiving your revised manuscript soon.

Best wishes,

Monica Busse, PhD

Trials

Thank you to the Associate Editor for expressing interest in our manuscript and allowing us the opportunity to provide a revised version. We agree, both Reviewers have provided valuable comments that were used to improve this revised manuscript.

Reviewer Reports:

Reviewer #1:

This is important and much needed area of study. However, I was disappointed in the lack of rigour and reporting. Method chapter in particular is not very clearly described with key information missing such design, recruitment process, education level of the sample, how many PTs completed what training, type and distribution of the data collected to warrant selection of the tests, or justification of the outcomes selected etc. It was also unclear why some form of formal assessment of the PTs' attainment of the learning objective was not included within the training package. I understand the aim of the study was to attempt to assess this but the choice of the outcomes (PTs' attitudes and confidence) may still not show whether PTs changed their practice or indeed were able to on basis of the training. However, given the importance of this work I would consider a review of a re-write under a major revision if editor feels this is appropriate publication. Below are my comments to aid authors in their re-submission if they so wish.
Thank you Reviewer 1 for providing valuable comments that will be addressed in revision. We completely agree that attitudes, beliefs, and confidence do not provide direct measures of behavior change in clinical practice and will specifically address this concern in revision.

1. Format – Please add page numbers

Page numbers have been added as suggested.

2. Title – I suggest adding 'Targeted Interventions to Prevent Transitioning from Acute to Chronic Low Back Pain in High Risk Patients…' to accurately represent what the therapy is aiming to do.

We have edited the title as suggested. Please keep in mind, we have also added complete title of trial (The Targeted Interventions to Prevent Chronic Low Back Pain in High Risk Patients – TARGET Trial) within trial overview section to be consistent with protocol paper that is currently in peer-review process.

3. Background 2nd paragraph – Authors state PIPT goal is 1/ identification of high risk individuals and 2/providing targeted treatment. This is confusing as PIPT is in fact a therapy and therefore not designed to identify and as later described in TARGET trial overview. Also, further in the text it becomes clear that another tool (STARTBACK) is used for the identification. I suggest authors rephrase this section clearly state what is the PIPT goal - arguably point 2 only.

We understand and respect Reviewer #1 concerns on this point, however would prefer to keep both steps of PIPT in the Introduction as it is a better match for how it is delivered as part of the TARGET trial. PIPT is an enhanced management approach to physical therapy that includes: 1) screening to identify individuals that may be at high risk for transitioning to chronic pain (using measures like the STARTBACK tool) and then 2) providing treatment aimed at targeting psychological factors (References 12 and 13). Therefore, a key first step to implementing PIPT is screening to identify risk status so that the tailored approach can be appropriately delivered.
4. Methods: Lacks important details (study design, total sample size, selection and recruitment of the participants, details on data type and normal distribution testing). It would be also useful to adopt more standard way of reporting of quantitative research.

Just to clarify, the current manuscript is a companion paper for the more traditional protocol paper that will provide full description of details listed above. The TARGET Trial protocol paper is currently in peer-review process and has not yet been published; therefore depending on timeline we may be able to reference protocol paper when formally accepted?

5. Methods: Beta testing paragraph and Modification of training paragraph (method) – This requires more detail including justification of Beta method being most appropriate to validate the training package? Who and How many PTs/researchers were involved, what was their qualification level, what exactly prompted the changes (e.g. adding videos) - this I would assume would have been added initially, was there a modification of the video resources?

We have provided additional information describing justification of the beta method used and have provided references for similar training programs that have used the same approach. We have also provided the number of licensed physical therapists that attended each PIPT training beta sessions, however did not collect data on qualification level. We acknowledge this was not the most rigorous approach because we were only able to do a quality improvement evaluation of the PIPT training program, consistent with its pragmatic design. Therefore, we were limited in the detail of the data we could collect. We have also clearly indicated that participant feedback promoted subsequent changes including the addition of brief video modules provided on PIPT website and during live course.

6. Methods: Final course objectives paragraph (method) – Later in the text the authors very well describe the utilisation of the teaching methods to obtain the learning objectives. However, in this paragraph the objectives appear randomly selected with not much attention to the words such as ‘understand’, ‘develop’, ‘implement' with no apparent appreciation how these relate to educational theory. I would advise to reflect on this feedback and re-write this paragraph in light of pedagogy principles (adding appropriate references). In addition, although further in the text (live workshop) authors indicate the use of formative assessment (real-time feedback, self-reflection), it is not clear whether or how the attainment of the learning objectives was formally assessed. This would significantly strengthen your case of ensuring intervention fidelity. I.e. just because the programme has objectives it doesn't mean they are met on completion of the
training. I would therefore suggest address this within this publication as well as the PIPT training programme content.

Thank you for these suggestions. At this point, we are not able to change the final course objectives as all PIPT training has been completed, however we value your suggestions and have edited this paragraph. We agree that objectives were randomly selected within text of manuscript as our intention was to provide examples with readers being able to reference Table 1 for specific learning objectives. Based on this comment, we have removed objectives from text and only reference Table 1. We have acknowledged that attainment of learning objectives was not formally assessed after PIPT training as a limitation in ‘Provider Training’ section.

7. Methods: Final course content paragraph (method) – What is the theoretical rationale of the training programme you are referring to?

We have removed the term ‘theoretical rationale’ and replaced with a description of the general theme for course ‘overview’ content (i.e., rationale and supporting data for PIPT approach).

8. PIPT website paragraph – There were 12 modules each taking up to 22 min to complete (4.4hrs). Yet only 2.5 hrs were awarded, was this representative of how much time people spent of the website? Or how was this averaged?

To clarify, there were 12 modules ranging between 8 and 22 minutes in duration with total viewing time amounting to 150 minutes (2.5 hours). We have specifically described total viewing time for all video modules in revised manuscript.

9. Live workshop – Within the PIPT website it states the 1 day live workshop is highly recommended. Was it monitored how many attended and was there a difference between those who did and did not in measured outcomes?

To clarify, the PIPT website states: “It is highly recommended that all of the online modules be viewed prior to attending the live workshop.” All sites participating in the TARGET Trial were required to host a live workshop. However, we were not able to monitor specific aspects of
participation due to evaluation being quality improvement based. We were also not able to measure PABS-PT or confidence outcomes for physical therapists that did not attend the workshop because the videos were never meant to be “stand alone” for training physical therapists.

10. Strategies to Enhance and Assess Quality and Impact of Provider Training paragraph – Here you state the principles followed but again the form of assessment, whether the trainees receive ‘pass’ or ‘fail’, are all trainees to be included regardless of whether they achieve the learning outcomes is not stated. I understand authors attempt to test this with the outcomes but even these appear not a true reflection of PTs learning or change of practice (assessment of physical therapist attitudes, beliefs and confidence; PIPT treatment checklists; and booster training) evaluating confidence and attitudes. Having a formal way of assessing PTs attainment would greatly enhance the quality of this manuscript and improve fidelity of the intervention within the trial (although I do appreciate this may further reduce how PTs engage with the training, which needs to be addressed and acknowledged in the discussion).

We thank Reviewer #1 for highlighting this point as it was a key limitation to assessing quality and impact of our PIPT training program. We have previously acknowledged that training quality and impact could have been further enhanced by including formal assessment of skill acquisition; and emphasized how that may have increased likelihood of PIPT implementation during trial as suggested. We have also indicated how this additional assessment may have reduced physical therapist engagement with training as suggested which we completely agree.

That being said, we also need to be completely transparent and acknowledge that these practices are much easier to implement in an explanatory trial where the training to fidelity link is more connected. We need to keep in mind that this was a pragmatic trial and we were limited in being able to conduct formal fidelity assessments. Finally, and related to the pragmatic component to this study, these were all licensed physical therapists and their ‘pass’ or ‘fail’ status would have had no impact on if they were able to treat patients the following day; which would be different if these were study therapists and we could in turn have required them to demonstrate specific skills before providing study related treatment.

11. Training quality of impact – The total sample size is not stated in the text (only in a table leaving the reader do the math). Table 3 is poorly signposted, not clear what test was used to look at the group differences or what this indicates. The data type for each outcome or its
distribution is not stated and so it is not clear whether the correct tests were selected. Also, rename this section as statistical analysis and move it to the end of the method (just before results).

We have decided to avoid using the term ‘statistical analysis’ as suggested. Rather, we have decided to add a section entitled: ‘Evaluation of Training Program’ to align with a quality improvement approach. Within that section, we have included a statement indicating the total number of physical therapists that attended the live workshop and completed pre-training questionnaires was 471. We have edited Table 3 as suggested and in response to Reviewer concerns, we used visual inspection of histograms was to assess distribution of post-course PABS-PT and confidence scores.

12. It is not clear why some outcomes were tested immediately post training whilst others were not. I would also recommend to standardize the writing to make it easier to follow when and why each of the outcomes was tested.

To clarify, PABS-PT (attitudes and beliefs) and confidence were administered before the live workshop and immediately afterwards. Four-month follow-up assessment was only conducted for the PABS-PT; not confidence scores.

We understand how description of this may lead to confusion amongst readers and because our follow-up response rates are not ideal (28.4%). However, it is our opinion that presenting this data will be informative because we did make an attempt to capture PABS-PT outcomes 4-months after training. Specifically, we only assessed PABS-PT to be consistent with other studies that have looked for attitudes and beliefs to remain “shifted” (Beneciuk and George, 2015 – doi: 10.2522/ptj.20140418). During planning stages, we were only interested in short term changes in confidence, however plan to capture longer time points in the future.

13. Results – There needs to be some attempt to present the descriptive data including, place of work, their qualification level (not just years qualified), how many attended which type of training is entirely missing from this manuscript. All this information would be important to discuss and help interpretation of the results.
In the revised manuscript we now indicate that all physical therapists practiced in outpatient clinical settings. We acknowledge that there are some important details lacking. However, this limited data collection is consistent with a pragmatic trial approach involving five different health systems. Ideally we would have collected additional data from physical therapists but this would have required additional research consent which would have limited the scale of our training.

14. Discussion – Unfortunately, the discussion chapter makes little attempt to discuss the results (other than a mention in the provider training section). Instead it is rather descriptive reflection commenting on the unreported qualitative elements of the experience of the process. I am not certain whether this was intentional but given the complexity of the analysis and results presented some interpretation of the results and how this relates to the previous literature is needed.

To clarify, the primary intention of this manuscript was to reflect on our TARGET Trial PIPT training program experiences and provide several important ‘lessons learned’ that can be used to guide future study of PIPT implementation for long-term sustainability (as indicated in Discussion – 1st paragraph). Providing description of physical therapist attitudes, beliefs, and confidence were provided as indirect measures of training impact; although we have acknowledged limitations to using this approach. We have referenced previous studies that have incorporated similar training and attempted to compare and contrast findings where appropriate in ‘Provider Training’ section within Discussion.

15. Table 3 shows that there was disparity in the years qualified. This was not discussed in terms of interpretation of the results. Nor was a potential impact of discussions between practitioners and potential contamination. I appreciate this may not be an issue for TARGET trials opting for cluster RCT but again that is an assumption not mentioned within this manuscript.

Thank you for this suggestion. In the Discussion, we have emphasized the need for specialized training and speculated on how ‘years in practice’ may have influenced our findings. We have also indicated that future PIPT training programs may need to be tailored to participant characteristics and clinical experience.
We have also added a statement about the TARGET Trial cluster RCT study design potentially decreased likelihood of contamination across clinical sites within the overview section entitled: ‘PIPT Training Program’.

16. Data not presented in the results section are discussed e.g. PIPT clinician champions paragraph (last sentence).

To clarify, this sentence is in reference to qualitative data collected from a previous smaller scale study (Reference #26) and not referring to personal communication with physical therapists participating in the TARGET Trial. We have edited sentence to avoid confusion.

17. Finally, the scalability section points to some very important insights. This section in particular would benefit from being better linked to the study findings.

Thank you for this suggestion. We have attempted to enhance this section by linking suggestions for scalability to study findings without providing excessive speculation.

Reviewer #2:

The authors aim is to describe the iterative process involved in developing teaching material for the TARGET trial called Psychologically Informed Physical Therapy. It is an ambitious paper that covers a huge amount of material but it is important paper and I believe it should be published to ensure this detail is available to others. The results of the trial are eagerly awaited by the back pain clinical and research community.

Thank you Reviewer 2 for providing comments and suggestions that will be incorporated to improve revised version of manuscript.

The strengths of the paper:

- the writing style is clear. References are appropriate. The team are excellent. The topic is important.
- the links to the trial website and to the course modules are useful and interesting
- the size of participants completing the course and providing data was large
- the discussion points were well structured and interesting

The weaknesses of the paper (all relatively minor points):

1. It is a fairly complex and lengthy article to read. Perhaps the introduction could be edited by omitting the first couple of paragraphs on information about LBP prevalence etc... as that could be the start of any LBP related paper and so is not strictly needed.

   We respect concerns of Reviewer #2 in regard to this point. However, we would prefer to keep these initial paragraphs as we believe they provide necessary background information for readers that may not be familiar with PIPT and why in our mind such pragmatic PIPT training programs are needed.

2. The usefulness of details about the iterative steps to improving the training content was unclear - perhaps that section could be reduced in length?

   We have edited the paragraph describing training modifications following beta testing to reduce length as suggested. Please keep in mind, we believe this information is also relevant as it is the only time we mention PIPT training course changes after beta testing. Consequently, this information provides description of the PIPT training course from development to delivery.

3. On the PIPT website link you can see that there is a presentation in the research section on the PABS measure. Some clarity to avoid it looking like participants were coached to take the test - would be useful.

   Thank you for this suggestion. We have added a statement to indicate course instructors did not provide any instructions for how to respond to individual questionnaire items.
4. The detail of the content within Table 1 and 2 was very limited. Could the authors consider adding more information to both of these Tables? For example, Table 1 point 5 - can you tell us which CBT assumptions and specific skills? For example, in Table 2 could you detail a little more about the content and add the time spent on the delivery?

We have edited Table 2 by providing approximate time allotted for each topic covered during the live workshop. We have also added an Appendix to provide more detailed description of content provided in Table 2 (as suggested by Reviewer) because we were limited with space to include this information in Table 2 current format.

I wish the authors all the best with their clinical trial.

Thank you Reviewer #2.