

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	The results of a feasibility randomized clinical trial on pain education for low back pain in Nepal: The PEN-LBP feasibility trial.
AUTHORS	Sharma, Saurab; Jensen, Mark; Moseley, G.; Abbott, J. Haxby

VERSION 1 - REVIEW

REVIEWER	Vinicius Cunha Oliveira Pós-Graduação em Reabilitação e Desempenho Funcional, Universidade Federal dos Vales do Jequitinhonha e Mucuri (UFVJM), Diamantina, Brazil
REVIEW RETURNED	19-Oct-2018

GENERAL COMMENTS	The feasibility RCT for LBP has good rationale and is well planned by authors. I believe that it adds important information in the field, for clinicians and researchers. I congratulate authors for their well-designed and well-written study and am looking forward to their full RCT.
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REVIEWER	Balkrishna Bhattarai B.P. Koirala Institute of Health Sciences (BPKIHS), Nepal
REVIEW RETURNED	20-Oct-2018

GENERAL COMMENTS	The manuscript is written very well. The issue addressed is very much relevant in Nepalese context.
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REVIEWER	Kory J Zimney University of South Dakota Have published books in Pain Neuroscience Education, which I receive royalties and provide educational lectures for which I receive honorariums for on Pain Neuroscience Education.
REVIEW RETURNED	27-Nov-2018

GENERAL COMMENTS	Main impression: The article is the results from a previously published protocol on a feasibility study for providing a RCT for pain education to individuals with back pain in Nepal. This is an interesting study on multiple levels as limited research has been done in developing countries in regards to pain education. The study protocol was sound as demonstrated by following through with the already
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published protocol paper in BMJ Open. The results of the study look to be useful in regards to informing the researchers the feasibility of carrying out a full RCT in the future with information gained from this feasibility study to improve study design even more.

Individual Section Review:

TITLE

- Main idea clear and concise

ABSTRACT

- Accurate, is in a structured format that is coherent and readable. Researchers could eliminate (CG) abbreviation provided in Interventions section as not used in the rest of the abstract.

INTRODUCTION

- Previous pertinent literature cited and discussed but the references to 'Explaining Pain'/'Pain neuroscience education' seem to be heavily in favor of one of the authors group (GLM) and limited to no mention of some of the other research groups involved in this line of study, some selective referencing may be involved.
- Introduction builds to the statement of purpose/research hypotheses and the purpose/research hypotheses clearly stated.
- Not sure on page 6 first sentence why it ends with (see13), same with second sentence is ended with (14,15).
- The authors point to the differences in length of education being brief or extended and point to the evidence for the sparse approach is sparse, yet they do not state that there is also no strong evidence to support that the extended method provides any better outcomes. The authors provide the benefits of the longer over the shorter time delivery, but do not list any limitations of the longer or benefits of the shorter. A non-bias presentation of the short and long methods should be provided; currently upon reading, it would appear as if there is a bias to the longer duration.

METHODS

- Study design appropriate to achieve study objective and was followed according to the already published protocol.
- Only question is how much and what kind of communication took place during the CG interventions. As currently written there is no indication of this. Recently published literature has shown that just providing communication with a patient may have an influence on outcomes, so this could be a confounder and should be reported on the differences between the PEG and CG.

RESULTS

- Results clearly presented
- Figures and tables are appropriately used to facilitate understanding of findings, necessary, and understandable

DISCUSSION

- Support of hypotheses noted
- Continuity with introduction and all information addressed
- Interpretation of findings not overstated, language of certainty match findings
- Limitations of study noted
- Avenues for future research provided

	CONCLUSIONS - Clearly stated
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REVIEWER	Hannu Luomajoki Zürcher Hochschule für Angewandte Wissenschaften ZHAW Departement Gesundheit, Institut für Physiotherapie Technikumstr. 71, CH - 8400 Winterthur Tel. +41 58 934 63134 Mob. +41 79 435 7871 luom@zhaw.ch
REVIEW RETURNED	04-Dec-2018

GENERAL COMMENTS	<p>Review to « The results of a feasibility randomized clinical trial on pain education for low back pain in Nepal: The PEN-LBP feasibility trial» in BMJ Open.</p> <p>Thank you for the opportunity to review this excellent paper. It is very well conducted and written. The trial was registered and the research protocol has been published before. SPIRIT and CONSORT guidelines were used in the development and documentation of the study.</p> <p>The design is adäquat. The main aim of the study was to test the feasibility of a larger trial with a methodology that has been successful elsewhere but not done in Nepal before. The main outcomes are appropriate for this setting.</p> <p>I have only a couple of minor comments on the paper, however these are more opinions than strict methodological concerns.</p> <p>Firstly, the role of therapists in the control group has been tested and discussed well. However, in the experimental group, seemingly the main author of the paper applied the education for the participants. I think this fact can cause a major bias in the study. It is obvious that the person who is most motivated in the whole study, is the main author. His person will have a huge impact on the results. It will be hard to motivate the therapists applying the control treatments, as they know that they are «only» in the control group. I think it would be worthwhile to discuss this topic at least at the discussion part. A more pragmatic option for a larger study would be to educate a few therapists applying the experimental patient education.</p> <p>Secondly, I was wondering why there were no disability measures as secondary outcome. This might be wise because the cultural environment is totally different to most western countries, in which earlier studies have been conducted. However, I think those other studies usually did use measures for experienced disability during all day life.</p> <p>Thirdly, I thought that maybe also some power calculations for a possible larger trial would be appropriate to report. I can see that the main aim was the feasibility and not pilot testing. So, this comment of mine can be questionable.</p> <p>As stated, these comments are merely more opinions and not a threat methodologically. So, the authors can think over these few ideas whether they might improve the otherwise already high quality of this report.</p>
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	Congratulations to the authors for this very nicely and clear documented study.
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VERSION 1 – AUTHOR RESPONSE

Reviewer(s) Reports:

Reviewer: 1

Reviewer Name: Vinícius Cunha Oliveira

Institution and Country: Pós-Graduação em Reabilitação e Desempenho Funcional, Universidade Federal dos Vales do Jequitinhonha e Mucuri (UFVJM), Diamantina, Brazil

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

The feasibility RCT for LBP has good rationale and is well planned by authors. I believe that it adds important information in the field, for clinicians and researchers. I congratulate authors for their well-designed and well-written study and am looking forward to their full RCT.

Response: Thank you for your kind comments about this work.

Reviewer: 2

Reviewer Name: Balkrishna Bhattarai

Institution and Country: B.P. Koirala Institute of Health Sciences (BPKIHS),
Nepal

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

The manuscript is written very well. The issue addressed is very much relevant in Nepalese context.

Response: Thank you for your kind comments.

Reviewer: 3

Reviewer Name: Kory J Zimney

Institution and Country: University of South Dakota

Please state any competing interests or state 'None declared': Have published books in Pain Neuroscience Education, which I receive royalties and provide educational lectures for which I receive honorariums for on Pain Neuroscience Education.

Please leave your comments for the authors below

Main impression:

The article is the results from a previously published protocol on a feasibility study for providing a RCT for pain education to individuals with back pain in Nepal. This is an interesting study on multiple levels as limited research has been done in developing countries in regards to pain education. The study protocol was sound as demonstrated by following through with the already published protocol paper in BMJ Open. The results of the study look to be useful in regards to informing the researchers the feasibility of carrying out a full RCT in the future with information gained from this feasibility study to improve study design even more.

Individual Section Review:

TITLE

- Main idea clear and concise

ABSTRACT

- Accurate, is in a structured format that is coherent and readable. Researchers could eliminate (CG) abbreviation provided in Interventions section as not used in the rest of the abstract.

Response: Thank you for this suggestion. We have removed the abbreviation from the Abstract.

INTRODUCTION

- Previous pertinent literature cited and discussed but the references to 'Explaining Pain'/'Pain neuroscience education' seem to be heavily in favor of one of the authors group (GLM) and limited to no mention of some of the other research groups involved in this line of study, some selective referencing may be involved.

Response: We have revised the Introduction to reflect and cite Pain Education research from other research groups which were not included in the original submission. Please see the changes on page 6, lines 1 – 4.

- Introduction builds to the statement of purpose/research hypotheses and the purpose/research hypotheses clearly stated.

Response: Thank you.

- Not sure on page 6 first sentence why it ends with (see13), same with second sentence is ended with (14,15).

Response: We have revised the way we cite references so it is consistent throughout the paper. See page 5, lines 23 - 25.

- The authors point to the differences in length of education being brief or extended and point to the evidence for the sparse approach is sparse, yet they do not state that there is also no strong evidence to support that the extended method provides any better outcomes. The authors provide the benefits of the longer over the shorter time delivery, but do not list any limitations of the longer or benefits of the shorter. A non-bias presentation of the short and long methods should be provided; currently upon reading, it would appear as if there is a bias to the longer duration.

Response: Thank you for this excellent suggestion. We have revised the text to make the presentation of the limitations and benefits of both shorter and longer delivery more balanced. See the changes on page 6, lines 5 – 8.

METHODS

- Study design appropriate to achieve study objective and was followed according to the already published protocol.
- Only question is how much and what kind of communication took place during the CG interventions. As currently written there is no indication of this. Recently published literature has shown that just providing communication with a patient may have an influence on outcomes, so this could be a confounder and should be reported on the differences between the PEG and CG.

Response: Thank you for this valuable comment. We have revised the manuscript to explicitly state the differences between the treatment conditions with respect to communication. See page 11, lines 8 – 11.

RESULTS

- Results clearly presented
- Figures and tables are appropriately used to facilitate understanding of findings, necessary, and understandable

Response: Thank you.

DISCUSSION

- Support of hypotheses noted
- Continuity with introduction and all information addressed
- Interpretation of findings not overstated, language of certainty match findings
- Limitations of study noted
- Avenues for future research provided

CONCLUSIONS

- Clearly stated

Response: Thank you.

Reviewer: 4

Reviewer Name: Hannu Luomajoki

Institution and Country:

Zürcher Hochschule für Angewandte Wissenschaften ZHAW

Departement Gesundheit, Institut für Physiotherapie

Technikumstr. 71, CH - 8400 Winterthur

Tel. +41 58 934 63134

Mob. +41 79 435 7871

luom@zhaw.ch

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

Review to « The results of a feasibility randomized clinical trial on pain education for low back pain in Nepal: The PEN-LBP feasibility trial» in BMJ Open.

Thank you for the opportunity to review this excellent paper. It is very well conducted and written. The trial was registered and the research protocol has been published before. SPIRIT and CONSORT guidelines were used in the development and documentation of the study.

The design is adäquat. The main aim of the study was to test the feasibility of a larger trial with a methodology that has been successful elsewhere but not done in Nepal before. The main outcomes are appropriate for this setting.

Response: Thank you.

I have only a couple of minor comments on the paper, however these are more opinions than strict methodological concerns.

Firstly, the role of therapists in the control group has been tested and discussed well. However, in the experimental group, seemingly the main author of the paper applied the education for the participants. I think this fact can cause a major bias in the study. It is obvious that the person who is most motivated in the whole study, is the main author. His person will have a huge impact on the results. It will be hard to motivate the therapists applying the control treatments, as they know that they are «only» in the control group. I think it would be worthwhile to discuss this topic at least at the discussion part. A more pragmatic option for a larger study would be to educate a few therapists applying the experimental patient education.

Response: Thank you for an excellent comment. We have revised the manuscript to reflect this important study in the Discussion section of the revision; see page 26, lines 16 - 21.

Secondly, I was wondering why there were no disability measures as secondary outcome. This might be wise because the cultural environment is totally different to most western countries, in which earlier studies have been conducted. However, I think those other studies usually did use measures for experienced disability during all day life.

Response: Thank you for your suggestion. Consistent with IMMPACT recommendations regarding the core outcome measures that should be used in chronic pain clinical trials (see, <https://www.ncbi.nlm.nih.gov/pubmed/15621359>), we classified pain interference as a disease-specific measure of physical functioning (or disability), and included a valid and reliable measure of this domain as one of the secondary outcome measures. The Nepali version of the PROMIS Pain Interference short form, in addition to its sound psychometric properties, is brief and is easy to administer. In addition, other disease-specific measures of disability (e.g., Roland Morris Disability Questionnaire and Oswestry Disability Index) which have been recommended as core outcome sets for clinical trials in low back pain (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5828378/>) were either not available in Nepali during the conduct of the study, or their psychometric properties were not adequately evaluated in a Nepalese sample. The translation and validation of Roland Morris Disability Questionnaire is currently underway in Nepal. If it is found to be valid, reliable and responsive, we will consider using it in the definitive clinical trial as suggested.

Thirdly, I thought that maybe also some power calculations for a possible larger trial would be appropriate to report. I can see that the main aim was the feasibility and not pilot testing. So, this comment of mine can be questionable.

Response: The reviewer is correct that the primary aim of the study was to assess the feasibility of a full trial, and not to perform power calculations for the larger trial.

As stated, these comments are merely more opinions and not a threat methodologically. So, the authors can think over these few ideas whether they might improve the otherwise already high quality of this report.

Congratulations to the authors for this very nicely and clear documented study.

Response: Thank you again for your thoughtful comments and suggestions.

VERSION 2 – REVIEW

REVIEWER	Kory Zimney University of South Dakota I have written and published books on pain neuroscience education and receive royalties from them. I receive honorariums for the teaching of post-professional seminars for a continuing education company on pain neuroscience education and neurodynamics.
REVIEW RETURNED	29-Jan-2019

GENERAL COMMENTS	My concerns during the original review have been adequately addressed.
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REVIEWER	Hannu Luomajoki Zürich University of Applied Sciences Winterthur, Switzerland
REVIEW RETURNED	24-Jan-2019

GENERAL COMMENTS	This is a very well conducted paper. COngratulaitons for the authros. I also thank for regarding the Points which I mentioned in the first Review. Though a notice of concern: I saw that the paper is already uploaded in Reserach gate although not yet through the review process?
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