PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Descriptive analysis of a 1:1 physiotherapy outpatient intervention post primary lumbar discectomy: one arm of a small scale parallel RCT across two UK sites
AUTHORS	Rushton, Alison; Calcutt, Adam; Heneghan, Nicola; Heap, Alison; White, Louise; Calvert, Melanie; Goodwin, Peter

VERSION 1 - REVIEW

REVIEWER	Dominic Hegarty Cork University Hospital, Cork, Ireland
REVIEW RETURNED	17-Apr-2016

GENERAL COMMENTS	Perhaps consider identifying the key data and limit the number / size of each table The only additional comments here are a) The random nature of the recruitment was open to bias, individuals may or may not have agreed to signing up for the project depending on their previous experience with Physiotherapy. Many individual have long protracted physiotherapy sessions trying to deal with the LBP and often may not have had a good experience. This would need to be clarified & accepted b) I note that there was no clear significance (p values) reported in the tables. While there was a large pool of data I would have expected some record analysis (even if not significant) c) Perhaps the editor could consider the volume of data in some tables & the authors advised to present the more “important results” and leave the detail to an appendix.

REVIEWER	Paul Salamh Duke University School of Medicine, North America
REVIEW RETURNED	05-May-2016

GENERAL COMMENTS	I applaud you for your efforts on taking on such a task as well as adding to the body of research within this area. I am recommending

	major revisions regarding your manuscript prior to consideration for publication. First off, the shear length of this manuscript would make it difficult for readability and one may easily get lost from the time you state your objective until they have made it through the manuscript. I appreciate the amount of data that was collected and the inherent desire to report it all but it may be best served with some of these findings discussed in a separate manuscript. The recruitment section requires further clarification regarding if all patients at the two locations were made aware of this study or not. The data analysis section is significantly lacking and I would like to see more detail in this section. I understand this was an observational study but the data lend themselves to be compared between the two groups. This leaves me a bit confused, again some of this may have been lost on me due to the length. I believe there would be a better way to present the tables aside from how it is currently displayed. How necessary is table 7, again as a reader it is very easy to become lost in this. Much of the discussion simply restates the results. The purpose of the discussion is to discuss the findings of the current study within the context of previous literature and bridge the gap between the results and the conclusion. I would like to restate that I believe there is merit to what you have sought to do but I believe the story of how you went about it, why, and what you found, could be told better.

REVIEWER	Raine Osborne Brooks Rehabilitation, United States
REVIEW RETURNED	04-Jul-2016

GENERAL COMMENTS	1. 2. Could be a bit more clear about how the intervention was structured and what is meant by "optimized". Also, consider a bit more explanation of how measures, especially the STarT Back were used. The findings and conclusion sections seems a bit disconnected from the prior sections. 3. The design could be stated a bit more clearly. In particular, the authors state "this was a small scale parallel RCT design, randomizing..." Although true, the analysis did not compare between groups and being more clear about that this study is only describing one arm for the RCT would be helpful. 4. 5. 6. This study would benefit from more explanation about rationale for the overall structure of the planned outcomes assessments (i.e. what domains were being targeted) as well as more information about why each particular outcome assessment instrument was chosen and their respective psychometric properties. 7. The reported findings would be enhance by providing information about between group statistical significance on items such as the

	number of problems identified, number of treatment sessions provided, and pre-post outcome measures. 8. Given the increasing emphasis on clinical practice guidelines, discussing how this intervention did or did not align with published guidelines would be valuable. 9. 10, 11, & 12. I was surprised that there was not more discussion about classifications or subgrouping of patients. While I agree that patients present differently and that diagnosis or surgical procedure alone is a poor indicator of patient needs, there are also many similarities among these patients that, if identified, may help in the selection on appropriate treatment strategies. To some extent this is recognized by the authors when they selected certain outcome measures and determined an set of intervention strategies to choose from. However, the lack of discussion around this issue, rather in support of or against subgrouping, seems to be a major limitation of this paper. The conclusion that patients present differently and should be treated differently seems a bit superficial and leaves the more robust discussion regarding what are meaningful similarities and differences lacking. 13. 14. 15. There are some minor editorial issues that need to be addressed such as sentence structure, but these are easily resolved.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

Perhaps consider identifying the key data and limit the number / size of each table
Thank you for your comment and we have prioritised the data presented a stage further.
The previously annotated tables 7 and 10 have now been moved to supplementary files. This has reduced the length of the manuscript considerably.

A] The random nature of the recruitment was open to bias, individuals may or may not have agreed to signing up for the project depending on their previous experience with Physiotherapy. Many individual have long protracted physiotherapy sessions trying to deal with the LBP and often may not have had a good experience. This would need to be clarified & accepted
All patients who underwent surgery and met the criteria were invited to participate thus reducing bias. The details of recruitment, recruitment factors and reasons for not participating are provided in reference 16. The paper shows that distance from hospital was the key reason for patients not participating. Minimal patients reported a prior poor experience with physiotherapy. This has been reported now in the manuscript on page 15.

I note that there was no clear significance (p values) reported in the tables. While there was a large pool of data I would have expected some record analysis (even if not significant)
For this descriptive study embedded within the trial, inferential analysis was not appropriate. Owing to the small number of participants and descriptive nature of the study we still feel that between group comparisons through inferential analysis would not add anything further to the analysis of the intervention owing to the limitations that this would then raise. In particular, type 1 error due to multiple statistical testing and small sample sizes.

Perhaps the editor could consider the volume of data in some tables & the authors advised to present the more “important results” and leave the detail to an appendix.
Thank you for your comment and we have prioritised the data presented a stage further.

The previously annotated tables 7 and 10 have now been moved to supplementary files. This has reduced the length of the manuscript considerably.
These were the largest tables and we agree that they are best presented as supplementary files for the interested reader.

Reviewer 2

I applaud you for your efforts on taking on such a task as well as adding to the body of research within this area. I am recommending major revisions regarding your manuscript prior to consideration for publication.
Thank you for your comment.

First off, the shear length of this manuscript would make it difficult for readability and one may easily get lost from the time you state your objective until they have made it through the manuscript. I appreciate the amount of data that was collected and the inherent desire to report it all but it may be best served with some of these findings discussed in a separate manuscript.
The previously annotated tables 7 and 10 have now been moved to supplementary files. This has reduced the length of the manuscript considerably.

The recruitment section requires further clarification regarding if all patients at the two locations were made aware of this study or not.
Participants at both clinical sites were made fully aware of the study. It has been clarified on page 10 that this applies to both sites.

The data analysis section is significantly lacking and I would like to see more detail in this section. I understand this was an observational study but the data lend themselves to be compared between the two groups. This leaves me a bit confused, again some of this may have been lost on me due to the length.
There was no study objective to compare data across the two sites recruiting to the trial. This was a descriptive study reporting the analysis of the physiotherapy intervention only. This has been stated clearly on page 9 to inform the reader.

I believe there would be a better way to present the tables aside from how it is currently displayed.
The tables have been left at this stage within the main text and cited in line with the guidelines to authors; however, 2 tables have now been moved to the supplementary files to improve readability.

How necessary is table 7, again as a reader it is very easy to become lost in this.
Table 7 has been moved to a supplementary file.

Much of the discussion simply restates the results. The purpose of the discussion is to discuss the findings of the current study within the context of previous literature and bridge the gap between the results and the conclusion.
As a descriptive analysis the discussion does in turn analyse the key findings and we can see how this may be perceived as repetition. We have gone through the discussion carefully to remove any aspects that simply repeat results and added to some aspects to develop the analysis further.

I would like to restate that I believe there is merit to what you have sought to do but I believe the story of how you went about it, why, and what you found, could be told better.
Thank you for your comment.

Reviewer 3

1. There was no comment to address under number 1.

2. Could be a bit more clear about how the intervention was structured and what is meant by "optimized". Also, consider a bit more explanation of how measures, especially the STarT Back were used. The findings and conclusion sections seems a bit disconnected from the prior sections.
The intervention has been explained further page 11.
'Optimised' has been explained on page 10.
Measures are reported in full in reference 16 but a summary has now been added on page 12.
For greater clarity a separate heading re the Keele STartBack tool has been added page 13. It has been clarified further, also on page 13, that the Start Back tool was used descriptively to provide preliminary data in this study.
We believe these changes improve the flow between the earlier sections and the findings/discussion.

3. The design could be stated a bit more clearly. In particular, the authors state "this was a small scale parallel RCT design, randomizing..." Although true, the analysis did not compare between groups and being more clear about that this study is only describing one arm for the RCT would be helpful.
The study as a descriptive analysis of one arm of the RCT has been clarified on page 10.

4. There was no comment to address under number 4.

5. There was no comment to address under number 5.

6. This study would benefit from more explanation about rationale for the overall structure of the planned outcomes assessments (i.e. what domains were being targeted) as well as more information about why each particular outcome assessment instrument was chosen and their respective psychometric properties.
This is not the focus of this study.
The outcomes are the main focus of the RCT paper reported in full elsewhere – reference 14.
This has been clarified further in the text – please see above.

7. The reported findings would be enhance by providing information about between group statistical significance on items such as the number of problems identified, number of treatment sessions provided, and pre-post outcome measures.
Thank you for your comment. There was no study objective to compare data across the two sites recruiting to the trial. This was a descriptive study reporting the analysis of the physiotherapy intervention only. This has been stated clearly on page 9 to inform the reader.
Owing to the small number of participants and descriptive nature of the study we still feel that between group comparisons through inferential analysis would not add anything further to the analysis of the intervention owing to the limitations that this would then raise. In particular, type 1 error due to multiple statistical testing and small sample sizes.
Pre-post outcome data is reported on page 23 and within the associated text. The reader is now referred to the published RCT for full data – reference 16 (page 24).

8. Given the increasing emphasis on clinical practice guidelines, discussing how this intervention did or did not align with published guidelines would be valuable.
There are no clinical guidelines to specifically address rehabilitation of patients following lumbar surgery.

9. There was no comment to address under number 9.

10, 11, & 12. I was surprised that there was not more discussion about classifications or subgrouping of patients. While I agree that patients present differently and that diagnosis or surgical procedure

alone is a poor indicator of patient needs, there are also many similarities among these patients that, if identified, may help in the selection on appropriate treatment strategies. To some extent this is recognized by the authors when they selected certain outcome measures and determined an set of intervention strategies to choose from. However, the lack of discussion around this issue, rather in support of or against subgrouping, seems to be a major limitation of this paper. The conclusion that patients present differently and should be treated differently seems a bit superficial and leaves the more robust discussion regarding what are meaningful similarities and differences lacking.
It is difficult to discuss classifications or subgroupings further owing to the small sample size in this study, hence the objective was to explore descriptively to afford preliminary data. We have made clearer within the discussion and conclusion this limitation and need for further data to take these findings forward to explore subgrouping further.

13. There was no comment to address under number 13.

14. There was no comment to address under number 14.

15. There are some minor editorial issues that need to be addressed such as sentence structure, but these are easily resolved.
We hope that we have addressed these in our final review prior to re-submission.

We hope that our responses have addressed the required revisions to a satisfactory level, and we thank the reviewers for their time in reviewing the draft manuscript.

VERSION 2 – REVIEW

REVIEWER	Paul Salamh Duke University North America
REVIEW RETURNED	07-Sep-2016

GENERAL COMMENTS	I would like to thank the authors for their time in making the necessary revisions in order to improve the overall readability of the manuscript. Thank you for your contribution to the body of evidence in this field.