Author's response to reviews

Title: Evaluating rehabilitation following lumbar fusion surgery (REFS): study protocol for a randomised feasibility study.

Authors:

Jim D Greenwood (james.greenwood@uclh.nhs.uk)
Alison Mcgregor (a.mcgregor@imperial.ac.uk)
Fiona Jones (F.Jones@sgul.kingston.ac.uk)
Michael V Hurley (Michael.Hurley@SGUL.Kingston.ac.uk)

Version: 6 Date: 18 March 2015

Author's response to reviews: see over
Response to Reviewer 4/3/2015

Peer reviewer; Dr Ann-Christin Johansson  
Corresponding author; Jim Greenwood  
Title: Evaluating a rehabilitation protocol following lumbar fusion surgery (REFS); a feasibility study

1- Will the study design adequately test the hypothesis?
   • Comment: The hypothesis can be clearer expressed.
   • Response; Thank you for highlighting this and I do accept that this could have been clearer. I have modified the expression of the hypothesis in the revised manuscript submitted. The hypothesis relates to the feasibility nature of the study ie; issues relating to recruitment, compliance and acceptability to evaluate if it is possible to provide group rehabilitation following fusion surgery and also is the study design feasible. I do hope this is clearer now.

2- Are sufficient details provided to allow replication of the work or comparison with related analyses: if not what is missing?
   • Comment; Some more information is needed in the methods section.
   • Response; I have tried to expand the methods section with the intention of increasing clarity to facilitate replication/fidelity. Specifically describing the content of the intervention as much as is possible given the individualised nature of the intervention. We also plan to provide further details of the intervention through manualisation. Thank you for raising this I think it reads more clearly following these comments.

3- Is the planned statistical analysis appropriate?
   • Comment; Yes seems appropriate.
   • Response; No significant changes made.

4- Do the figures appear to be genuine, ie; without evidence of manipulation?
   • Comment; Yes.
   • Response; Nil changes made.

5- Is the writing acceptable?
   • Comment; Yes
   • Response; I have rewritten some parts of the paper to try and aid clarity and improve consistency.

Beyond this there are a few supplementary questions/comments to the manuscript listed below.

**Background, Aims and objectives**

Comment; The hypothesis can be clearer expressed.
Response; This has been addressed in keeping with point 1 above. We hope the modifications will allow a clearer understanding of the study aspirations and hypothesis. It is important that this aspect of the study is clear and we have tried, following your review, to achieve this.

**Methods**

**Comment; Design of the trial, page 7 first paragraph, why say single centre?**

Response; We just wanted to make it clear that this is not a multi-centre study.

**Comment; Participants, page 7. Which post-operative complications will be the ground for the exclusion? Please clarify.**

Response; Thank you, we have improved clarity around this listing the most common reasons for technical problems with the surgical site in the early post operative period. Ultimately the final decision regarding fitness to continue with rehabilitation will rest with the surgical consultant. This was an error in our first submission and we are glad to have had your review and the opportunity to correct it.

**Comment; Randomisation and blinding, page 10. Why is randomisation done before surgical treatment? If the time point for randomisation is changed to after surgical treatment dropout rate might be minimized (everything else could be done before surgery as planned).**

Response; Again thank you for this comment. We discussed this very point extensively amongst the supervisors and the research design service (RDS). The primary reason for randomising pre-operatively allows us to evaluate the possibility that expectation plays a role in recovery. It is possible that just knowing you are going to receive a structured rehab program in may influence the behaviour of participants through the first 3 months when they are limited in what they can do. We do agree that this will undoubtedly reduce our numbers due to drop out, however as we are not powered for evaluating efficacy this approach was thought to be worthwhile. We agree opinion will vary and only time will tell if this recruitment strategy is reasonable. The strengths and weaknesses of our recruitment strategy will form a major part of our overall assessment of feasibility and subsequent reporting.

**Comment; Why are patients not allowed to walk more than 2 miles per day?**

Response; This is a very good point and one of the post-operative aspects of care that is used largely for historic reasons. We hope very much that evaluating both rehabilitation and usual care (particularly the nested qualitative analysis) will allow us to establish the acceptability or
otherwise of these principles which although common practice in our unit, do not seem to have any evidence base beyond surgeon preference.

Comment: Rehabilitation group content, page 12 last paragraph. The CBT intervention should be more explicitly described, what principles of CBT? Any references to this treatment? What education has the physiotherapist for delivering this treatment?

Response; Thank you for raising this point, I found it difficult to answer succinctly, please accept my apologies for the length of my response. We have tried to convey that principles of CBT will be employed throughout the process. This is in contrast to a formal session(s) of CBT but rather an approach that underpins the principles of provision of the programme. This is difficult to encapsulate but I have tried in the revised manuscript to be clearer about this. We hope that there may be elements of cognitive restructuring and in vivo exposure therapy.

There are problem solving sessions as part of the peer review component and the education sessions have some dedicated sessions on the relationship between thoughts, feelings and behaviour. What we are trying to describe can be thought of ‘psychologically informed physiotherapeutic approaches’ as opposed to a dedicated behavioural intervention.

In the revisions I have described the experience and training that the therapists have had beyond that which is included in their undergraduate education. I am hopeful that this will produce an intervention that, if successful, can be adopted and run by physiotherapists. As such I hope that it reflects good clinical practice. I do hope this addresses your concerns and I hope you can see from my comments and the revised submission that we are trying to help create a template for good post-operative care, undoubtedly though it will require modifications.

Figure 2

Comment: Point 5 and 10. Thoughts, feelings and behaviour, could the author’s say anything more about these educational subjects?

Response; Many thanks for raising this, which is something I have thought about a great deal. All of the education sessions do have speaker notes to add consistency to the messages given. This is done in bullet point format to allow the therapist the flexibility to tailor each session to the group dynamics. It was thought to be beyond the scope of the paper to list this in detail but I can see that there would be merit in expanding this. We hope to manualise the intervention, providing more detail on this and all the education sessions.

Particularly this session explains how thoughts and beliefs can influence behaviour. We use different problem solving scenarios and support
patients to use these strategies to identify any maladaptive thoughts/feelings and engage positively with rehabilitation and everyday life.

**Page 13 second paragraph**

Comment: What educational message?

Response: This is just referring to the education provided in the first 20 minutes or so of each rehabilitation session. One of the consistent concerns of patients relates to conflicting advice. We hope that this will provide a clear and consistent set of messages, discussed within the personal context of the patient that can be applied to rehabilitation and general function away from the group. In the revised manuscript I have tried to be clearer about this point.

Comment: Why is not the CBT intervention individualised? The educational component (page 15), exercise component (page 15) and peer support component (page 16) are described, why not the CBT component?

Response: Thank you very much for raising this point. The reply to this is similar to that for comment above about the detail of the CBT component. The amended manuscript I hope is clearer about these issues.

In many ways the CBT component will be individualised, as those patients with greater need will receive more support, closer supervision and may well receive more detailed or expanded educational sessions within the structure of the group. This would be part of a flexible program that can adapt to the needs of the group/individual whilst retaining an overall structure that is consistent between sessions. At this early stage in evaluation (feasibility study) we have adopted an approach that applies principles of CBT as an adjunct to a physical rehabilitation regime and educational process.

I would make that point that this is not a psychologically based intervention but an integrative combined approach to rehabilitation employing principles of CBT to support a physical rehabilitation program. This is why we have not described it as a separate entity but tried to convey that behavioural principles will influence the way in which the therapists deliver the programme. I hope this addresses your concerns and I am grateful for the suggestions.

Comment: The patients might have different needs in relation to behavioural treatment. Why not tailoring this treatment individually, as is done with the individualised progressive exercise regime?

Response: We agree the patients will undoubtedly have varying needs with regards to all aspects of the rehabilitation, including the need for behavioural therapy. My answer relates to the way in which we deliver
the intervention. I have tried to clarify this in the revision. Those who have greater needs may be slow to progress or express worrying thoughts/behaviours (diaries and supervision should highlight this) and any blocks to recovery are discussed on an individual basis during the group.

As this series of work proceeds we may be better able to identify those who need more focused behavioral therapy earlier in the process. We do not feel we are currently able to do this, as such we have chosen to apply a uniform approach with flexibility to try and modify the behavioural support given to patients who are not improving as we would expect. This is why we are using very senior therapists who will be able to individualise to an extent the behavioural component of the programme.

This is a very interesting aspect of this feasibility study and we will be asking people about their experiences in order to inform subsequent programs. Thank you for highlighting this.

Comment: Some patients might have efficient coping strategies, no misleading thoughts etc and not even need behavioural treatment, how do the authors consider this?

Response: But for the purpose of a feasibility study in which we are learning about the intervention and the cohort under examination we decided to trial this approach in which we anticipate the therapists running the sessions will be able to tailor the behavioural component the needs of the individual/group (ie; some requiring more support, some requiring less or none).

Comment: Could an accessible solution be to measure the influence on behavioural factors before inclusion? And accordingly have minimal level for giving the CBT treatment?

Response: This is a very good suggestion and we are grateful to you for making it. It is we think likely that quantifying behavioural factors prior to inclusion may well be one of the strategies that comes out of this work. It is something we will be looking at closely in our results. Many thanks.

Usual care arm, page 16

Comment: How will the authors control that patients in the control group not get cognitive behaviour treatment of cognitive behaviour influenced treatment?

Response: We are mindful that this may occur and in the strictest sense we are not controlling for it. We are recording it and it will form a part of our summation. In reality access to behavioural therapies in the UK is limited and in this post operative period our experience is that many people are sent away with little or no rehabilitation beyond simple advice. Of course local therapists may provide components of behavioral
interventions as part of a rehabilitation strategy for those in the UC group. In many ways we hope they do but in reality one of the reason for identifying this patient cohort and designing this study reflected the fact there is precious little out there in rehabilitation terms for patients following fusion surgery.

**Secondary outcome, page 18**

Comment; have the authors considered measuring pain catastrophising?

Response; Thank you for raising this the simple answer is yes we did consider this initially. As the design progressed with input from a variety of sources including the RDS, the NIHR (funding body), the supervisory team and the R and D dept at the host organisation we opted not to include it. The selected outcomes we felt were manageable and would achieve the aims of the study, however we will reconsider the cluster of outcome measures employed in keeping with the feasibility nature of the study. As such this is a really helpful and constructive comment that we will duly consider.

**Qualitative analysis**

Comment; In relation to what will patients experience of facilitators and barriers be analysed?

Response; With respect the qualitative ‘commentary’ there will be very little analysis. The bulk of the detailed analysis will come from the interviews with the purposive sample. The ‘commentary’ merely helps us develop the topic guide for the qualitative analysis and identify 20 subjects (extreme and mid point opinions) for inclusion in that nested aspect.

With direct respect to facilitators and barriers we will use the commentary data to gauge whether this is a theme that is necessary to include in the topic guide specifically. Many thanks for the detailed and insightful comments which have helped shape this manuscript.