Reviewer's report

Title: A rehabilitation intervention to promote physical recovery following intensive care: A detailed description of construct development, rationale and content together with proposed taxonomy to capture processes in a randomised controlled trial.

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Reviewer: Elizabeth Skinner

Reviewer's report:

General Comments
I commend the authors for their intent, which is to ensure that clear reporting of what was done during the RECOVER trial for both intervention and usual care groups occurs; as this is a particularly important area (Parker, Tehranchi and Needham, 2013 Crit Care 17:183) and one that has previously lacked attention. The manuscript is generally well written and easy to read although in parts the manuscript lacks clarity.

The authors have attempted to describe the construct development, rationale, content and proposed taxonomy of a rehabilitation intervention designed to promote physical recovery following intensive care; primarily for the processes of ensuring appropriate and detailed reporting of the intervention as currently being evaluated in a randomized controlled trial. However my main concern is that the process the authors have followed is not repeatable in its current form, even though the manuscript aims to report on the steps that were followed. The authors would be better, in my opinion, to restructure the manuscript as a generic series of steps (i.e. a framework) that can be followed, using the steps they have taken to highlight the steps or give practical examples of how they achieved the steps; along with rationale for the steps of the framework. The authors should also aim to describe the ideal framework and how their application of this achieved/failed to achieve a 'gold standard' development of intervention. For example, the performance of a literature review is obviously a key step, however the authors did not perform a systematic review, which should be expected, rather a narrative review which may have resulted in a biased outcome.

Fortuitously, the NICE guidelines were published during the development of the intervention (good luck rather than good management), however if they had not been, a systematic search of the literature would not have been carried out, which would ultimately affect the validity of the developed intervention. The framework should be discussed in the context of its internal and external validity, repeatability and feasibility. For example: Step 1. Systematic Literature Review; etc etc; Step 4. Involvement of an Independent Chair (with expert skills or key policy work already in the area). How feasible would it be to involve an Independent Chair in this manner, for example, had the NICE guidelines not been developed and published? How should this person be selected? Etc. Why two independent content experts and not five?
The manuscript is not as succinct as it could be. The Results section in particular (up until the Final construct for complex intervention heading) is largely a repetition of a constellation of other work, the primary sources of which have been referred to, however large segments of the text repeat text that is present in the original sources. These sections could be summarized much better, as the aim of the manuscript is to report on the final construct of the rehabilitation and the details it comprises, rather than to repeat the development steps.

In addition, there is a substantive lack of referencing in the final construct summary of the intervention – which should be relatively easy to justify given the extensive background work the authors describe they have undertaken. There needs to be better linkage of the steps undertaken and specific details as to how they resulted in the decisions being made, as the construct and taxonomy sections of the Results are under-referenced (specific examples given in the specific comments). An example as to where this has been done well is in the second last paragraph of the final construct section in the results.

The authors have not acknowledged adequately the significant sources of bias present in the development of their intervention; and in addition, the reasoning behind several of the key methodological features that can be open to criticism of the RECOVER trial (such as excluding the ICU stay, limiting the intervention period to 3 months), is not clear, despite the point of this manuscript being to do just that.

Major compulsory revisions
1. Restructure manuscript into generalizable framework as suggested in general comments.

2. Was the literature review systematic? Whilst the details might be beyond the scope the authors are suggesting their method is repeatable and so some key information should be provided.

3. Summarize key points in each of the sub-sections of the Results section and reference previously conducted work with key points rather than restating significant text of the results/findings.

4. The paragraph about why the ICU stay was excluded from the intervention should be moved up to the end of Paragraph 1. This is a critically important decision that has been made by the authors, as the literature acknowledges that early intervention is critical given patients lose muscle mass in the ICU stay (Poulsen et al., 2011 CCM 39:456-61). Many papers have demonstrated the feasibility at least if not always the benefit of commencing rehabilitation within the ICU (Schweickert et al., 2009 Lancet (as referenced by the authors); Pohlm et al., 2010 CCM: 38(11):2089-94; Berney et al., 2012 Physical Therapy 92(12):1524-1535; Deney et al., 2013 Crit Care 17(4): R156; Zanni et al., 2010 J Crit Care 25(2):254-262; Skinner et al., 2009 Critical Care and Resuscitation 11(2): 110-115; and this will be one of the most significant criticisms of the completed RECOVER trial. This is the authors’ opportunity to make a watertight case as to their reasons for the ICU stay exclusion and they need to expand on the current text pertaining to this, particularly as the current text is not necessarily
5. As per Point 3, the authors need to provide stronger justification as to why the intervention period was ceased at 3 months and provide relevant data/references to justify the assumption that this would cover up to a period of living at home or other placement for most patients.

6. More justification should be given as to why the intervention was focused primarily on physical rehabilitation; in particular with referencing.

7. Discuss the implications of using 5 years to develop the intervention. Is this feasible? Should we recommend this for all intervention development? How was the constant updating of referencing/literature undertaken/incorporated? How relevant is this process if it takes 5 years?

8. Why did the authors choose to provide intervention after discharge home as a key point in the study given the results of the PRACTICAL trial (a negative trial, cited as one of the influential studies affecting the development of the intervention)?

9. Why were the multiple other studies that would have come to the authors attention during their literature review (e.g. Burtin et al 2009 CCM; Morris et al 2008 CCM; Bailey et al., 2007 CCM; Martin et al., 2005 CCM; Chiang et al 2006 Physical Therapy; Zanotti et al., 2003 Chest) not included in the rehabilitation trials that influenced intervention development?

10. Some of the text around the GRAs (Lines 4 to 5 in particular) lacks clarity and is difficult to understand. Please rephrase.

11. Tables 4 and 5 are the most useful part of the Results section (indeed the crux) and should be given higher emphasis and moved up in the text. More detail could be provided in Table 4 (not in text but in succinctness) – for example – the component of the intervention “Meeting with ICU consultant” – is this the GRA, or the patient, or both? Obviously these probably all relate to the patient, but this could be stated explicitly, either in the Table header/footer or specific e.g. patient meeting with ICU consultant. The theory/rationale aspect of Table 4 in particular should be referenced so that the reasons for the decisions/inclusion are transparent and the reader can examine how evidence-based the theory/rationale was. In addition, the intervention would not be repeatable by following the Table. For example on the ward, regular assessment by GRA is noted as a component of the intervention – what is “regular” assessment? Daily? Twice daily (as described by others (Berney et al., 2012 PTJ)? Weekly? Using words such as regular, frequent etc are not specific enough. What was the frequency of therapy sessions provided or aimed to be provided? Was there a standard minimum? The authors have nominated that physical recovery was a focus – was physiotherapy prioritized over dietetic or occupational therapy?

12. Given the aim of the manuscript is to describe the intervention, less text is required for the trial outcome measures/qualitative data measurement/analysis (all of this information should be located in the trial protocol manuscript). Re:
outcome measures, it is sufficient to say that the detailed description is available in the trial protocol paper, to cover this area off for the reader who might be interested as to how these were selected. In my opinion, the authors could almost reproduce this manuscript in the context of selection of outcome measures as that is almost if not more important than the description of the intervention (given the sparse literature on the best measures (i.e. the ones with the strongest psychometric properties) in the population of patients with and following critical illness). Remove also the text at the end of paragraph five in the final construct section which pertains to outcome measures; and remove Table 7. Remove the text at the end of the taxonomy section in the results which pertains to qualitative/focus group data/comparisons.

13. Does the text in the first paragraph of the Taxonomy section in the Results “pilot data indicated that these measures can be collected on a weekly basis from patient case notes for both intervention and usual care groups by research staff independent from clinical teams treating patients” mean that the intervention data will be extracted from the medical record retrospectively? The text goes on to say that GRAs will be recording their treatment prospectively using a dedicated proforma – does this mean usual care won’t be documented in this manner and be subject only to retrospective audit? There are significant implications to the validity of the data should this be recorded retrospectively rather than prospectively.

14. The discussion focuses on addressing whether the questions set out in the MRC complex intervention guidance have been addressed. This method is fine for the Discussion however the answers to the questions are wordy and general. They should be succinct and specific. Please revise. In particular the first and third answers say a lot (of words) without actually saying very much. I also don’t agree with some of the authors conclusions (e.g. whether the intervention has a coherent theoretical basis) based on the gaps in specificity and inability to replicate the author steps based on what is currently presented. I encourage the authors to revise in the context that the theoretical basis for the intervention is much clearer). In addition, the authors are advised to compare their intervention with the interventions delivered by others in randomized controlled trials (referenced throughout the reviewer comments and in the manuscript) and discuss the differences, similarities and why these exist (or may exist). I think based on the detail presented, the answer to the third question is no. I encourage the authors to consider gaining external review of the manuscript by somebody uninvolved in the development of the trial (aside from the reviewers!) to gain an additional understanding of whether that individual could replicate the intervention based on the detail provided in the manuscript. All I feel I could do would be to provide a GRA, provide them some general training (and be unsure when they achieved the standard) and provide specific assessments/information at specific time points. This could result in an incredibly different intervention than that received in the RECOVER trial. The answer to the question regarding effectiveness and cost-effectiveness is an excellent example of the authors answering the question specifically and well (although the efficacy section is a bit wordy).
15. There are too many supplemental documents and only one of these is explicitly referred to in the text (the JLA newsletter). Please make it clear which files have already been published as supplemental files to the trial protocol (which should not be attached to this submission and readers should be directed to the relevant citation) and which are supplemental files to this manuscript (e.g. first paragraph under taxonomy says “also available in a supplementary file as part of the trial analysis plan” – here or in the protocol document? Most readers would expect it to be in the protocol document and already published).

Supplemental documents that could be removed are:

a. The clinical research protocol unless substantively different from that published in BMJ Open 2012 (and in which case the supplemental file should note what differs from the published protocol)

Supplemental documents that should be included with the current manuscript at a minimum are suggested as follows:

b. Details of the competency-based training and content for the GRA, as this is most relevant to the delivery of the intervention (already included)

i. However – how was competency of the GRA in each of these training goals assessed and was this done in a consistent/standardized manner? In whose opinion did the GRA meet competence and how was the standard of competence defined? This document requires more detail in order to allow repeatability of training the GRAs to a consistent standard.

c. The detail referred to in the JLA newsletter could be included as a supplementary document, however only this section should be reproduced as the remainder of the newsletter is irrelevant and the key message gets lost in managing and searching the document for relevant text.

d. Example documents (e.g. example lay summary) so that the reader can interpret the understandability (if you like) of the information provided.

The other supplemental files may be useful if they haven’t already been published (the trigger forms, goal setting record; consultant checklists; Your time in intensive care; the analysis plan (although I would have expected the latter to be published as a supplemental file to the trial protocol)). If they are retained, there needs to be more explicit instruction given in the text about i) when the reader should refer to the documents and ii) how the documents fit in with the intervention description. Given the lack of clarity around whether these documents have been previously published, I have not reviewed these in detail.

Minor essential revisions

1. Avoid the use of the personal voice (“we have provided”) and use the scientific “a detailed account has been provided”).

2. Discussion opening sentence implies that the intervention is designed to improve disability at three months following ICU discharge, however the trial has longer coverage. Please reword or delete this text.

3. The introduction should be bolstered by including references for some of the
statements (e.g. the trajectories of recovery vary – how do we know this? Where does the terminology come from? Rehab interventions evaluated should be ref’d (first para last sentence). Suggest including some more recent references in the Introduction, particularly Denehy et al., 2013 Crit Care. In addition, there was a recent reference that did report on usual care in the context of a clinical trial (Berney et al 2012 PTJ) which should be included in paragraph four of the introduction and used by the authors in the Discussion.

4. State the intervention evolved (para 2 of methods) in response to the review process rather than developed.

5. Specify details of the interviews accessed at Healthtalkonline. Were they all used? Some used? Which ones?

6. Rephrase the manuscript especially method/results in the past tense.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

The only non-financial competing interest to declare is that I am a researcher in the area (which is obviously why I was invited to review the manuscript).